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DEPARTMENT OF ENERGY

10 CFR Part 431

[Docket No. EERE–2012–BT–DET–0033]

RIN 1904–AC83

Energy Conservation Program for Consumer Products and Certain Commercial and Industrial Equipment: Final Determination of Compressors as Covered Equipment

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (DOE) is classifying certain varieties of compressors as covered equipment under Part A–1 of Title III of the Energy Policy and Conservation Act (EPCA), as amended. Accordingly, this document establishes the definition of equipment that are considered compressors.

DATES: This rule is effective December 15, 2016.

ADDRESSES: This rulemaking can be identified by docket number EERE–2012–BT–DET–0033 and/or Regulatory Information Numbers (RIN) 1904–AC83.

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index may not be publicly available, such as those containing information that is exempt from public disclosure.

A link to the docket Web page can be found at: *https://www.regulations.gov/docket?D=EERE-2012-BT-DET-0033.* The *www.regulations.gov* Web page contains simple instructions on how to access all documents, including public comments, in the docket.

For further information on how to review the docket, contact the Appliance and Equipment Standards Program staff at (202) 586–6636 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

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I. Statutory Authority

Title III of the Energy Policy and Conservation Act of 1975, as amended (''EPCA'' or, in context, ''the Act''), sets forth a variety of provisions designed to improve energy efficiency. (42 U.S.C. 6291, *et seq.*) Part C of Title III, which for editorial reasons was re-designated as Part A–1 upon incorporation into the U.S. Code (42 U.S.C. 6311–6317), establishes the ''Energy Conservation Program for Certain Industrial Equipment.'' The purpose of Part A–1 is to improve the efficiency of electric motors and pumps and certain other industrial equipment in order to conserve the energy resources of the Nation. (42 U.S.C 6312(a))

EPCA provides that DOE may include a type of industrial equipment, including compressors, as covered equipment if it determines that to do so is necessary to carry out the purposes of Part A–1. (42 U.S.C. 6311(2)(B)(i) and 6312(b)). Industrial equipment, including compressors, must be of a type that consumes, or is designed to consume, energy in operation; is distributed in commerce for industrial or commercial use; and is not a covered product as defined in 42 U.S.C. 6291(a)(2) of EPCA. (42 U.S.C. 6311 (2)(A)). DOE has determined that compressors, the definition of which DOE is adding to subpart T of 10 CFR 431 and discusses in this rule, meet the statutory requirements under 42 U.S.C. 6311(2)(B)(i) and 6312(b) and is classifying them as covered equipment.

Separately, DOE is conducting rulemakings to consider test procedures, and energy conservation standards for compressors. Pursuant to EPCA, any new or amended energy conservation standard for compressors must be designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A) and 6316(a)). Furthermore, the new or amended standard must result in a significant conservation of energy. (42 U.S.C. 6295(o)(3)(B) and 6316(a)). DOE will determine if compressors satisfy these provisions during the course of the energy conservation standards rulemaking.

II. Current Rulemaking Process

On December 31, 2012 (77 FR 76972), DOE issued a Proposed Determination of Coverage (2012 NOPD) that proposed to determine that compressors qualify as covered equipment under part A–1 of Title III of EPCA, as amended (42 U.S.C. 6311 *et seq*). DOE proposed that coverage was necessary for the purposes of Part A–1 because (1) DOE may only prescribe energy conservation standards for covered equipment; and (2) energy conservation standards for compressors would improve the efficiency of such equipment more than would be likely to occur in the absence of standards. The 2012 NOPD tentatively determined adoption of energy conservation standards for compressors likely would satisfy the provisions of 42 U.S.C. 6311(2)(B)(i). On February 7, 2013 (78 FR 8998), DOE published a notice reopening the comment period on the 2012 NOPD.

On February 5, 2014 (79 FR 6839), DOE published a notice of public meeting and provided a framework document that addressed potential standards and test procedures rulemakings for compressors. DOE held a public meeting to discuss the framework document on April 1, 2014. At this meeting, DOE discussed and received comments on the framework document, which covered the analytical framework, models, and tools that DOE used to evaluate potential standards; and all other issues raised relevant to the development of energy conservation standards for the different categories of compressors. On March 18, 2014 (79 FR 15061), DOE extended the comment period.

On May 5, 2016 (81 FR 27219), DOE issued a notice of proposed rulemaking (NOPR) to propose a definition for the term ''compressor'' and to propose test procedures for certain compressors (hereafter, the ''test procedure NOPR''). On May 19, 2016 (81 FR 31680), DOE issued a NOPR to propose energy conservation standards for certain varieties of compressors (hereafter, the ''energy conservation standards NOPR''). On June 20, 2016, DOE held a public meeting to discuss the test procedure and energy conservation standards NOPRs and to accept comments from interested parties.

In this final rule, DOE responds to the seven comments received from interested parties in response to the 2012 NOPD. DOE notes that certain comments received in response to the 2012 NOPD discussed topics such as: Technology options to improve the efficiency of compressors, scope of potential energy conservations standards, and test methods for compressors, among other comments. These comments relate to the ongoing test procedure and/or energy conservation standards rulemakings and are, or will, be addressed in those rulemakings, as applicable. In this document, DOE also responds to certain comments that were submitted in response to the test procedure NOPR and pertain to the definition of ''compressor.''

In this document, DOE addresses comments submitted by the following: The Air-Conditioning, Heating, and Refrigeration Institute (AHRI); American Council for an Energy-Efficient Economy (ACEEE); Appliance Standards Awareness Project (ASAP); Alliance to Save Energy (ASE); Atlas Copco AB (Atlas Copco); the Compressed Air & Gas Institute (CAGI); Compressed Air Systems; the Edison Electric Institute (EEI); Ingersoll Rand; Kaeser Compressors; the National Rural Electric Cooperative Association (NRECA); the Northwest Energy Efficiency Alliance (NEEA); the Northeast Energy Efficiency Partnerships (NEEP); the National Resources Defense Council (NRDC); the Pacific Gas and Electric Company (PG&E), San Diego Gas and Electric (SDG&E), Southern California Edison (SCE), and Southern California Gas Company (SCGC), collectively referred to as the California Investor Owned Utilities (CA IOUs); Scales Industrial Technologies; Sullair; Saylor-Beall Manufacturing Company and Sullivan-Palatek, collectively referred to as Sullivan-Palatek.

DOE will identify comments received in response to the test procedure NOPR by the number of the docket maintained at *www.regulations.gov* (Docket No. EERE–2014–BT–TP–0054), the commenter, the number of document as listed in that docket, and the page number of that document where the comment appears (for example: EERE–2014–BT–TP–0054, CAGI, No. 0010 at p. 3CAGI, No. 10 at p. 4). DOE will identify comments received in response to the energy conservation standards NOPR by the commenter, the number of document as listed in the docket maintained at *www.regulations.gov* (Docket No. EERE–2013–BT–STD–0040), and the page number of that document where the comment appears. DOE will cite comments in this rule's docket (EERE–2012–BT–DET–0033) solely using the commenter name, commenter number, and page number, without a docket reference.

III. Covered Equipment

''Compressor'' is not an existing defined term under EPCA. In the 2012 NOPD, DOE tentatively determined to add compressors as a type of covered equipment and proposed a definition for ''compressor.'' 77 FR 76972, 76973 (Dec 31, 2012). Specifically, DOE proposed to define compressor as an electric-powered device that takes in air or gas at atmospheric pressure and delivers the air or gas at a higher pressure. DOE also clarified that compressors typically have a specific ratio, the ratio of delivery pressure to supply pressure, greater than 1.20 and compressors are classified as positive-displacement, dynamic, or hybrid. 77 FR 76972, 76973–76974 (Dec 31, 2012). Finally, DOE noted that compressors may have pistons, rollers, rotors, impeller wheels, spiral disks, cylinders, lubricant, motors and transmissions, controls, treatment equipment, filters, and/or a lubricant/air separators. 77 FR 76972, 76974 (Dec 31, 2012). In the 2016 test procedure NOPR, after considering comments in response to the February 5, 2014 framework document (79 FR 6839), DOE proposed revisions to its initial proposed ''of a compressor''. Specifically, DOE proposed that a compressor means a machine or apparatus that converts different types of energy into the potential energy of gas pressure for displacement and compression of gaseous media to any higher pressure values above atmospheric pressure and has a pressure ratio greater than 1.3. 81 FR 27220, 27224 (May 5, 2016)

Several parties commented in response to the definition of ''compressor'' considered in the 2012 NOPD and proposed in the 2016 test procedure NOPR (and its associated public meeting). These comments are discussed by topic, in the sections that follow.

A. Compressors in Covered Products

In response to the 2012 NOPD, AHRI stated that DOE's proposed definition of ''compressor'' may unintentionally include some products as covered equipment. Specifically AHRI was concerned that heating, ventilating, air conditioning, and refrigeration (HVACR) equipment may meet the proposed definition, and suggested that DOE include a statement to exclude them. (AHRI, No. 0002 at pp. 1–2) AHRI stated that the energy consumption of HVACR compressors is already accounted for in the efficiency ratings for regulated HVACR equipment, which means that covering those compressors under separate regulations would lead to unwarranted double regulation on

HVACR products. (AHRI, No. 0002 at p. 2).

EEI commented that certain electric motors sized under 500 horsepower (which are used on certain compressors), are already subject to DOE energy conservation standards, and DOE should take this into consideration in any future energy conservation standards, in order to avoid duplicative regulation of these motors. (EEI, No. 0009 at p. 4)

This final rule establishes a definition for ''compressors'' and classifies them as covered equipment under EPCA; it does not establish scope for any potential energy conservation standards. As such, AHRI's comment that compressors in HVACR systems and EEI comments regarding motors should be excluded from regulation will be addressed in the ongoing energy conservation standards rulemaking.

B. Pressure Ratio

In response to the 2016 test procedure NOPR, Atlas Copco commented that DOE should harmonize with international precedent to aid manufacturers in exporting their products, and reduce the minimum pressure ratio from 1.3 to 1.1, as is stated in European Union (EU) Lot 31 draft standard.[1] (EERE–2014–BT–TP–0054, Atlas Copco, No. 0009 at p. 11).

In response to Atlas Copco, DOE reiterates that it proposed a lower-bound pressure ratio of 1.3 to align the coverage determination of compressors with the coverage determination being considered in the fans and blowers rulemaking, with the intent that DOE regulations do not leave any gaps in coverage. 81 FR 27220, 27224 (May 5, 2016). DOE further reiterates that an Appliance Standards Rulemaking Advisory Committee (ASRAC) Working Group was established to negotiate proposed energy conservation standards for fans and blowers and this group discussed and came to general agreement on a maximum fan energy limit of 25 kJ/kg, which translates approximately to a 1.3 pressure ratio, as the appropriate cutoff to distinguish between fans and compressors. (EERE–2014–BT–TP–0054, Docket No. EERE–2013–BT–STD–0006; EERE–2014–BT–TP–0054, Public Meeting, No. 84 at p. 11) and 81 FR 27220, 27224 (May 5, 2016). If, through the fans and blowers rulemaking, DOE establishes coverage for equipment that incorporates a maximum1.3 pressure ratio limit, DOE would have the authority to establish test procedures and energy conservation standards for equipment with pressure ratios between 1.1 and 1.3, under the coverage of fans and blowers, rather than compressors. (*see:* Docket No. EERE–2013–BT–STD–0006). Alternatively, incorporating a minimum 1.1 pressure ratio into the definition of ''compressor'' would result in an overlap in coverage with fans and blowers, and create confusion in the market.

Additionally, incorporating a definition for ''compressor'' as covered equipment by itself has no material impact on manufacturers. Rather, a decision by DOE to establish test procedures and/or energy conservation standards for certain compressors could materially impact manufacturers and trade. As such, DOE's decision to establish coverage for compressors based on a minimum pressure ratio of 1.3 has no impact on manufacturing or exporting, as claimed by Atlas Copco.

In response to the 2012 NOPD, CAGI commented that the 1.2 compression ratio proposed by DOE is too low. CAGI suggested a compression ratio of 2.5 instead. CAGI noted that what are referred to as ''low-pressure blowers'' can reach pressure ratios below 2.5, but are not generally viewed as compressors. CAGI also stated that a compression ratio of 1.2 may result in the inclusion of blowers for hand drying and vending machine compressors. (CAGI, No. 0003 at pp. 6–7) Both Ingersoll Rand and Kaeser Compressors supported CAGI's recommendation to use a pressure ratio of 2.5 instead of 1.2. (Kaeser Compressors, No. 0007 at p. 1; Ingersoll Rand, No. 0004 at pp. 1–2). However, DOE notes that, in response to the 2016 test procedure NOPR, CAGI and Ingersoll Rand updated their opinions and provided support for the definition of ''compressor,'' with a 1.3 minimum pressure ratio, as proposed by DOE in the test procedure NOPR. (EERE–2014–BT–TP–0054, CAGI, No. 0010 at p. 3; EERE–2014–BT–TP–0054, Ingersoll Rand, No. 0011 at p. 1; EERE–2014–BT–TP–0054, Sullair, No. 0006 at p. 1) Kaeser Compressors provided no updated comments related minimum pressure ratio, in response to the 2016 test procedure NOPR.

In response to the 2016 test procedure NOPR, Scales Industrial Technologies commented that the term ''compressor'' was historically used for equipment with pressure values above 18–25 psig, corresponding to pressure ratios of 2.2–2.7, and that equipment with pressure values below this range were referred to as ''blowers.'' (EERE–2014–BT–TP–0054, Scales Industrial Technologies, No. 0013, at p. 3)

In response to Kaeser Compressors and Scales Industrial Technologies, DOE acknowledges that lower pressure compressors are often termed ''blowers'' in industry. However, significant industry precedent exists that classifies blowers (and other lower pressure ratio machines) as sub-varieties of compressors. Specifically, in the test procedure NOPR, DOE noted that the International Organization for Standardization (ISO) Technical Report 12942:2012, ''Compressors—Classification—Complementary information to ISO 5390,'' (ISO/TR 12942:2012) defines ''compressor'' as a machine or apparatus converting different types of energy into the potential energy of gas pressure for displacement and compression of gaseous media to any higher pressure values above atmospheric pressure with pressure-increase ratios exceeding 1.1. 81 FR 27219, 27223 (May 5, 2016). Additionally, the European Union (EU) Lot 31 draft standard,[2] as previously discussed by Atlas Copco, also defines ''compressor'' using a minimum pressure ratio of 1.1.[3] Technically, any machine with a pressure ratio of greater than 1.0 could meet the first clause of the proposed definition for ''compressor''. In other words, it can convert different types of energy into the potential energy of gas pressure for displacement and compression of gaseous media to any higher pressure values above atmospheric pressure. Given the precedent established by ISO/TR 12942:2012 and the EU Lot 31 draft standard, DOE believes that 1.1 is the minimum pressure ratio used in the industry to describe compressors. Consequently, a machine that converts different types of energy into the potential energy of gas pressure for displacement and compression of gaseous media to any higher pressure values above atmospheric pressure and has a pressure ratio of 1.3 would technically be considered a compressor by the compressor industry.

Finally, DOE notes that the CA IOUs, CAGI, Sullivan-Palatek, Ingersoll Rand, and Sullair all support the definition of ''compressor'' with a 1.3 minimum pressure ratio, as proposed in the test procedure NOPR. (EERE–2014–BT–TP–0054, CA IOUs, No. 0012 at p. 3; EERE–

[1] The EU Lot 31 draft standard is available at: *http://www.regulations.gov/contentStreamer?documentId=EERE-2013-BT-STD-0040-0031&disposition=attachment&contentType=pdf.*

[2] The EU Lot 31 draft standard is available at: *http://www.regulations.gov/contentStreamer?documentId=EERE-2013-BT-STD-0040-0031&disposition=attachment&contentType=pdf.*

[3] As discussed in the previous paragraph, DOE is adopting a minimum pressure ratio of 1.3, rather than 1.1, in order to align with the fans and blowers rule.

2014–BT–TP–0054, CAGI, No. 0010 at p. 3; EERE–2014–BT–TP–0054, Sullivan-Palatek, No. 0007 at p. 1; EERE–2014–BT–TP–0054, Ingersoll Rand, No. 0011 at p. 1; EERE–2014–BT–TP–0054, Sullair, No. 0006 at p. 1). For these reasons, DOE reaffirms its conclusion that a minimum pressure ratio of 1.3 is appropriate for use in the definition of ''compressor.''

C. Equipment Configuration

In response to the 2012 NOPD, Ingersoll Rand made two recommendations regarding which components should be included in the definition of ''compressor.'' First, Ingersoll Rand suggested that ''compressor'' should be defined to include ''onboard'' controls that are integrated into the compressor package and solely for the operation of the compressor package to which they are mounted. (Ingersoll Rand, No. 0004 at p. 2).

Second, Ingersoll Rand suggested that ''compressor'' should be defined to include filters and treatment equipment that are integral and necessary to operate the compressor, such as oil coolers, aftercoolers, and filters, and deliver a certain quality of compressed air. (Ingersoll Rand, No. 0004 at p. 2).

In response, this final rule establishes a definition for ''compressors'' and classifies them as covered equipment under EPCA; it does not establish scope for any potential energy conservation standards. To that end, DOE notes that the definition of ''compressor'' adopted in this final rule (see section III.H), is broad and does not exclude the components recommended by Ingersoll Rand. However, DOE notes that it may limit the applicability of any test procedures and energy conservations standards it chooses to pursue in the future to address the (components/controls) identified by Ingersoll Rand.

D. Electrical Connection Method

In response to the 2012 NOPD, CAGI commented that the definition of ''compressor'' should not apply to compressors that are connected through a wall outlet using a plug connection. CAGI explained that these compressors generally have intermittent usage patterns, are small, and are not designed for continuous duty and, therefore, do not represent significant energy use. (CAGI, No. 0003 at p. 7)

DOE recognizes the benefits of focusing on compressors likely to account for significant energy use for the purposes of setting regulatory requirements. However, DOE notes that compressors can be modified to add or remove electrical plugs, without great cost or difficulty, by a party aiming to circumvent standards. Additionally, for certain compressor sizes (*i.e.,* smaller horsepower), the presence of a plug has no bearing on end user utility, as plugs can be added or removed at a nominal cost to the end user. Therefore, many compressors with and without plugs may serve the same markets and applications and should be treated similarly.

Finally, DOE prefers to use attributes more native to a compressor (*e.g.,* pressure ratios) to delineate, where needed, which compressors may fall within the coverage determination. As a result, DOE is declining CAGI's recommendation to remove from the coverage determination those compressors that are connected through a wall outlet using a plug connection.

E. Non-Electric Compressors

In response to the 2012 NOPD, EEI commented that DOE should use a definition that applies to non-electric in addition to electric compressors, arguing that limiting the definition to electric compressors would be inconsistent with DOE's other recent actions for similar products, and equipment such as pumps and fans, and would be inconsistent with the intent of EPCA. (EEI, No. 0009, at p. 2) NRECA also commented that any compressor definition should be fuel-neutral. (NRECA, No. 0008, at p. 2) EEI also noted that DOE provided no rationale supporting the exclusion of non-electric compressors, and that there are significant numbers of fossil fuel-driven compressors operating in the United States. (EEI, No. 0009, at p. 5)

Further, in response to the 2012 NOPD, EEI stated that excluding non-electric compressors carries the potential to distort markets—presumably by incentivizing end users to substitute unregulated compressors. (EEI, No. 0009, at p. 7) NRECA also commented that an electric-only compressor definition could encourage fuel-switching to non-electric compressors and not result in economic or energy savings. (NRECA, No. 0008, at p. 2)

In response to EEI's and NRECA's argument not to limit the definition of ''compressor'' to electric compressors, DOE notes that it is adopting a fuel-neutral definition of ''compressor.''

F. Variety of Equipment Covered

In response to the 2016 test procedure NOPR, Compressed Air Systems commented that the term ''compressor'' may unintentionally include other equipment, such as refrigerators, air conditioners, bellows, hand air pumps, or turbochargers, and suggested a more narrow definition of the term that would encompass just the products intended for regulation. (EERE–2014–BT–TP–0054, Compressed Air Systems, No. 0008 at p. 1).

In response, DOE notes that the definition of ''compressor,'' as proposed in the test procedure NOPR, does not specifically include or exclude compressors installed as components of other covered products or equipment such as refrigerators and air conditioners. Nonetheless, it may apply to subcomponents of such equipment. Further, if equipment commonly referred to as bellows, hand air pumps, or turbochargers meets the definition of ''compressor,'' as proposed in the test procedure NOPR and adopted in this document, such equipment would fall within the coverage determination for compressors. However, DOE will determine appropriate scope(s) of applicability for future test procedure and energy conservation standards rulemakings based on the particular circumstances of the market.

G. Federal Preemption

In response to DOE's May 19, 2016 energy conversation standards NOPR (81 FR 31680), the CA IOUs, ASAP, ACEEE, NEEA, NRDC, NEEP, and ASE commented that if there are no energy conservation standards for reciprocating compressors, then reciprocating compressors should not be covered equipment in order to allow states to pursue standards. (EERE–2013–BT–STD–0040, CA IOUs, No. 0059 at pp. 2–3; EERE–2013–BT–STD–0040, CA IOUs, Public Meeting Transcript, No. 0044 at p. 153; EERE–2013–BT–STD–0040, ASAP, ACEEE, NEEA, NRDC, NEEP, ASE, No. 0060 at pp. 2–3)

In this final rule, DOE is establishing a broad definition for ''compressors;'' it is not establishing a definition for specific categories of compressors. DOE will define specific categories of compressors and the scope of applicability of test procedures and energy conservation standards in their respective rules. In turn, DOE is classifying compressors as covered equipment under EPCA because the agency concludes that commercial and industrial compressors qualify as covered equipment under part A–1 of Title III of EPCA, as amended. (42 U.S.C. 6311 *et seq.*). Once DOE has classified equipment as covered, any State regulation concerning the energy use or energy efficiency of the covered product is preempted by Federal coverage. (42 U.S.C. 6297(b), 6316(a)).

H. Conclusion

Ultimately, for the reasons discussed in this section and established in the test procedure NOPR, DOE is adopting the definition of ''compressor,'' as proposed in the test procedure NOPR, with one minor modification in nomenclature. Specifically, DOE is replacing the term ''pressure ratio'' with ''pressure ratio at full-load operating pressure.''.

DOE will develop specific methods to determine pressure ratio at full-load operating pressure as a part of a separate test procedure rulemaking process.[4]

IV. Evaluation of Compressors as a Covered Equipment

The following sections describe DOE's evaluation of whether compressors fulfill the criteria for being added as covered equipment pursuant to 42 U.S.C. 6311(2) and 42 U.S.C. 6312. Compressors are listed as a type of industrial equipment at 42 U.S.C. 6311(2)(B)(i). The following discussion addresses DOE's consideration of the three requirements of 42 U.S.C. 6311(2)(A) and 42 U.S.C. 6312.

A. Energy Consumption in Operation

In the 2012 NOPD, DOE cited data from the 2002 United States Industrial Electric Motor Systems Market Opportunities Assessment, which estimated total annual industrial compressor energy use (from Manufacturing SIC codes 20–39) at 91,050 million kWh per year.[5] DOE noted that, because industrial activity in 2012 is greater than it was in 2002, it was likely that annual compressor energy use was higher than this figure. 77 FR 76972, 76974 (Dec 31, 2012).

In response to DOE's NOPD conclusions, EEI commented that data referenced in the proposed determination of coverage was neither accurate nor current. EEI noted that although DOE asserted industrial activity in 2012 exceeded that of 2002, the amount of industrial electricity consumed and number of industrial customers in 2011 were lower than in 2003 and 2004, respectively. (EEI, No. 0009 at pp. 2–3).

In its energy conservation standards NOPR, DOE revised the sources used to characterize the compressor market, DOE revised both initial shipments, (discussed in section IV.B) and industrial and commercial growth indicators. DOE projected future growth using Energy Information Administration's (EIA's) Annual Energy Outlook (AEO) Macroeconomic projections for the Value of Manufacturing Shipments, and Commercial Floor Space for industrial and commercial sectors, respectively.[4] Based on the energy savings results discussed in section IV.D, DOE reaffirms its conclusion that compressors consume a significant amount of energy in the industrial and commercial sectors.

B. Distribution in Commerce

In the 2012 NOPD, DOE tentatively concluded that compressors are distributed in commerce for both the industrial and commercial sectors. Specifically, DOE estimated that 1.3 million motors are shipped annually to drive compressors in the U.S. commercial and industrial sectors, based on the 2011 International Energy Agency (IEA) Survey. DOE also assumed that only a small fraction of these motors are used as a motor only replacement in compressor systems (based on additional 2004 U.S. Census data); consequently, DOE estimated that nearly 1.3 million compressors were distributed in commerce annually for industrial or commercial use. 77 FR 76972, 76974 (Dec 31, 2012).

In response to DOE's NOPD conclusions, Ingersoll Rand commented that the estimate of annual compressor shipments provided by DOE is grossly inflated. (Ingersoll Rand, No. 0004 at p. 2) CAGI commented that DOE's estimates most likely incorporate compressors going into consumer applications, and if only commercial and industrial applications were counted, the number would be significantly lower. (CAGI, No. 0003 at p. 7) EEI recommended that DOE elaborate on how it derived the 1.3 million compressor shipment estimate, if DOE is to use it in in any future energy conservation standards analyses. (EEI, No. 0009 at p. 3)

In response to comments from Ingersoll Rand, CAGI, and EEI, DOE sought, and received, shipments data for rotary screw compressors from a number of manufacturer stakeholders and subject matter experts, which DOE published in its energy conservation standards NOPR. However, DOE was able to find only limited shipments data for reciprocating compressors, so DOE continued to use the data from the U.S. Census Bureau.[5] DOE estimated in its energy conservation standards NOPR shipments analysis that 31 thousand rotary screw and 538 thousand reciprocating compressors were shipped to commercial and industrial sectors in 2013. (EERE–2013–BT–STD–0040–0037) Based on these revised shipments estimates, DOE reaffirms its conclusion that compressors are distributed in commerce to commercial and industrial sectors.

C. Prior Inclusion as a Covered Product

Compressors are not currently included as covered products under Title 10 of the Code of Federal Regulations, part 430.

D. Coverage Necessary To Carry Out Purposes of Part A–1 of the Energy Policy and Conservation Act

The purpose of part A–1 of EPCA is to improve the energy efficiency of electric motors, pumps and certain other industrial equipment to conserve the energy resources of the Nation. (42 U.S.C. 6312 (a)). In the 2012 NOPD, DOE proposed that coverage of compressors was necessary to carry out the purposes of part A–1 of EPCA because coverage will promote the conservation of energy resources. DOE concluded that efficiency standards that may result from coverage would help to capture some portion of the potential for improving the efficiency of compressors. 77 FR 76972, 76974 (Dec 31, 2012).

In response to DOE's conclusion that efficiency standards that may result from coverage of compressors would help to capture some portion of the potential for improving the efficiency of compressors, CAGI commented that compressor designs are mature and compressor manufacturers have already incorporated the most efficient motor designs and technologies available in the market. CAGI believes that including compressors as covered equipment would inhibit investment in research and development because of the hurdles involved in approving new designs for the market. (CAGI, No. 0003 at p. 8) CAGI also argued that, due to variation in field applications that lead to changes in overall efficiency, regulation of compressor packages is an ineffective way to capture significant energy savings. CAGI suggested that, therefore, DOE exclude commercial and industrial compressors under Part A–1 of Title III of EPCA. (CAGI, No. 0003 at pp. 4–5)

Kaeser Compressors commented that since manufacturers already publish test data at various load levels and that data is verified by a third-party and since annual energy costs are dependent on the dynamics of an individual system, Kaeser does not believe that including

[4] U.S. DOE—Energy Information Administration (2015), Annual Energy Outlook 2015, DOE/EIA–0383 (Available at: *http://www.eia.gov/forecasts/archive/aeo15/pdf/0383(2015).pdf*).

[5] U.S. Department of Commerce, Census Bureau, Manufacturing and Construction Division, Series MA333P(10)–1, Stationary Air Compressors, Reciprocating, Single and Double Acting (333912110T), 2011.

compressors alone as covered equipment would be beneficial to carrying out the purposes of Part A–1 of EPCA. (Kaeser Compressors, No. 0007 at pp. 3)

DOE published consumer saving for lubricated rotary screw, lubricant-free rotary screw, and reciprocating compressors in its energy conservation standard NOPR TSD.[6] These equipment account for over 90 percent of compressors in the commercial and industrial sectors and are used in a wide variety of applications. While DOE did not propose an increase in efficiency above the baseline for lubricant-free rotary screw, or, new standards for reciprocating compressors, DOE's analysis found that there was energy, and consumer savings for these equipment at most efficiency levels. Further, DOE published national energy saving estimates for lubricated rotary screw compressors in its energy conservation standard NOPR. DOE estimated, at the proposed level, significant national energy savings of 0.18 quads.

These estimated saving presented in the energy conservation standard TSD and NOPR are an indication that coverage will result in conservation of energy resources. While DOE proposed new energy conservation standards for a sub-set of compressor designs currently available in commerce, broadening of the energy conservations standards beyond lubricated rotary screw compressors will likely increase the amount of energy savings.

Based on the preceding discussion, DOE reaffirms its conclusion that incorporating compressors as covered equipment is necessary to carry out the purposes of Part A–1 of EPCA, and that efficiency standards that may result from coverage would improve the efficiency of compressors and help to capture some portion of the potential for energy savings from this improved efficiency. Based on the information in sections IV.A, IV.B, and IV.C of this rule, DOE determines that commercial and industrial compressors qualify as covered equipment under part A–1 of Title III of EPCA, as amended (42 U.S.C. 6311 *et seq.*).

V. Procedural Issues and Regulatory Review

DOE has reviewed this final rule, which determines coverage for compressors, under the following executive orders and acts.

A. Review Under Executive Order 12866

The Office of Management and Budget (OMB) has determined that coverage determination rulemakings do not constitute ''significant regulatory actions'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this final action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA) in the OMB.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996) requires preparation of a regulatory flexibility analysis for any rule that, by law, must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. A regulatory flexibility analysis examines the impact of the rule on small entities and considers alternative ways of reducing negative effects. Also, as required by E.O. 13272, ''Proper Consideration of Small Entities in Agency Rulemaking'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003 to ensure that the potential impact of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990 (Feb. 19, 2003). DOE makes its procedures and policies available on the Office of the General Counsel's Web site at *www.gc.doe.gov.*

DOE reviewed this final rule under the provisions of the Regulatory Flexibility Act and the policies and procedures published on February 19, 2003. This final rule sets no test procedures or standards; it only positively determines that compressors meet the criteria for classification as covered equipment and that future standards may be warranted to regulate their energy use. Economic impacts on small entities would be considered in the context of such rulemakings. On the basis of the foregoing, DOE certifies that the determination has no significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this final rule. DOE will transmit this certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act of 1995

This final rule, which concludes that compressors meet the criteria for a covered product for which the Secretary may prescribe an energy conservation standard pursuant to 42 U.S.C. 6295(o) and (p), imposes no new information or record-keeping requirements. Accordingly, the OMB clearance is not required under the Paperwork Reduction Act. (44 U.S.C. 3501 *et seq.*)

D. Review Under the National Environmental Policy Act of 1969

In this document, DOE positively determines that compressors meet the criteria for classification as covered equipment and that future standards may be warranted to regulate their energy use. Should DOE pursue that option, the relevant environmental impacts would be explored as part of that rulemaking. As a result, DOE has determined that this action falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, this action establishes a class of equipment (compressors) for which energy conservation standards would be appropriate. However, this action does not establish energy conservation standards, and, therefore, does not result in any environmental impacts. Thus, this action is covered by Categorical Exclusion A6 ''Procedural rulemakings'' under 10 CFR part 1021, subpart D. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order (E.O.) 13132, ''Federalism'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to assess carefully the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in developing regulatory policies that have Federalism implications. On March 14, 2000 (65 FR 13735), DOE published a statement of policy describing the intergovernmental

[6] U.S. Department of Energy, Energy Efficiency and Renewable Energy Office (2015), NOPR Technical Support Document (TSD): Energy Efficiency Program for Consumer Products and Commercial and Industrial Equipment: Air Compressors (Available at: *https://www.regulations.gov/document?D=EERE-2013-BT=STD-0040-0037*).

consultation process that it will follow in developing such regulations. DOE has examined this final rule and concludes that it does not preempt State law or have substantial direct effects on the States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the product that is the subject of this final rule. States can petition DOE for exemption from such preemption to the extent permitted, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) No further action is required by E.O. 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, ''Civil Justice Reform'' 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the duty to: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. Section 3(b) of E.O. 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation specifies the following: (1) The preemptive effect, if any; (2) any effect on existing Federal law or regulation; (3) a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) the retroactive effect, if any; (5) definitions of key terms; and (6) other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of E.O. 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether these standards are met, or whether it is unreasonable to meet one or more of them. DOE completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of E.O. 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4, codified at 2 U.S.C. 1501 *et seq.*) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and tribal governments and the private sector. For regulatory actions likely to result in a rule that may cause expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any 1 year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a) and (b)). UMRA requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and tribal governments on a proposed ''significant intergovernmental mandate.'' UMRA also requires an agency plan for giving notice and opportunity for timely input to small governments that may be potentially affected before establishing any requirement that might significantly or uniquely affect them. On March 18, 1997 (62 FR 12820), DOE published a statement of policy on its process for intergovernmental consultation under UMRA. (This policy also is available at *www.gc.doe.gov*). DOE reviewed this final rule pursuant to these existing authorities and its policy statement and determined that the rule contains neither an intergovernmental mandate nor a mandate that may result in the expenditure of $100 million or more in any year, so the UMRA requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act of 1999

Section 654 of the Treasury and General Government Appropriations Act of 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This final rule does not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

Pursuant to E.O. 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights'' 53 FR 8859 (Mar. 15, 1988), DOE determined that this final rule does not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act of 2001

The Treasury and General Government Appropriation Act of 2001 (44 U.S.C. 3516, note) requires agencies to review most disseminations of information they make to the public under guidelines established by each agency pursuant to general guidelines issued by the OMB. The OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

E.O. 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates a final rule or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under E.O. 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of the Office of Information and Regulatory Affairs (OIRA) as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use if the proposal is implemented, and of reasonable alternatives to the proposed action and their expected benefits on energy supply, distribution, and use.

DOE has concluded that this regulatory action establishing certain definitions and determining that compressors meet the criteria for a covered product for which the Secretary may prescribe an energy conservation standard pursuant to 42 U.S.C. 6295(o) and (p) does not have a significant adverse effect on the supply, distribution, or use of energy. This action is also not a significant regulatory action for purposes of E.O. 12866, and the OIRA Administrator has not designated this final determination as a significant energy action under E.O. 12866 or any successor order. Therefore, this final rule is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

L. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is a ''major rule'' as defined by 5 U.S.C. 804(2).

M. Review Under the Information Quality Bulletin for Peer Review

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (OSTP), issued its Final Information Quality Bulletin for Peer Review (the Bulletin). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal government, including influential scientific information related to agency regulatory actions. The purpose of the Bulletin is to enhance the quality and credibility of the Government's scientific information. DOE has determined that the analyses conducted for the regulatory action discussed in this document do not constitute ''influential scientific information,'' which the Bulletin defines as ''scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.'' 70 FR 2667 (Jan. 14, 2005). The analyses were subject to pre-dissemination review prior to issuance of this rulemaking.

DOE will determine the appropriate level of review that would apply to any future rulemaking to establish energy conservation standards for compressors.

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

Issued in Washington, DC, on October 28, 2016.

David J. Friedman,

Acting Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons stated in the preamble, DOE amends part 431 of chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 431—ENERGY EFFICIENCY PROGRAM FOR CERTAIN COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 2. Add subpart T to part 431 to read as follows:

Subpart T—Compressors

Sec.

Subpart T—Compressors

§ 431.341 Purpose and scope.

This subpart contains and energy conservation requirements for compressors, pursuant to Part A–1 of Title III of the Energy Policy and Conservation Act, as amended, 42 U.S.C. 6311–6317.

§ 431.342 Definitions concerning compressors.

Compressor means a machine or apparatus that converts different types of energy into the potential energy of gas pressure for displacement and compression of gaseous media to any higher pressure values above atmospheric pressure and has a pressure ratio at full-load operating pressure greater than 1.3.

[FR Doc. 2016–26693 Filed 11–14–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2015–3680; Airspace Docket No. 13–ASW–15]

RIN 2120–AA66

Establishment of and Modification to Restricted Areas; Fort Sill, OK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes 2 new restricted areas (R–5601G and R–5601H) to the special use airspace (SUA) complex located at Fort Sill, OK, to provide additional maneuvering airspace for current and planned hazardous training activities. Specifically, the restricted areas provide participating fighter and bomber aircraft with non-eye safe laser firing and maneuvering airspace when training at the Falcon Bombing Range contained in R–5601C, the West Range Target Area contained in R–5601B, or the East Range Target Area contained in R–5601A. Additionally, the using agency information for all Fort Sill restricted areas is updated for standardization and to reflect the current organization. This action also updates a number of geographic coordinates for R–5601A–E, G, and H as a result of more accurate digital charting capabilities, updates the arc radius distance in R–5601B and R–5601H from statute miles to nautical miles (NM), and corrects the controlling agency information for R–5601H. This action ensures realistic U.S. Army training on current tactics for employing hazardous targeting laser systems and weapons capabilities at longer ranges from the target area.

DATES: Effective date 0901 UTC, March 2, 2017.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 restructures the restricted airspace at Fort Sill, OK, enhancing safety and accommodating essential military training.

History

On October 19, 2015, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) (80 FR 63153), Docket No. FAA–2015–3680, to establish two restricted areas and amend using agency information for six other restricted areas designated to support hazardous training activities conducted within the Fort Sill, OK, special use airspace (SUA) complex. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. One comment from the Aircraft Owners and Pilots Association (AOPA) was received.

Discussion of Comments

In their response to the NPRM, AOPA raised several substantive issues. AOPA contended the proposed airspace design would have a negative impact on general aviation aircraft and offered the following recommendations to mitigate the negative effects: consider other types of SUA before establishing additional restricted areas; change the ceiling of R–5601G so it aligns with the Minimum Enroute Altitude (MEA) of V–436; if

unable to change the ceiling altitude, update the enroute charts to show V–436 penetrates R–5601G; reduce the northern boundary of V–436 to provide additional lateral spacing from V–436; and synchronize the effective date of any new restricted areas to coincide with sectional chart dates.

Having considered the issues and recommendations provided by AOPA, the FAA offers the following responses.

Consider Other Types of Special Use Airspace (SUA) Before Enacting a Restricted Area

The purpose of a restricted area is to confine or segregate activities considered hazardous to nonparticipating aircraft. The FAA recognizes that R–5601G and H, when activated, would restrict access by non-participating aircraft. As noted in the NPRM, the U.S. Army requested this action to allow realistic training on current tactics developed and refined during recent combat operation for employing hazardous (non-eye safe) combat targeting laser systems and weapons capabilities at longer ranges from the target area. It was also noted that there was no alternative SUA complex within 200 NM where combat lasers could be employed that would support this aircrew training requirement. Therefore, the FAA has determined restricted area airspace is the appropriate SUA solution for conducting the hazardous activities associated with the U.S. Army's training requirement.

Reduce the Maximum Altitude of R–5601 To Align With the Minimum Enroute Altitude of VHF Omnidirectional Range (VOR) Federal Airway V–436

This recommendation would drop the ceiling of R–5601G from ''to but not including 8,000 feet MSL'' to 5,400 feet MSL. Such a lowered ceiling would prevent laser employment at ranges beyond 10 miles due to graze angle restrictions and result in loss of the increased standoff ranges proposed for realistic aircrew combat training. Additionally, the western portion of R–5601G overlies the Wichita Mountains National Wildlife Refuge. As mitigation to adverse effects when R–5601F was established in 2007, the Army agreed to restrict flights below 5,500 feet MSL over the Wildlife Refuge. Observing this local flight restriction to not overfly the Wildlife Refuge below 5,500 feet MSL and AOPA's recommended restricted area ceiling of 5,400 feet MSL would actually result in no available restricted area airspace over the Wichita Mountains National Wildlife Refuge and compression of the remaining portions of R–5601G to the point that the restricted area would not meet the military's training requirements any longer. The FAA does not support lowering the R–5601G ceiling as recommended.

The R–5601G boundaries description information in the regulatory text is being amended to reflect the U.S. Army's local flight restriction to not overfly the Wichita Mountains National Wildlife Refuge below 5,500 feet MSL and match the corresponding flight restriction documented in the R–5601F legal description and on the applicable aeronautical charts.

If Unable To Reduce the Ceiling of R–5601G, Update the Enroute Charts To Show V–436 Penetrates an Established Restricted Area

It is common practice for the FAA to depict Air Traffic Service (ATS) Routes and SUA areas on IFR and VFR aeronautical charts in accordance with established charting standards. Additionally, SUA times are published in a tab on the associated IFR and VFR charts to identify the SUA times of use. As such, V–436 will be charted on the IFR enroute charts, depicting it running through R–5601G and the R–5601 times of use will be published on the associated charts.

Truncate the Northern Boundary of R–5601G To Preserve V–436 Through Lateral Separation

The FAA acknowledges that amending the proposed R–5601G northern boundary to provide a 4 NM buffer from the V–436 centerline would allow unimpeded use of the airway when the restricted area is active. However, this recommendation reduces the north-south lateral dimension of R–5601G by approximately 7 NM at its northeast corner. One of the stated purposes of this action, as noted in the NPRM, was to allow realistic training on current tactics developed during recent combat operation for employing hazardous targeting laser systems and weapons capabilities at longer ranges from the target area. Modern rangefinder and laser designators can be employed at ranges out to 25 NM. As proposed, the distance from the target arrays in R–5601C (Falcon Range) to the northeast corner of R–5601G is approximately 22 NM and the distance from the targets in R–5601B to the proposed northeast corner is approximately 17 NM. Amending the R–5601G northern boundary as recommended by AOPA would reduce these distances to 17 NM and 12 NM, respectively. As such, the FAA does not support this recommendation since the reduced distances to the target areas would be inadequate for the military to conduct realistic training on current tactics employing targeting laser systems and weapons systems at longer ranges.

Synchronize the Effective Date of Any New Restricted Areas To Coincide With Sectional Chart Dates

The FAA normally makes regulatory airspace actions, including restricted areas, effective on a 56-day enroute chart date; however, consideration is given to selecting a sectional aeronautical chart date when deemed appropriate based on the potential aeronautical impacts associated with the airspace action being taken. This action is being made effective on a sectional chart date that matches the 56-day enroute chart dates.

Differences From the NPRM

Subsequent to publication of the NPRM, the FAA identified a number of geographic lat./long. coordinate updates to the R–5601A–E, G, and H boundaries information to more accurately reflect the existing boundaries using digital charting capabilities. Additionally, the arc radius distance listed in the R–5601B and R–5601H descriptions was determined to be described using statute miles and is being updated to reflect the corresponding nautical mile distance. Finally, the R–5601H controlling agency title proposed in the NPRM did not match the controlling agency title for the other R–5601 complex restricted areas and is being updated to match. The using agency, controlling agency, and boundaries updates are administrative in nature and do not affect the overall restricted area boundaries; designated altitudes; times of designation; or activities conducted within those restricted areas. The following restricted area updates are incorporated in this action.

The geographical lat./long. coordinates for the points located on Interstate Highway 44 (I–44) listed in the R–5601A and R–5601B descriptions, and a corresponding point listed in the R–5601H description, are actually located west of I–44. The geographical coordinates are updated to accurately reflect the points on I–44.

The 3-mile arc radius distance listed in the existing R–5601B and proposed R–5601H descriptions is not clear that it is defined in reference to statute miles. The 3-mile [statute miles] arc radius is updated to reflect it as 2.6 NM to retain the boundary, unchanged, and comply with FAA Order JO 7400.2, Procedures for Handling Airspace Matters, guidance.

The geographical lat./long. coordinates listed for the eastern-most point located on the 2.6 NM arc radius (formerly 3-mile arc radius as noted above) in the existing R–5601B and proposed R–5601H descriptions is actually located north of the arc. The geographical coordinates are updated to accurately reflect the point on the 2.6 NM arc.

The geographical lat./long. coordinates listed for the northern boundary point located on Oklahoma State Highway No. 115 in the R–5601B and R–5601C descriptions, and the corresponding point listed in the R–5601D description, is actually located east of the highway. The geographical coordinates are updated to accurately reflect the point on Oklahoma State Highway No. 115.

The geographical lat./long. coordinates for one point listed in the R–5601E description does not match the geographical coordinates for the corresponding point listed in the R–5601B and R–5601C descriptions. The geographical coordinates for the point are updated to match the information published in the R–5601B and R–5601C descriptions.

The geographical lat./long. coordinates for the first point listed in the R–5601G description does not create a shared boundary with R–5601F and results in a gap between the two restricted areas. The geographical lat./long. coordinates for the point are updated to ensure a shared R–5601F and R–5601G boundary.

The controlling agency information listed in the R–5601H description does not match the controlling agency information verbatim in all the other R–5601 restricted areas. The controlling agency information is updated to standardize the information in all R–5601 restricted areas.

The Rule

The FAA is amending 14 CFR part 73 to establish 2 new restricted areas (R–5601G and R–5601H) at Fort Sill, OK, and update the using agency information listed for the existing restricted areas (R–5601A–F) as noted in the NPRM. The FAA is also incorporating the restricted area updates noted in the Differences from the NPRM section. The FAA is taking this action to ensure containment of the hazardous activities associated with aircrew training missions that are incorporating non-eye safe targeting laser employment and weapons delivery tactics used by the military today, at increased distances from the target range, within restricted area airspace. The amendments are as follows:

R–5601A: The geographic coordinates ''lat. 34°40′47″ N., long. 98°23′09″ W.,'' in the boundaries description are changed to ''lat. 34°40′47″ N., long. 98°23′07″ W.,'' and the geographic coordinates ''lat. 34°43′30″ N., long. 98°24′01″ W.,'' are changed to ''lat. 34°43′30″ N., long. 98°23′59″ W.,'' to coincide with I–44.

R–5601B: The geographic coordinates ''lat. 34°40′47″ N., long. 98°23′09″ W.,'' in the boundaries description are changed to ''lat. 34°40′47″ N., long. 98°23′07″ W.,'' and the geographic coordinates ''lat. 34°43′30″ N., long. 98°24′01″ W.,'' are changed to ''lat. 34°43′30″ N., long. 98°23′59″ W.,'' to coincide with I–44. Additionally, the geographic coordinates ''lat. 34°40′54″ N., long. 98°37′54″ W.,'' are changed to ''lat. 34°40′54″ N., long. 98°37′56″ W.,'' to coincide with Oklahoma State Highway No. 115. Lastly, the arc radius ''3-mile″ is changed to ''2.6 NM'' to retain the existing boundary defined in terms of NM and the geographic coordinates ''lat. 34°40′12″ N., long. 98°26′18″ W.,'' are changed to ''lat. 34°40′11″ N., long. 98°26′18″ W.,'' to coincide with the 2.6 NM arc radius.

R–5601C: The geographic coordinates ''lat. 34°40′54″ N., long. 98°37′54″ W.,'' in the boundaries description are changed to ''lat. 34°40′54″ N., long. 98°37′156″ W.,'' to coincide with Oklahoma State Highway No. 115.

R–5601D: The geographic coordinates ''lat. 34°40′54″ N., long. 98°37′54″ W.,'' in the boundaries description are changed to ''lat. 34°40′54″ N., long. 98°37′56″ W.,'' to coincide with Oklahoma State Highway No. 115.

R–5601E: The geographic coordinates ''lat. 34°38′15″ N., long. 98°37′58″ W.,'' in the boundaries description are changed to ''lat. 34°38′15″ N., long. 98°37′57″ W.,'' to match the corresponding point in R–5601B and R–5601C.

R–5601G: Establish R–5601G to abut the northern boundary of R–5601F, to the north, underlying the Washita MOA. The new restricted area extends upward from 500 feet above ground level (AGL) to, but not including 8,000 feet MSL; excluding the airspace below 5,500 feet MSL over the Wichita Mountains National Wildlife Refuge, as noted in the Discussion of Comments section. R–5601G extends laterally across approximately three quarters of the restricted area complex, west to east, and northward between 5 NM to 11 NM along the northern boundary of R–5601F. Additionally, the geographic coordinates ''lat. 34°46′07″ N., long. 98°25′50″ W.,'' in the proposed boundaries description are changed to ''lat. 34°46′03″ N., long. 98°25′50″ W.,'' to ensure a shared boundary with R–5601F. Lastly, the controlling agency ''FAA, Fort Worth Center'' is changed to ''FAA, Fort Worth ARTCC.''

R–5601H: Establish R–5601H to fill a small airspace area over Fort Sill Army Post, OK, surrounded by two continuously active restricted areas (R–5601A and R–5601B). The new restricted area extends upward from the surface to FL400. Additionally, the geographic coordinates ''lat. 34°40′47″ N., long. 98°23′09″ W.,'' in the proposed boundaries description are changed to ''lat. 34°40′47″ N., long. 98°23′07″ W.,'' to match the corresponding point in R–5601A. Lastly, the arc radius ''3-mile″ is changed to ''2.6 NM'' to retain the existing boundary defined in terms of NM and the geographic coordinates ''lat. 34°40′12″ N., long. 98°26′18″ W.,'' are changed to ''lat. 34°40′11″ N., long. 98°26′18″ W.,'' to coincide with the 2.6 NM arc radius.

The two new restricted areas allow participating aircraft to maneuver within the current Fort Sill Approach Control Airspace and contain the hazardous combat laser energy within restricted airspace. As noted in the NPRM, R–5601G will be used for aircraft maneuvering and combat laser targeting employment and R–5601H will be used for aircraft conducting Close Air Support (CAS) training. There are no changes to the existing pattern of firing, ordnance delivery runs, or weapons impact areas and all weapons release continue to occur in R–5601A, R–5601B, or R–5601C, as they are now. Further, no supersonic flight will occur.

This action also changes the using agency information ''U.S. Army, Commanding General, Fort Sill, OK,'' listed for R–5601A–E to ''U.S. Army, Commanding General, U.S. Army Fires Center of Excellence (USAFCOE) and Fort Sill, Fort Sill, OK'' and the using agency ''Commanding General, United States Army Field Artillery Center (USAFACFS), Fort Sill, OK,'' listed for R–5601F is changed to ''U.S. Army, Commanding General, U.S. Army Fires Center of Excellence (USAFCOE) and Fort Sill, Fort Sill, OK.'' These changes reflect the current organizational responsibilities and match the using agency information published in R–5601G and R–5601H.

The boundaries, designated altitudes, times of designation, and controlling agency information for restricted areas R–5601A–F are not changed by this action.

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 Department of Transportation (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

In accordance with FAA Order 1050.1F, paragraphs 6–3.c and 8–2, the FAA has conducted an independent evaluation of the U.S. Army's Final Environmental Assessment (EA) for the Creation of Restricted Areas (RAs) R–5601G and R–5601H. The FAA determined that no significant impacts would occur as a result of the Federal action and therefore, preparation of an Environmental Impact Statement is not warranted and a Finding of No Significant Impact in accordance with 40 CFR 1501.4(e) is appropriate. Subsequently, and in accordance with 40 CFR 1506.3, the FAA adopted the U.S. Army's final EA and prepared a Finding of No Significant Impact/ Record of Decision dated November 7, 2016.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 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.

§ 73.56 [Amended]

■ 2. Section 73.56 is amended as follows:

R–5601A Fort Sill, OK [Amended]

By removing the current boundaries and using agency information and substituting the following:

Boundaries. Beginning at lat. 34°38′15″ N., long. 98°17′01″ W.; to lat. 34°38′15″ N., long. 98°20′56″ W.; to lat. 34°38′30″ N., long. 98°21′41″ W.; to lat. 34°38′50″ N., long. 98°22′06″ W.; to lat. 34°39′53″ N., long. 98°22′16″ W.; to lat. 34°40′47″ N., long. 98°23′07″ W.; thence north along the western edge of Interstate Highway 44 to lat. 34°43′30″ N., long. 98°23′59″ W.; to lat. 34°43′30″ N., long. 98°21′21″ W.; to lat. 34°43′45″ N., long. 98°21′01″ W.; to lat. 34°46′06″ N., long. 98°21′01″ W.; to lat. 34°46′06″ N., long. 98°17′01″ W.; to the point of beginning.

Using agency. U.S. Army, Commanding General, U.S. Army Fires Center of Excellence (USAFCOE) and Fort Sill, Fort Sill, OK.

R–5601B Fort Sill, OK [Amended]

By removing the current boundaries and using agency information and substituting the following:

Boundaries. Beginning at lat. 34°40′47″ N., long. 98°23′07″ W.; thence counterclockwise along an arc, 2.6 NM radius centered at lat. 34°38′18″ N., long. 98°24′07″ W.; to lat. 34°40′11″ N., long. 98°26′18″ W.; to lat. 34°38′15″ N., long. 98°26′19″ W.; to lat. 34°38′15″ N., long. 98°37′57″ W.; thence north along Oklahoma State Highway No. 115 to lat. 34°40′54″ N., long. 98°37′56″ W.; to lat. 34°42′07″ N., long. 98°37′20″ W.; to lat. 34°43′21″ N., long. 98°36′02″ W.; to lat. 34°43′30″ N., long. 98°35′40″ W.; to lat. 34°43′30″ N., long. 98°23′59″ W.; thence south along the western edge of Interstate Highway 44 to the point of beginning.

Using agency. U.S. Army, Commanding General, U.S. Army Fires Center of Excellence (USAFCOE) and Fort Sill, Fort Sill, OK.

R–5601C Fort Sill, OK [Amended]

By removing the current boundaries and using agency information and substituting the following:

Boundaries. Beginning at lat. 34°38′15″ N., long. 98°37′57″ W.; to lat. 34°38′15″ N., long. 98°45′21″ W.; to lat. 34°41′47″ N., long. 98°45′21″ W.; to lat. 34°41′47″ N., long. 98°44′17″ W.; to lat. 34°41′21″ N., long. 98°44′17″ W.; to lat. 34°41′21″ N., long. 98°40′36″ W.; to lat. 34°40′54″ N., long. 98°40′36″ W.; to lat. 34°40′54″ N., long. 98°37′56″ W.; thence south along Oklahoma State Highway No. 115 to the point of beginning.

Using agency. U.S. Army, Commanding General, U.S. Army Fires Center of Excellence (USAFCOE) and Fort Sill, Fort Sill, OK.

R–5601D Fort Sill, OK [Amended]

By removing the current boundaries and using agency information and substituting the following:

Boundaries. Beginning at lat. 34°38′15″ N., long. 98°45′21″ W.; to lat. 34°38′15″ N., long. 98°48′01″ W.; to lat. 34°42′15″ N., long. 98°50′01″ W.; to lat. 34°45′00″ N., long. 98°40′31″ W.; to lat. 34°43′30″ N., long. 98°35′40″ W.; to lat. 34°43′21″ N., long. 98°36′02″ W.; to lat. 34°42′07″ N., long. 98°37′20″ W.; to lat. 34°40′54″ N., long. 98°37′56″ W.; to lat. 34°40′54″ N., long. 98°40′36″ W.; to lat. 34°41′21″ N., long. 98°40′36″ W.; to lat. 34°41′21″ N., long. 98°44′17″ W.; to lat. 34°41′47″ N., long. 98°44′17″ W.; to lat. 34°41′47″ N., long. 98°45′21″ W.; to the point of beginning.

Using agency. U.S. Army, Commanding General, U.S. Army Fires Center of Excellence (USAFCOE) and Fort Sill, Fort Sill, OK.

R–5601E Fort Sill, OK [Amended]

By removing the current boundaries and using agency information and substituting the following:

Boundaries. Beginning at lat. 34°38′15″ N., long. 98°37′57″ W.; to lat. 34°36′00″ N., long. 98°46′46″ W.; to lat. 34°38′15″ N., long. 98°48′01″ W.; to lat. 34°38′15″ N., long. 98°45′21″ W.; to the point of beginning.

Using agency. U.S. Army, Commanding General, U.S. Army Fires Center of Excellence (USAFCOE) and Fort Sill, Fort Sill, OK.

R–5601F Fort Sill, OK [Amended]

By removing the current using agency and substituting the following:

Using agency. U.S. Army, Commanding General, U.S. Army Fires Center of Excellence (USAFCOE) and Fort Sill, Fort Sill, OK.

R–5601G Fort Sill, OK [New]

Boundaries. Beginning at lat. 34°46′03″ N., long. 98°25′50″ W.; to lat. 34°45′03″ N., long. 98°29′46″ W.; thence counterclockwise via the 46 NM arc of SPS VORTAC to lat. 34°43′46″ N., long. 98°49′55″ W.; to lat. 34°47′00″ N., long. 98°51′00″ W.; to lat. 34°50′30″ N., long. 98°46′02″ W.; to lat. 34°57′51″ N., long. 98°25′47″ W.; to the point of beginning. Excluding that airspace below 5,500 feet MSL over the Wichita Mountains National Wildlife Refuge.

Designated altitudes. 500 feet AGL to, but not including, 8,000 feet MSL.

Time of designation. Sunrise to 2200 local time, Monday-Friday; other times by NOTAM.

Controlling agency. FAA, Fort Worth ARTCC.

Using agency. U.S. Army, Commanding General, U.S. Army Fires Center of Excellence (USAFCOE) and Fort Sill, Fort Sill, OK.

R–5601H Fort Sill, OK [New]

Boundaries. Beginning at lat. 34°38′15″ N., long. 98°20′56″ W.; to lat. 34°38′30″ N., long. 98°21′41″ W.; to lat. 34°38′50″ N., long. 98°22′06″ W.; to lat. 34°39′53″ N., long. 98°22′16″ W.; to lat. 34°40′47″ N., long. 98°23′07″ W.; thence counterclockwise along an arc, 2.6 NM radius centered at lat. 34°38′18″ N., long. 98°24′07″ W.; to lat. 34°40′11″ N., long. 98°26′18″ W.; to lat. 34°38′15″ N., long. 98°26′19″ W.; to the point of beginning.

Designated altitudes. Surface to FL 400.

Time of designation. By NOTAM.

Controlling agency. FAA, Fort Worth ARTCC.

Using agency. U.S. Army, Commanding General, U.S. Army Fires Center of Excellence (USAFCOE) and Fort Sill, Fort Sill, OK.

Issued in Washington, DC, on November 8, 2016.

Leslie M. Swann,

Acting Manager, Airspace Policy Group.

[FR Doc. 2016–27441 Filed 11–14–16; 8:45 am]

BILLING CODE 4910–13–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

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

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in December 2016. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective December 1, 2016.

FOR FURTHER INFORMATION CONTACT: Deborah C. Murphy (*Murphy.Deborah@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4400 ext. 3451. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4400 ext. 3451.)

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

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

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for December 2016.[1]

The December 2016 interest assumptions under the benefit payments regulation will be 0.75 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for November 2016, these interest assumptions represent an increase of 0.25 percent in the immediate rate and are otherwise unchanged.

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

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during December 2016, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

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

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

List of Subjects in 29 CFR Part 4022

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

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

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

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

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

■ 2. In appendix B to part 4022, Rate Set 278, as set forth below, is added to the table.

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

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*	*	*	*	*	*	*	*
278	12–1–16	1–1–17	0.75	4.00	4.00	4.00	7	8

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

■ 3. In appendix C to part 4022, Rate Set 278, as set forth below, is added to the table.

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

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*	*	*	*	*	*	*	*
278	12–1–16	1–1–17	0.75	4.00	4.00	4.00	7	8

Judith Starr,

General Counsel, Pension Benefit Guaranty Corporation.

[FR Doc. 2016–27384 Filed 11–14–16; 8:45 am]

BILLING CODE 7709–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2345–IFC]

RIN 0938–AT09

Medicaid Program; Covered Outpatient Drug; Delay in Change in Definitions of States and United States

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: The Covered Outpatient Drug final rule with comment period was published in the February 1, 2016 **Federal Register**. As part of that final rule with comment, we amended the regulatory definitions of ''States'' and ''United States'' to include the U.S. territories (American Samoa, the Northern Mariana Islands, Guam, the Commonwealth of Puerto Rico, and the Virgin Islands) beginning April 1, 2017. This interim final rule with comment period delays the inclusion of the territories in the definition of ''States'' and ''United States'' until April 1, 2020.

DATES: *Effective date:* These regulations are effective on November 15, 2016.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 17, 2017.

ADDRESSES: In commenting, please refer to file code CMS–2345–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2345–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

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–2345–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Wendy Tuttle, (410) 786–8690.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Introduction

The Covered Outpatient Drug final rule with comment period was published in the February 1, 2016 **Federal Register** (81 FR 5170). That final rule with comment period implemented provisions of section 1927 of the Social Security Act (the Act) that were added by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and

Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) pertaining to Medicaid reimbursement for covered outpatient drugs (CODs). That final rule with comment period also revised other requirements related to CODs, including key aspects of Medicaid coverage and payment and the Medicaid Drug Rebate (MDR) program under section 1927 of the Act. The rule became effective on April 1, 2016. However, the regulatory definitions of ''States'' and ''United States'' under § 447.502, included the U.S. territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) beginning April 1, 2017.

We stated in the preamble to the final rule with comment period that U.S. territories may use existing waiver authority to elect not to participate in the MDR program consistent with the statutory waiver standards. The Northern Mariana Islands and American Samoa may seek to opt out of participation under the broad waiver that has been granted to them in accordance with section 1902(j) of the Act. Puerto Rico, the Virgin Islands, and Guam may use waiver authority under section 1115(a)(1) of the Act to waive section 1902(a)(54) of the Act, which requires state compliance with the applicable requirements of section 1927 of the Act (81 FR 5203 through 5204).

We also stated in the final rule with comment period that, effective with the change in the definition of ''United States,'' drug manufacturers would be required to include prices paid by entities located in one of the U.S. territories in the same manner in which they include prices paid by entities located in one of the 50 states and District of Columbia (81 FR 5224) in their calculations of average manufacturer price (AMP) and best price. This change requires manufacturers to include eligible sales and associated discounts, rebates, and other financial transactions that take place in the U.S. territories in their calculations of AMP and best price once the revised definitions of States and United States become effective, regardless of whether the U.S. territories seek to waive participation in the MDR program.

B. Impracticability of Implementation by April 1, 2017

Based on discussions with the U.S. territories, it has become evident that interested U.S. territories could not be ready to implement the program by April 1, 2017, although a few territories have expressed interest in participating once they have made the necessary systems changes. Specifically, the territories need time to develop and change electronic claims processing systems to identify and report utilization (taking into account all of the complexities in tracking utilization by National drug code numbers) and to match utilization with the unit rebate amounts to generate rebate invoices. Further, these systems must be capable of collecting, reporting, validating and tracking drug utilization on an ongoing basis. In addition, they require extensive advance planning and budgeting. We received comments during the comment period of the proposed rule which requested that CMS delay the inclusion of the territories in the MDR program because the manufacturers and territories would need this additional time to implement provisions necessary to include territories in all aspects of the MDR program. We took these comments into consideration and in the final rule delayed the inclusion of the territories into the definitions of States and United States until 1 year after the effective date of the final rule (81 FR 5203, 5204). Despite this 1 year delay, it has since become evident that we underestimated the timeline required, particularly in light of other demands on territorial systems development and the fact that the territories are at various stages of planning and development with respect to these systems. While the U.S. territories have the ability to seek a waiver from the requirements that they would have to meet when classified as ''states,'' doing so would impose some burdens on a territory, particularly for those territories that are not included in the broad waiver authority under section 1902(j) of the Act. Moreover, waivers under section 1115 of the Act are limited to requirements applicable to states or territories under section 1902(a) of the Act, and would not apply to the requirements placed on drug manufacturers that sell in the territories. These manufacturers cannot be waived from the section 1927 of the Act requirements under which manufacturers must include sales that take place in the U.S. territories when determining AMP and best price.

We have heard from various stakeholders who have reiterated many of the concerns that were summarized in the final rule with comment (81 FR 5224) that drug manufacturers will likely be prompted to increase drug prices, including prices paid by U.S. territory Medicaid programs. This would result in the U.S. territories that receive a waiver realizing an increase in their Medicaid drug costs without the offsetting benefit of receiving Medicaid rebates. Furthermore, the increase in Medicaid costs could adversely impact territories because of their Medicaid funding cap.

II. Provisions of the Interim Final Rule

For the reasons discussed in the Background section, this interim final rule with comment period amends the regulatory definitions of ''States'' and ''United States'' under § 447.502 to include the U.S. territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) beginning April 1, 2020 rather than April 1, 2017.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

As discussed in section I.B. of this interim final rule with comment period, in light of the longer time frames needed by territories for planning, budgeting and developing systems necessary to implement the Medicaid drug rebate program, the competing demand on system development resources, and the long time frames for manufacturer pricing determinations, we believe it is necessary to provide territories and manufacturers with advance notice of any change in the timing for the inclusion of territories in the Medicaid drug rebate program. Issuance of a proposed rule would be impracticable because it would result in a notice of the final rule without sufficient time for territories or manufacturers to adjust their actions to take into account the revised timing. Thus, we find good cause to waive the requirement for proposed rulemaking because the short time frame before the inclusion of territories would otherwise take effect does not permit sufficient time to both undertake proposed rulemaking and provide the necessary advance notice for territories and manufacturers to meaningfully adjust planning and systems development to accommodate the revised timing. Furthermore, we find good cause to waive the requirement for proposed rulemaking

because it would be contrary to public interest to delay notifying manufacturers of the change in the timing of the territorial inclusion in light of the potential that, absent sufficient advance notice, drug manufacturers may raise prices on drugs sold in the territories and thereby increase drug costs for both Medicaid and non-Medicaid consumers in the territories.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

IV. Collection of Information Requirements

This rule's delay in including the territories in the definitions of ''States'' and ''United States'' until April 1, 2020, does not impose any new or revised information collection, reporting, recordkeeping or third-party disclosure requirements or burden. 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.*).

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 Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

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 and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this interim final rule with comment period will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this interim final rule with comment period will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts state law, or otherwise has federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

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

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 2. Section 447.502 is amended by revising the definitions of ''States'' and ''United States'' to read as follows:

§ 447.502 Definitions.

* * * * *

States means the 50 States and the District of Columbia and, beginning April 1, 2020, also includes the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa.

United States means the 50 States and the District of Columbia and, beginning April 1, 2020, also includes the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa.

* * * * *

Dated: October 5, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 8, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–27423 Filed 11–14–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 121004518–3398–01]

RIN 0648–XF005

Reef Fish Fishery of the Gulf of Mexico; 2017 Recreational Accountability Measures and Closure for Gulf of Mexico Gray Triggerfish

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements accountability measures (AMs) for the gray triggerfish recreational sector in the exclusive economic zone (EEZ) of the Gulf of Mexico (Gulf) for the 2017 fishing year through this temporary rule. NMFS has determined that the 2016 recreational annual catch limit (ACL) for Gulf gray triggerfish was exceeded; therefore, NMFS reduces the gray triggerfish recreational ACL and annual catch target (ACT) in 2017. As a result of the recreational ACL and ACT overages in 2016, the gray triggerfish 2017 recreational season in the Gulf EEZ will not open on January 1, 2017, and will remain closed for the entire 2017 fishing year. This closure is necessary to protect the Gulf gray triggerfish resource.

DATES: This rule is effective from 12:01 a.m., local time, January 1, 2017, until 12:01 a.m., local time, January 1, 2018.

FOR FURTHER INFORMATION CONTACT: Rich Malinowski, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *rich.malinowski@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS manages the Gulf reef fish fishery, including gray triggerfish, under the Fishery Management Plan for the Reef Fish Resources of the Gulf (FMP). The Gulf of Mexico Fishery Management Council (Council) prepared the FMP and NMFS implements the FMP under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. All gray triggerfish weights discussed in this temporary rule are in round weight.

The recreational ACL for Gulf gray triggerfish specified in 50 CFR 622.41(b)(2)(iii) is 241,200 lb (109,406 kg) and the recreational ACT is 217,100 lb (98,475 kg). However, in 2015, gray triggerfish landings exceeded the 2015 ACL by 39,977 lbs. Therefore, the 2016 ACL and ACT were adjusted to 201,223 lb (91,273 kg) and 177,123 lb (80,342 kg), respectively. In 2016, the recreational fishing season did not re-open after the annual spawning season closure from June 1 through July 31, and the recreational harvest of gray triggerfish exceeded the 2016 recreational ACL by 221,213 lb (100,341 kg). Therefore, consistent with the AM requirements specified in 50 CFR 622.41(b)(2)(ii), NMFS reduces the recreational ACL and ACT for gray triggerfish in 2017 by the amount of the recreational ACL overage to 19,987 lb (9,066 kg) and 0 lb (0 kg), respectively.

Under 50 CFR 622.41(b)(2)(i), NMFS is required to close the recreational sector for gray triggerfish when the recreational ACT is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS has determined that the recreational ACT for the 2017 fishing year is 0 lb (0 kg). Therefore, NMFS closes the recreational harvest of gray triggerfish for the 2017 fishing year.

During the recreational closure, the bag and possession limits for gray triggerfish in or from the Gulf EEZ are zero. The prohibition on possession in the Gulf on board a vessel for which a valid Federal charter vessel/headboat permit for Gulf reef fish has been issued applies regardless of whether gray triggerfish were harvested in state or Federal waters.

The recreational sector for gray triggerfish in the Gulf EEZ will reopen on January 1, 2018, the beginning of the 2018 recreational fishing year, unless changed by subsequent notification in the **Federal Register**.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of Gulf gray triggerfish and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.41(b)(2)(i) and (ii) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best scientific information available. The Assistant Administrator for NOAA Fisheries (AA), finds that the need to immediately implement this action to close the recreational sector for gray triggerfish constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment on this temporary rule pursuant to the authority set forth in 5 U.S.C. 553(b)(B), because such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the rule establishing the closure provisions was subject to notice and comment, and all that remains is to notify the public of the closure. Such procedures are contrary to the public interest because the public requires as much advanced notice as possible of season closures to allow time to adequately plan for recreational fishing trips during the 2017 fishing year.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: November 9, 2016.

Tracey Thompson,

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

[FR Doc. 2016–27415 Filed 11–9–16; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XF032

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; reallocation.

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

DATES: *Effective* November 9, 2016, through 2400 hours, Alaska local time (A.l.t.), December 31, 2016.

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

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

The 2016 Pacific cod TAC specified for catcher vessels using trawl gear in the BSAI is 46,638 metric tons (mt) as established by the final 2016 and 2017 harvest specifications for groundfish of the BSAI (81 FR 14773, March 18, 2016) and reallocations (81 FR 69445, October 6, 2016, 81 FR 76530, November 3, 2016). The Regional Administrator has determined that catcher vessels using trawl gear will not be able to harvest 1,500 mt of the remaining 2016 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*9*).

The 2016 Pacific cod TAC specified for catcher vessels greater than or equal to 60 feet (18.3 m) LOA using pot gear in the BSAI is 17,598 mt as established by the final 2016 and 2017 harvest specifications for groundfish of the BSAI (81 FR 14773, March 18, 2016) and reallocation (81 FR 69445, October 6, 2016). The Regional Administrator has determined that catcher vessels greater than or equal to 60 feet (18.3 m) LOA using pot gear will not be able to harvest 3,000 mt of the remaining 2016 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*5*).

Therefore, in accordance with § 679.20(a)(7)(iii), taking into account the capabilities of the sectors to harvest reallocated amounts of Pacific cod, and following the hierarchies set forth in § 679.20(a)(7)(iii)(A) and § 679.20(a)(7)(iii)(B), NMFS reallocates 4,500 mt of Pacific cod to C/Ps using hook-and-line gear and C/Ps using pot gear in the Bering Sea and Aleutian Islands management area.

The harvest specifications for Pacific cod included in the final 2016 and 2017 harvest specifications for groundfish of the BSAI (81 FR 14773, March 18, 2016, 81 FR 57491, August 23, 2016, 81 FR 61143, September 6, 2016, 81 FR 69445, October 6, 2016, 81 FR 76530, November 3, 2016) are revised as follows: 45,138 mt for catcher vessels using trawl gear, 14,598 for catcher vessels greater than or equal to 60 feet (18.3 m) LOA using pot gear, 111,783 for C/Ps using hook-and-line gear, and 6,607 mt for C/Ps using pot gear.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the reallocation of Pacific cod specified from multiple sectors to C/Ps using hook-and-line gear and C/Ps using pot gear in the Bering Sea and Aleutian Islands management area. Since these fisheries are currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 7, 2016.

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

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

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

Dated: November 9, 2016.

Tracey Thompson,

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

[FR Doc. 2016–27419 Filed 11–9–16; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 220
Tuesday, November 15, 2016

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

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket Number EERE–2016–BT–STD–0004]

RIN 1904–AD61

Appliance Standards and Rulemaking Federal Advisory Committee: Notice of Open Meetings for the Circulator Pumps Working Group To Negotiate a Notice of Proposed Rulemaking (NOPR) for Energy Conservation Standards and Test Procedures

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Announcement of public meetings.

SUMMARY: The Department of Energy (DOE) announces public meetings and webinars for the Circulator Pumps Working Group. The Federal Advisory Committee Act requires that agencies publish notice of an advisory committee meeting in the **Federal Register**.

DATES: See **SUPPLEMENTARY INFORMATION** section for meeting dates.

ADDRESSES: The meetings will be held at Navigant, 1200 19th St. NW., Suite 700, Washington, DC, unless otherwise stated in the **SUPPLEMENTARY INFORMATION** section. Individuals will also have the opportunity to participate by webinar. To register for the webinars and receive call-in information, please register at DOE's Web site: *https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=66&action=viewcurrent.*

FOR FURTHER INFORMATION CONTACT: Mr. Joe Hagerman, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–4549. Email: *asrac@ee.doe.gov.*

Ms. Johanna Jochum, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–6307 Email: *Johanna.Jochum@Hq.Doe.Gov.*

SUPPLEMENTARY INFORMATION: On January 20, 2016, ASRAC met and unanimously passed the recommendation to form a circulator pumps working group. The purpose of the working group is to discuss and, if possible, reach consensus on a proposed rule regarding definitions, test procedures, and energy conservation standards, as authorized by the Energy Policy and Conservation Act (EPCA) of 1975, as amended. The working group consists of representatives of parties having a defined stake in the outcome of the proposed standards, and will consult as appropriate with a range of experts on technical issues. Per the ASRAC Charter, the working group is expected to make a concerted effort to negotiate a final term sheet by December 31, 2016. This notice announces the next series of meetings for this working group.

DOE will host public meetings and webinars on the below dates.

- Tuesday, November 29, 2016 from 9:00 a.m. to 5:00 p.m. at 1200 19th St. NW., Suite 700, Washington, DC.
- Wednesday, November 30, 2016 from 8:00 a.m. to 4:00 p.m. at 1200 19th St. NW., Suite 700, Washington, DC.
- Thursday, December 1, 2016 from 8:00 a.m. to 4:00 p.m. at 1200 19th St. NW., Suite 700, Washington, DC.

Members of the public are welcome to observe the business of the meeting and, if time allows, may make oral statements during the specified period for public comment. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, email *asrac@ee.doe.gov.* In the email, please indicate your name, organization (if appropriate), citizenship, and contact information. Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If you are a foreign national, and wish to participate in the public meeting, please inform DOE as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *Regina.Washington@ee.doe.gov* so that the necessary procedures can be completed. Anyone attending the meeting will be required to present a government photo identification, such as a passport, driver's license, or government identification. Due to the required security screening upon entry, individuals attending should arrive early to allow for the extra time needed.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS) recent changes have been made regarding ID requirements for individuals wishing to enter Federal buildings from specific states and U.S. territories. Driver's licenses from the following states or territory will not be accepted for building entry and one of the alternate forms of ID listed below will be required.

DHS has determined that regular driver's licenses (and ID cards) from the following jurisdictions are not acceptable for entry into DOE facilities: Alaska, Louisiana, New York, American Samoa, Maine, Oklahoma, Arizona, Massachusetts, Washington, and Minnesota.

Acceptable alternate forms of Photo-ID include: U.S. Passport or Passport Card; an Enhanced Driver's License or Enhanced ID-Card issued by the states of Minnesota, New York or Washington (Enhanced licenses issued by these states are clearly marked Enhanced or Enhanced Driver's License); A military ID or other Federal government issued Photo-ID card.

Docket: The docket is available for review at *www.regulations.gov,* including **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

Issued in Washington, DC, on November 8, 2016.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2016–27358 Filed 11–14–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9191; Directorate Identifier 2016–NM–106–AD]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace Corporation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Gulfstream Aerospace Corporation Model GVI airplanes. This proposed AD was prompted by a report indicating that there are design deficiencies in the software used for monitoring the disconnect for the flight control computer (FCC)-hosted flight controls actuation main ram linear variable differential transducer (LVDT). This proposed AD would require an update of the FCC software. We are proposing this AD to prevent the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by December 30, 2016.

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

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

For service information identified in this NPRM, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402–2206; telephone: 800–810–4853; fax: 912–965–3520; email: *pubs@gulfstream.com;* Internet: *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9191; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Myles Jalalian, Aerospace Engineer, Systems and Equipment Branch, ACE–119A, FAA, Atlanta Aircraft Certification Office (ACO), 1701 Columbia Avenue, College Park, GA 30337; phone: 404–474–5572; fax: 404–474–5606; email: *Myles.Jalalian@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–9191; Directorate Identifier 2016–NM–106–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We have received a report indicating that there are design deficiencies in the FCC software used for monitoring the disconnect for the FCC-hosted flight controls actuation main ram LVDT. When a failure occurs, if the actuator LVDT mechanical disconnect monitor and oscillatory monitor are not reliably triggered, there could be an undetected actuation of the main ram LVDT. This condition, if not corrected, could result in undetected actuation of the main ram LVDT. Undetected actuation of the main ram LVDT, if not corrected, could result in mechanical failure of the flight control surface actuator mechanism under force fight (the actuator is working against the intended load forces), causing primary surface hardover, spoiler hardover, and loss of control of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed Gulfstream G650 Aircraft Service Change Number 037, Revision A, dated June 28, 2016; and Gulfstream G650ER Aircraft Service Change Number 037, Revision A, dated June 28, 2016. The service information describes procedures for doing an update of the FCC software. These documents are distinct since they apply to different airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

Interim Action

We consider this proposed AD interim action. The manufacturer is currently developing an additional software update that will complete the actions necessary to address the unsafe condition identified in this proposed AD. Once this additional software update is developed, approved, and available, we might consider additional rulemaking.

Costs of Compliance

We estimate that this proposed AD affects 90 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Software update	57 work-hours × $85 per hour = $4,845	$9,126	$13,971	$1,257,390

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Gulfstream Aerospace Corporation: Docket No. FAA–2016–9191; Directorate Identifier 2016–NM–106–AD.

(a) Comments Due Date

We must receive comments by December 30, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Gulfstream Aerospace Corporation Model GVI airplanes, certificated in any category, serial numbers 6001 through 6164 inclusive.

Note 1 to paragraph (c) of this AD: Model GVI airplanes are also referred to by marketing designations G650 and G650ER.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a report indicating that there are design deficiencies in the software used for monitoring the disconnect for the flight control computer (FCC)-hosted flight controls actuation main ram linear variable differential transducer (LVDT). We are issuing this AD to prevent undetected actuation of the main ram LVDT. Undetected actuation of the main ram LVDT, if not corrected, could result in mechanical failure of the flight control surface actuator mechanism under force fight (the actuator is working against the intended load forces), causing primary surface hardover, spoiler hardover, and loss of control of the airplane.

(f) Compliance

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

(g) Software Update for FCC

Within 24 months after the effective date of this AD, do an FCC software update, in accordance with the Modification Instructions of Gulfstream G650 Aircraft Service Change Number 037, Revision A, dated June 28, 2016; or Gulfstream G650ER Aircraft Service Change Number 037, Revision A, dated June 28, 2016; as applicable.

(h) Reporting Not Required

Although Gulfstream G650 Aircraft Service Change Number 037, Revision A, dated June 28, 2016; and Gulfstream G650ER Aircraft Service Change Number 037, Revision A, dated June 28, 2016; specify to submit certain information to the manufacturer, this AD does not require that action.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta 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 (j)(1) of this AD.

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

(j) Related Information

(1) For more information about this AD, contact Myles Jalalian, Aerospace Engineer, Systems and Equipment Branch, ACE–119A, FAA, Atlanta ACO, 1701 Columbia Avenue, College Park, GA 30337; phone: 404–474–5572; fax: 404–474–5606; email: *Myles.Jalalian@faa.gov.*

(2) For service information identified in this AD, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402–2206; telephone: 800–810–4853; fax: 912–965–3520; email: *pubs@gulfstream.com;* Internet: *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on October 12, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–25354 Filed 11–14–16; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 314

RIN 3084–AB35

Standards for Safeguarding Customer Information

AGENCY: Federal Trade Commission.

ACTION: Request for public comment; reopening for public comments.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') is extending the deadline for filing public comments on its recent Request for Public Comment on the Standards for Safeguarding Customer Information (''Safeguards Rule'' or ''Rule'').

DATES: The comment period for the request for public comment published in the **Federal Register** on September 7, 2016 (81 FR 61632), is reopened. Comments must be received on or before November 21, 2016.

ADDRESSES: Interested parties may file a comment online or on paper by following the Instructions for Submitting Comments part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Safeguards Rule, 16 CFR 314, Project No. P145407,'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/safeguardsrulenprm* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex B), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex B), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: David Lincicum or Katherine McCarron, Division of Privacy and Identity Protection, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW., Washington, DC 20580, (202) 326–2773 or (202) 326–2333.

SUPPLEMENTARY INFORMATION:

I. Comment Period Extension

On September 7, 2016 (81 FR 61632), as part of the Commission's systematic review of all current FTC rules and guides, the Commission published a Request for Comments requesting public comment on the overall costs, benefits, necessity, and regulatory impact of the Safeguards Rule, with a deadline for filing comments of November 7, 2016. On September 12, 2016 (81 FR 63435), the Commission published a Request for Public Comment on its Disposal Rule, with a deadline for comments of November 21, 2016. On October 21, 2016, the American Financial Services Association, Consumer Data Industry Association, and the National Auto Dealer Association, requested that the comment period be extended until November 21, 2016 to coincide with the comment period for Disposal Rule Request for Comments. The requesters explained that the two rules are closely related and that comments on the two rules may overlap. Therefore, having the two comment periods coincide would make it easier for commenters to provide feedback on both rules.

The Commission agrees that allowing additional time for filing comments on the Safeguards Rule would help facilitate the creation of a more complete record. In addition, extending the comment period would not harm consumers because the current Rule will remain in effect during the review process. Therefore, the Commission has decided to extend the comment period to November 21, 2016.

II. Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before November 21, 2016. Write ''Safeguards Rule, 16 CFR 314, Project No. P145407'' on the comment. Your comment, including your name and your state, will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *https://www.ftc.gov/policy/public-comments.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as a Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or payment card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information.

In addition, do not include any ''[t]rade secret or any commercial or financial information which is . . . privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you must follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comments to be withheld from the public record. Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comment online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/safeguardsrulenprm* by following the instructions on the web-based form. If this document appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''Safeguards Rule, 16 CFR 314, Project No. P145407'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex B), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex B), Washington, DC 20024.

Visit the Commission Web site at *http://www.ftc.gov* to read this document and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public

comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before November 21, 2016. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *http://www.ftc.gov/ftc/privacy.htm.*

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–27266 Filed 11–14–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 5, 6, and 19

[FAR Case 2013–018; Docket No. 2013–0018, Sequence No. 1]

RIN 9000–AM90

Federal Acquisition Regulation: Clarification of Requirement for Justifications for 8(a) Sole Source Contracts

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to clarify the guidance for sole-source 8(a) contract awards exceeding $22 million.

DATES: Interested parties should submit written comments to the Regulatory Secretariat Division at one of the addresses shown below on or before January 17, 2017 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to FAR Case 2013–018 by any one of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''FAR Case 2013–018'' under the heading ''Enter Keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''FAR Case 2013–018.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''FAR Case 2013–018'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), ATTN: Ms. Flowers, 1800 F Street NW., 2nd floor, Washington, DC 20405.

Instructions: Please submit comments only and cite FAR Case 2013–018, in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *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. Mahruba Uddowla, Procurement Analyst, via email at *mahruba.uddowla@gsa,* or telephone at 703–605–2868, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755. Please cite FAR Case 2013–018.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA are proposing to revise the FAR to further clarify guidance for justifications of 8(a) sole-source contract awards in excess of $22 million. This proposed rule responds to the recommendations made by the Government Accountability Office (GAO) in its report, GAO–13–118, ''Slow Start to Implementation of Justifications for 8(a) Sole-Source Contracts.'' The GAO report focuses on the revisions made to the FAR to implement section 811 of the National Defense Authorization Act for Fiscal Year 2010 (Pub. L. 111–84) (see 77 FR 23369). Section 811 established the requirement that the head of an agency may not award a sole-source 8(a) contract for an amount exceeding $20 million (subsequently updated to $22 million) unless—

- The contracting officer justifies the use of a sole-source contract in writing;
- The justification is approved by the appropriate official designated to approve contract awards for dollar amounts that are comparable to the amount of the sole-source contract; and
- The justification and related documentation are made available to the public in accordance with 10 U.S.C. 2304(f)(1)(C) and (l), and 41 U.S.C. 253(f)(1)(C) and (j) (recodified at 41 U.S.C. 3304(e)(1)(C) and (f)), as applicable.

The FAR Council published an interim rule in the **Federal Register** at 76 FR 14559 on March 16, 2011 implementing section 811 requirements. The interim rule was subsequently adopted without change as a final rule and published in the **Federal Register** at 77 FR 23369 on April 18, 2012. Prior to publication of the rule, three tribal consultations were conducted in the Fall of 2010 to address the implementation of section 811.

On December 12, 2012, the GAO released its report regarding the use of the of the sole-source 8(a) justification across the Federal Government. The GAO–13–118 report indicates that the FAR needed additional clarification of justification and recommended that clarifying guidance is needed to help ensure that agencies are applying the justification requirement consistently. The GAO report recommended that OFPP, in consultation with the FAR Council, promulgate guidance to clarify the circumstances in which an 8(a) justification is required. As recommended, OFPP and the FAR Council agree to clarify the FAR with guidance that will:

- Clarify whether an 8(a) justification is required for 8(a) contracts that are subject to a pre-existing Competition in Contracting Act of 1984 (Pub. L. 98–369) (CICA) class justification.
- Provide additional information on actions contracting officers should take to comply with the justification requirement when the contract value rises above or falls below $22 million between the Small Business Administration's (SBA's) acceptance of the contract for negotiation under the 8(a) program and the contract award.
- Clarify whether and under what circumstances a separate sole-source justification is necessary for out-of-scope modifications to 8(a) sole-source contracts.
- This rule does not expand on the requirements of section 811. The intent of the proposed rule is to further clarify the processes and procedures in the FAR to ensure uniform, consistent, and coherent guidance regarding the use of sole-source 8(a) justifications.

II. Discussion and Analysis

The following is a summary of the proposed FAR amendments associated with this rule:

A. Clarify Whether an 8(a) Justification Is Required for 8(a) Contracts That Are Subject to a Pre-Existing CICA Class Justification

The proposed rule will clarify that a justification executed under any other authority cannot be substituted for a sole-source 8(a) justification.

B. Provide Additional Information on Actions Contracting Officers Should Take To Comply With the Justification Requirement When the Contract Value Rises Above or Falls Below $22 Million Between SBA's Acceptance of the Contract for Negotiation Under the 8(a) Program and Contract Award

The current requirement in the FAR to prepare and approve the sole-source 8(a) justification prior to negotiation remains intact to ensure that the justification ''. . . is executed prior to negotiation, a critical juncture in the contract award continuum'' (77 FR 23369). However, the FAR will be amended to clarify the appropriate actions contracting officers should take in the event the estimated contract value rises above or falls below $22 million prior to award. DoD, GSA and NASA propose to add the following:

- If the estimated contract value at the time of submission of the offering letter exceeds $22 million, include the approved justification with the offering letter.
- If the estimated contract value at the time of submission of the offering letter is less than or equal to $22 million, but the contract value at time of award exceeds $22 million, send the approved justification prior to contract award.

C. Clarify Whether and Under What Circumstances a Separate Sole-Source Justification Is Necessary for Out-of-Scope Modifications to Sole-Source 8(a) Contracts

At FAR 43.102, the FAR provides guidance to contracting officers acting within the scope of their authority. In general, if the modification to the contract is out of scope, then it would be considered a new contract and would therefore, need to go through the appropriate procurement process for a new contract. Agencies' contracting officers use their discretion to determine if a modification is within the scope of the original contract.

D. Other Changes

Conforming changes were proposed to part 6 and subpart 19.8. Other minor editorial clarifications were made.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD, GSA, and NASA do not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the rule does not impose any new requirements, limitations, or restrictions on small businesses. However, an Initial Regulatory Flexibility Analysis (IRFA) has been prepared and is summarized as follows:

The proposed rule responds to the recommendations made in GAO–113–118 issued on December 12, 2012, to promulgate clarifying guidance in the FAR regarding sole-source 8(a) justifications for contract awards exceeding $22 million. This clarification pertains to processes and procedures that have already been established in the FAR pursuant to section 811 of the National Defense Authorization Act for Fiscal Year 2010.

This rule does not impose any new reporting, recordkeeping, or other compliance requirements. It does not duplicate, overlap, or conflict with any other Federal rules. There are no known alternatives which would accomplish the stated objectives of the applicable statues.

DoD, GSA, and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities. DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule consistent with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAR Case 2013–018), in correspondence.

VII. Paperwork Reduction Act

The proposed rule clarifies guidance that implemented section 811, which prohibited the award of a sole-source contract in an amount over $20 million (subsequently revised to $22 million) under the 8(a) program authority (15 U.S.C. 637(a)) without the contracting officer first obtaining a written justification and approval approved by an appropriate official and making public the justification and approval and related information (see 76 FR 14559). This clarifying guidance pertains to documentation that is internal to the Government and does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 5, 6, and 19

Government procurement.

Dated: November 7, 2016.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

For the reasons set forth in the preamble, 48 CFR parts 5, 6, and 19 are proposed to be amended as follows:

■ 1. The authority citation for 48 CFR parts 5, 6, and 19 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 5—PUBLICIZING CONTRACT ACTIONS

■ 2. Amend section 5.406 by adding paragraph (d) to read as follows:

5.406 Public disclosure of justification documents for certain contract actions.

* * * * *

(d) Sole-source 8(a) justifications for awards exceeding $22 million shall be posted in accordance with 6.305.

PART 6—COMPETITION REQUIREMENTS

■ 3. Amend section 6.204 by revising paragraph (b) to read as follows:

6.204 Section 8(a) competition.

* * * * *

(b) No separate justification or determination and findings is required under this part to limit competition to eligible 8(a) contractors except for sole source 8(a) awards exceeding $22 million (see 6.302–5 and 6.303–1).

* * * * *

6.302–5 [Amended]

■ 4. Amend section 6.302–5 by removing from paragraph (b)(4) ''6.303'' and adding ''6.303–2 and 19.804–3'' in its place; removing ''over'' and adding ''exceeding'' in its place; and removing ''(*See* subpart 19.8).''.

■ 5. Amend section 6.303–1 by—

■ a. Revising paragraph (b); and

■ b. Removing from paragraph (d) ''above'' and adding ''of this section'' in its place.

The revisions read as follows:

6.303–1 Requirements.

* * * * *

(b)(1) In accordance with section 811 of the National Defense Authorization Act for Fiscal Year 2010 (Pub. L. 111–84), the contracting officer shall not award a sole-source contract under the 8(a) authority (15 U.S.C. 637(a)) for an amount exceeding $22 million unless—

(i) The contracting officer justifies the use of a sole-source contract in writing in accordance with 6.303–2; and

(ii) The justification is approved by the appropriate official designated at 6.304; (see 19.804–2(a)(15) and 19.804–2(b) for required information for agency offering letter).

(2) The justification and related information shall be made public after award in accordance with 6.305.

(3) The requirement for a sole-source 8(a) justification and approval shall not be satisfied by any other justification and approval executed under a different authority (*e.g.,* justification and approval in accordance with 6.302–2).

* * * * *

■ 6. Amend section 6.303–2 by—

■ a. Revising the introductory text of paragraph (b);

■ b. Removing from the introductory text of paragraph (d) the word ''over'' and adding ''exceeding'' in its place; and

■ c. Revising paragraph (d)(2).

The revisions read as follows:

6.303–2 Content.

* * * * *

(b) As a minimum, each justification, except for sole-source 8(a) contracts exceeding $22 million (see paragraph (d) of this section), shall include the following information:

* * * * *

(d) * * *

(2) A specification of the statutory provision providing the exception from the requirement at 19.805–1(a) to use competitive procedures in entering into the contract (15 U.S.C. 637(a); and 10 U.S.C. 2304(c)(5) or 41 U.S.C. 3304(a)(5)).

* * * * *

PART 19—SMALL BUSINESS PROGRAMS

■ 7. Amend section 19.804–2 by revising paragraph (b)(3) to read as follows:

19.804–2 Agency offering.

* * * * *

(b) * * *

(3) Sole source requirements, other than construction, should be forwarded directly to the district office that services the nominated firm. If the contracting officer is not nominating a specific firm, the offering letter should be forwarded to the district office servicing the geographical area in which the contracting office is located. For sole-source requirements with an estimated contract value exceeding $22 million, an approved sole source 8(a) justification (see 6.303–1(b)) shall be included in the agency's offering letter.

* * * * *

19.804–3 through 10.804–6 [Redesignated]

■ 8. Redesignate sections 19.804–3 through 19.804–6 as sections 19.804–4 through 19.804–7, respectively.

■ 9. Add new section 19.804–3 to read as follows:

19.804–3 Sole-source 8(a) contract awards.

This subsection implements section 811 of the National Defense Authorization Act for Fiscal Year 2010, (Pub. L. 111–84), which requires justification for the award of a sole-source 8(a) contract exceeding $22 million.

(a)(1) The contracting officer shall not award a sole-source 8(a) contract exceeding $22 million unless—

(i) The contracting officer has justified, in writing, the use of a sole-source 8(a) contract in accordance with 6.303—1(b) and 6.303–2(d); and

(ii) The justification has been approved by the appropriate official designated at 6.304.

(2) A copy of the approved justification shall be provided to the SBA District Office identified in the agency's offering letter (see 19.804–2(a)(15) and 19.804–2(b)).

(i) If the estimated contract value at the time of submission of the offering letter exceeds $22 million, include the approved justification with the offering letter.

(ii) If the estimated contract value at the time of submission of the offering letter is less than or equal to $22 million, but the contract value at time of award exceeds $22 million, send the approved justification prior to contract award.

(b) The justification and related information shall be made public after award, using the procedures at 6.305.

19.805–1 [Amended]

■ 10. Amend section 19.805–1 by removing from the introductory text of paragraph (b) ''sole source'' and adding ''sole-source'' in its place.

19.805–2 [Amended]

■ 11. Amend section 19.805–2 by removing from paragraph (a) ''19.804–3'' and adding ''19.804–4'' in its place.

■ 12. Amend section 19.808–1 by revising paragraph (a) to read as follows:

19.808–1 Sole source.

(a) The SBA may not accept for negotiation a sole-source 8(a) contract that exceeds $22 million unless the requesting agency has submitted an approved sole-source 8(a) justification in accordance with the requirements of 6.303–1(b).

* * * * *

[FR Doc. 2016–27245 Filed 11–14–16; 8:45 am]

BILLING CODE P

Notices

Federal Register
Vol. 81, No. 220
Tuesday, November 15, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

International Trade Administration

Trade Promotion Coordinating Committee

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice and request for nominations from state, local, and municipal governments to the Trade Promotion Coordinating Committee State and Federal Export Promotion Coordination Working Group; extension of deadline.

SUMMARY: The Secretary of Commerce, as Chair of the Trade Promotion Coordinating Committee (TPCC), announces the establishment of the State and Federal Export Promotion Coordination Working Group as a subcommittee of the TPCC. The Trade Facilitation and Trade Enforcement Act of 2015 (the Act) requires the President to establish this Working Group as a subcommittee of the TPCC to identify issues related to the coordination of Federal resources relating to export promotion and export financing with such resources provided by State and local governments. The original notice (FR Doc. 2016–23501) ([citation]) called for nominations to be submitted by October 24, 2016. This notice hereby extends the deadline to November 25, 2016.

DATES: Nominations for immediate consideration for the Working Group must be received electronically on or before 5:00 p.m. (ET) on November 25, 2016. After that date, ITA will continue to accept submissions under this notice for a period of up to two years from the deadline to fill any vacancies that may arise.

FOR FURTHER INFORMATION CONTACT: Patrick Kirwan, Director, Trade Promotion Coordinating Committee Secretariat, Room 31027, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, telephone: 202–482–5455, email: *StateandLocal@trade.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Establishment of Working Group

Section 504(a) of the Trade Facilitation and Trade Enforcement Act of 2015 (''Act''), amended the Export Enhancement Act of 1988 to add a new section 2313A. Section 2313A notes that U.S. policy is to promote exports as an opportunity for small businesses, and in exercising their powers and functions to advance that policy, all Federal agencies shall work constructively with State and local agencies engaged in export promotion and export financing activities. Section 2313A directs the President to establish the State and Federal Export Promotion Coordination Working Group (''Working Group'') under the TPCC with the purposes to:

(1) Identify issues related to the coordination of Federal resources relating to export promotion and export financing with such resources provided by State and local governments;

(2) identify ways to improve coordination with respect to export promotion and export financing activities through the TPCC annual strategic plan;

(3) develop a strategy for improving coordination of Federal and State resources relating to export promotion and export financing, including methods to eliminate duplication of effort and overlapping functions; and

(4) develop a strategic plan for considering and implementing the suggestions of the Working Group as part of the TPCC annual strategic plan.

The President issued Executive Order No. 13733, Delegation of Certain Authorities and Assignment of Certain Functions under the Trade Facilitation and Trade Enforcement Act of 2015, on July 22, 2016, assigning to the Secretary of Commerce the function under Section 2313A(b) of establishing the Working Group. In the Executive Order, the President further directed that, in carrying out its functions, the State and Federal Export Promotion Coordination Working Group shall also coordinate with local and municipal governments representing regionally diverse areas.

II. Member and Meeting Information

The Secretary of Commerce shall select the members of the Working Group, who shall include representatives from State trade agencies and local and municipal governments representing regionally diverse areas and representatives of the federal departments and agencies that are represented on the TPCC. The Working Group will comprise up to sixteen members. Representatives from State trade agencies must be: (1) Elected officers of a State, or (2) State employees designated by an elected State officer to represent the State trade agency with authority to act on his or her behalf. Representatives from local and municipal governments must be: (1) Elected officers or (2) local or municipal employees designated by an elected officer to represent the local and municipal government with authority to act on his or her behalf.

Because the Working Group will be an intergovernmental committee composed wholly of full-time or part-time Federal Government officers or employees, State government elected officers or their designees, and local and municipal elected officials or their designees, all of whom will be acting in their official capacities solely to exchange views, information, or advice relating to the management and implementation of Federal programs established by statute that explicitly share intergovernmental responsibilities and administration, the Working Group is not covered by the Federal Advisory Committee Act, 5 U.S.C. App.

Members appointed as representatives from State trade agencies and local and municipal governments will not receive any Federal compensation for their services and will not be reimbursed for travel expenses. Meetings will be held in person and/or via teleconference. The TPCC will make every effort to use technology to allow for remote participation in meetings, but there will be times when in-person meetings will be necessary. The TPCC will strive to provide members of the Working Group notice of meetings at least 15 calendar days in advance.

III. Request for Nominations

The TPCC Secretariat seeks nominations for representatives from

State trade agencies and local and municipal governments to the Working Group. For purposes of this notice, a ''State trade agency'' is the lead official governmental trade promotion agency for a State, and includes separately established trade agencies as well as trade offices within a State agency or department or the Office of the Governor. A ''local or municipal government'' includes, but is not limited to, town, city, and county governments. The TPCC seeks representation of regionally diverse areas. Qualified individuals may self-nominate or be nominated by a senior level State government or local or municipal government official. To be considered, nominators should submit the following information:

(1) Name, title, and relevant contact information (including phone and email address) for the nominee, the state trade agency that the nominee would represent or the local or municipal government the nominee would represent;

(2) A resume or short biography of the nominee, including professional and academic credentials.

(3) A statement of the nominee's role in state, local, or municipal export promotion activities. Should more information be needed, TPCC staff will contact the nominee. If nominees are not an elected official, a letter may be requested from an elected official that indicates the nominee has been designated to participate in the Working Group on his or her behalf.

Nominators should submit the above information via electronic transmission to *StateandLocal@trade.gov.* The submission must be received on or before 5:00 p.m. (ET) on November 25, 2016. Nominations submitted in response to the prior notice, including those received after October 24, 2016, will be considered and do not need to be resubmitted.

Dated: November 8, 2016.

Patrick Kirwan,

Director, Trade Promotion Coordinating Committee Secretariat.

[FR Doc. 2016–27392 Filed 11–14–16; 8:45 am]

BILLING CODE 3510–25–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF034

Mid-Atlantic Fishery Management Council (MAFMC); Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council (MAFMC) will hold a public meeting of its Atlantic *Mackerel, Squid,* and *Butterfish* (MSB) Committee and its MSB Advisory Panel.

DATES: The meeting will be held on Thursday, December 1, 2016, from 10 a.m. to 5 p.m., to view the agenda see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held at The Doubletree Baltimore-BWI Airport, 890 Elkridge Landing Road, Linthicum, MD 21090; telephone: 410–859–8400. There will be a listen-only Webinar link available, at *http://www.mafmc.org/council-events/dec-1-msb-committee-ap-meeting.*

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331 or on their Web site, at *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION:

Agenda

The Mid-Atlantic Fishery Management Council's Atlantic *Mackerel, Squid,* and *Butterfish* (MSB) Committee will meet jointly with the MSB Advisory Panel to develop recommendations on alternatives to include in an Amendment that could affect the *squid* fisheries. The amendment could reduce the capacities of the longfin *squid* and *Illex squid* fleets. The Council is considering this action because of concern that activation of latent capacity in the *squid* fisheries could lead to excessive fishing effort and increased catch of non-target species. Several other issues are being considered as well: (1) New permits for Maine/northern states; (2) re-evaluation of longfin *squid* trimesters; (3) longfin *squid* buffer zones beyond state waters in the area south of Martha's Vineyard/Nantucket; and (4) revision of the goals and objectives of the MSB Fishery Management Plan. A detailed agenda and background documents will be made available on the Council's Web site, at *www.mafmc.org,* prior to the meeting. Additional information is also available at the Web page for this action: *http://www.mafmc.org/actions/squid-capacity-amendment.*

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 business days prior to the meeting date.

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

Dated: November 9, 2016.

Tracey L. Thompson,

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

[FR Doc. 2016–27433 Filed 11–14–16; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[0648–XE753]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Operation, Maintenance, and Repair of the Northeast Gateway Liquefied Natural Gas Port and the Algonquin Pipeline Lateral Facilities in Massachusetts Bay

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

ACTION: Notice; proposed incidental harassment authorization; request for comments and information.

SUMMARY: NMFS has received a request from Excelerate Energy, L.P. (Excelerate) and Tetra Tech, Inc. (Tetra Tech), on behalf of the Northeast Gateway® Energy Bridge™, L.P. (Northeast Gateway or NEG) and Algonquin Gas Transmission, L.L.C. (Algonquin) for an authorization to take small numbers of 14 species of marine mammals, by Level B harassment, incidental to operating, maintaining, and repairing a liquefied natural gas (LNG) port and the Algonquin Pipeline Lateral (Pipeline Lateral) facilities by NEG and Algonquin, in Massachusetts Bay. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an authorization to NEG and Algonquin to incidentally take, by Level B harassment, small numbers of marine mammals during the specified activity for a period of one year.

DATES: Comments and information must be received no later than December 15, 2016.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. The mailbox address for

providing email comments on this action is *ITP.Guan@noaa.gov.* Comments sent via email, including all attachments, must not exceed a 25-megabyte file size. A copy of the application and a list of references used in this document may be obtained by writing to this address, and are also available at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications.* NMFS is not responsible for comments sent to addresses other than those provided here.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications* without change. All personal identifying information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

The Maritime Administration (MARAD) and U.S. Coast Guard (USCG) Final Environmental Impact Statement (Final EIS) on the Northeast Gateway Energy Bridge NEG Deepwater Port license application is available for viewing at *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications.*

FOR FURTHER INFORMATION CONTACT: Shane Guan, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (Secretary) to allow, upon request, the incidental, but not intentional taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the U.S. can apply for a one-year authorization to incidentally take small numbers of marine mammals by harassment, provided that there is no potential for serious injury or mortality to result from the activity. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization.

Summary of Request

On June 9, 2015, NMFS received an application from Excelerate and Tetra Tech, on behalf of NEG and Algonquin, for an annual IHA and a subsequent five-year letter of authorization (LOA) pursuant to a rulemaking under section 101(a)(5)(A), to take 14 species of marine mammals by Level B harassment incidental to operations, maintenance, and repair of the NEG Port and the Pipeline Lateral facilities in Massachusetts Bay. They are: North Atlantic right whale, humpback whale, fin whale, sei whale, minke whale, long-finned pilot whale, Atlantic white-sided dolphin, bottlenose dolphin, short-beaked common dolphin, killer whale, Risso's dolphin, harbor porpoise, harbor seal, and gray seal. Since the NEG Port and Pipeline Lateral operation, maintenance, and repair activities have the potential to take marine mammals, a marine mammal take authorization under the MMPA is warranted. NMFS issued an IHA to NEG and Algonquin on December 22, 2015 (81 FR 744; January 7, 2016). The IHA is valid until December 22, 2016. In June 2016 NMFS learned that NEG and Algonquin are considering decommissioning the NEG Port in the foreseeable future. Upon discussion with Excelerate and Tetra Tech, it was agreed that instead of conducting a rulemaking for five years of incidental take authorization that may not be needed, NMFS will process another one-year IHA to NEG and Algonquin to cover marine mammal takes from its operations, maintenance, and repair work from December 23, 2016 through December 22, 2017.

NMFS first issued an IHA to NEG and Algonquin to allow for the incidental harassment of small numbers of marine mammals resulting from the construction and operation of the NEG Port and the Pipeline Lateral (72 FR 27077; May 14, 2007). Subsequently, NMFS issued five one-year IHAs for the take of marine mammals incidental to the operation of the NEG Port activity pursuant to section 101(a)(5)(D) of the MMPA (73 FR 29485; May 21, 2008, 74 FR 45613; September 3, 2009 75 FR 53672; September 1, 2010, and 76 FR 62778; October 11, 2011). After that, NMFS issued two one-year IHAs to NEG and Algonquin to take marine mammals incidental to the operations of the NEG Port as well as maintenance and repair (79 FR 78806; December 31, 2014, 81 FR 744; January 7, 2016).

Description of the Specified Activity

The proposed NEG and Algonquin activities include the following:

NEG Port Operations: The NEG Port operations involve docking of NEG vessels and regasification of NEG for delivery to shore. Noises generated during these activities, especially from the NEG vessel's dynamic positioning (DP) thrusters during docking, could result in takes of marine mammals in the port vicinity by level B behavioral harassment.

NEG Port Maintenance and Repair: Regular maintenance and occasional repair of the NEG Port are expected to occur throughout the NEG Port operation period. Machinery used during these activities generate noises that could result in takes of marine mammals in the port vicinity by Level B behavioral harassment.

Algonquin Pipeline Lateral Routine Operations and Maintenance: The Algonquin Pipeline Lateral that is used for gas delivery would be inspected regularly to ensure proper operations. The work would be done using support vessels operating in dynamic positioning mode. Noises generated from these activities could result in takes of marine mammals in the vicinity of Pipeline Lateral by Level B behavioral harassment.

Unplanned Pipeline Repair Activities: Unplanned repair activities may be required from time to time at a location along the Pipeline Lateral in west Massachusetts Bay, as shown in Figure 2.1 of the application. The repair would involve the use of a dive vessel operating in dynamic positioning mode. Noise generated from this activity could result in takes of marine mammals in the vicinity of repair work by Level B behavioral harassment.

An IHA was previously issued to NEG and Algonquin for this activity on December 22, 2014 (79 FR 78806; December 31, 2014), based on activities described on Excelerate and Tetra Tech's IHA application submitted in June 2014 and on the **Federal Register**

notice for the proposed IHA (78 FR 69049; November 18, 2013). The latest application submitted by Excelerate and Tetra Tech on June 9, 2015 contains the same information on project descriptions as described in the June 2014 IHA application. There is no change on the NEG and Algonquin's proposed NEG Port and Pipeline Lateral operations and maintenance and repair. Please refer to these documents for a detailed description of NEG and Algonquin's proposed NEG Port and Pipeline Lateral operations and maintenance and repair activities.

Description of Marine Mammals in the Area of the Specified Activities

Marine mammal species that potentially occur in the vicinity of the Northeast Gateway facility include the North Atlantic right whale, humpback whale, fin whale, sei whale, minke whale, long-finned pilot whale, Atlantic white-sided dolphin, bottlenose dolphin, common dolphin, killer whale, Risso's dolphin, harbor porpoise, harbor seal, and gray seal. General information on the distribution of these marine mammal species can be found in NMFS Stock Assessment Reports (Waring *et al.,* 2016). This latter document is available at: *http://www.nmfs.noaa.gov/pr/sars/pdf/atlantic2015_final.pdf.* Additional information regarding these species within the NEG's proposed action area is provided below, with a summary in Table 1.

Humpback Whale

The highest abundance for humpback whales is distributed primarily along a relatively narrow corridor following the 100–meter (m) (328–feet (ft)) isobath across the southern Gulf of Maine from the northwestern slope of Georges Bank, south to the Great South Channel, and northward alongside Cape Cod to Stellwagen Bank and Jeffreys Ledge. The relative abundance of whales increases in the spring with the highest occurrence along the slope waters (between the 40– and 140–m, or 131– and 459–ft, isobaths) off Cape Cod and Davis Bank, Stellwagen Basin and Tillies Basin and between the 50– and 200–m (164– and 656–t) isobaths along the inner slope of Georges Bank. High abundance is also estimated for the waters around Platts Bank. In the summer months, abundance increases markedly over the shallow waters (<50 m, or <164 ft) of Stellwagen Bank, the waters (100–200 m or 328–656 ft) between Platts Bank and Jeffreys Ledge, the steep slopes (between the 30– and 160–m isobaths) of Phelps and Davis Bank north of the Great South Channel towards Cape Cod, and between the 50– and 100–m (164– and 328–ft) isobath for almost the entire length of the steeply sloping northern edge of Georges Bank. This general distribution pattern persists in all seasons except winter, when humpbacks remain at high abundance in only a few locations including Porpoise and Neddick Basins adjacent to Jeffreys Ledge, northern Stellwagen Bank and Tillies Basin, and the Great South Channel. The best estimate of abundance for Gulf of Maine, formerly western North Atlantic, humpback whales is 823 animals (Waring *et al.,* 2016).

Fin Whale

Spatial patterns of habitat utilization by fin whales are very similar to those of humpback whales. Spring and summer high-use areas follow the 100–m (328 ft) isobath along the northern edge of Georges Bank (between the 50– and 200–m (164– and 656–ft) isobaths), and northward from the Great South Channel (between the 50–and 160–m, or 164– and 525–ft, isobaths). Waters around Cashes Ledge, Platts Bank, and Jeffreys Ledge are all high-use areas in the summer months. Stellwagen Bank is a high-use area for fin whales in all seasons, with highest abundance occurring over the southern Stellwagen Bank in the summer months. In fact, the southern portion of the Stellwagen Bank National Marine Sanctuary (SBNMS) is used more frequently than the northern portion in all months except winter, when high abundance is recorded over the northern tip of Stellwagen Bank. In addition to Stellwagen Bank, high abundance in winter is estimated for Jeffreys Ledge and the adjacent Porpoise Basin (100– to 160–m, 328– to 656–ft, isobaths), as well as Georges Basin and northern Georges Bank. The best estimate of abundance for the western North Atlantic stock of fin whales is 1,618 (Waring *et al.,* 2016). Currently, there are insufficient data to determine population trends for this species.

Minke Whale

Like other piscivorous baleen whales, highest abundance for minke whale is strongly associated with regions between the 50– and 100–m (164– and 328–ft) isobaths, but with a slightly stronger preference for the shallower waters along the slopes of Davis Bank, Phelps Bank, Great South Channel and Georges Shoals on Georges Bank. Minke whales are sighted in the SBNMS in all seasons, with highest abundance estimated for the shallow waters (approximately 40 m, or 131 ft) over southern Stellwagen Bank in the summer and fall months. Platts Bank, Cashes Ledge, Jeffreys Ledge, and the adjacent basins (Neddick, Porpoise and Scantium) also support high relative abundance. Very low densities of minke whales remain throughout most of the southern Gulf of Maine in winter. The best estimate of abundance for the Canadian East Coast stock, which occurs from the western half of the Davis Strait to the Gulf of Mexico, of minke whales is 20,741 animals (Waring *et al.,* 2016). Currently, there are insufficient data to determine population trends for this species.

North Atlantic Right Whale

North Atlantic right whales are generally distributed widely across the southern Gulf of Maine in spring with highest abundance located over the deeper waters (100– to 160–m (328– to 525–ft) isobaths) on the northern edge of the Great South Channel and deep waters (100–300 m, 328–984 ft) parallel to the 100–m (328–ft) isobath of northern Georges Bank and Georges Basin. High abundance is also found in the shallowest waters (< 30 m, or <98 ft) of Cape Cod Bay, over Platts Bank and around Cashes Ledge. Lower relative abundance is estimated over deep-water basins including Wilkinson Basin, Rodgers Basin and Franklin Basin. In the summer months, right whales move almost entirely away from the coast to deep waters over basins in the central Gulf of Maine (Wilkinson Basin, Cashes Basin between the 160– and 200–m (525– and 656–ft) isobaths) and north of Georges Bank (Rogers, Crowell and Georges Basins). Highest abundance is found north of the 100–m (328–ft) isobath at the Great South Channel and over the deep slope waters and basins along the northern edge of Georges Bank. The waters between Fippennies Ledge and Cashes Ledge are also estimated as high-use areas. In the fall months, right whales are sighted infrequently in the Gulf of Maine, with highest densities over Jeffreys Ledge and over deeper waters near Cashes Ledge and Wilkinson Basin. In winter, Cape Cod Bay, Scantum Basin, Jeffreys Ledge, and Cashes Ledge were the main high-use areas. Although SBNMS does not appear to support the highest abundance of right whales, sightings within SBNMS are reported for all four seasons, albeit at low relative abundance. Highest sighting within SBNMS occurred along the southern edge of the Bank.

The western North Atlantic minimum stock size is based on a census of individual whales identified using photo-identification techniques. A review of the photo-ID recapture database as it existed on 20 October 2014 indicated that 476 individually

recognized whales in the catalog were known to be alive during 2011. This number represents a minimum population size. This is a direct count and has no associated coefficient of variation (Waring *et al.,* 2016). Examination of the minimum number alive population index calculated from the individual sightings database, as it existed on 20 October 2014, for the years 1990–2011 suggests a positive and slowly accelerating trend in population size. These data reveal a significant increase in the number of catalogued whales with a geometric mean growth rate for the period of 2.8 percent (Waring *et al.,* 2016).

Long-Finned Pilot Whale

The long-finned pilot whale is more generally found along the edge of the continental shelf (a depth of 330 to 3,300 ft or 100 to 1,000 m), choosing areas of high relief or submerged banks in cold or temperate shoreline waters. This species is split between two subspecies: The Northern and Southern subspecies. The Southern subspecies is circumpolar with northern limits of Brazil and South Africa. The Northern subspecies, which could be encountered during operation of the NEG Port, ranges from North Carolina to Greenland (Reeves *et al.,* 2002; Wilson and Ruff 1999). In the western North Atlantic, long-finned pilot whales are pelagic, occurring in especially high densities in winter and spring over the continental slope, then moving inshore and onto the shelf in summer and autumn following squid and mackerel populations (Reeves *et al.,* 2002). They frequently travel into the central and northern Georges Bank, Great South Channel, and Gulf of Maine areas during the summer and early fall (May and October) (NOAA 1993). According to the species stock report, the population estimate for the Western North Atlantic long-finned pilot whale is 5,636 individuals (Waring *et al.,* 2010). Currently, there are insufficient data to determine population trends for the long-finned pilot whale.

Atlantic White-Sided Dolphin

In spring, summer and fall, Atlantic white-sided dolphins are widespread throughout the southern Gulf of Maine, with the high-use areas widely located either side of the 100–m (328–ft) isobath along the northern edge of Georges Bank, and north from the Great South Channel to Stellwagen Bank, Jeffreys Ledge, Platts Bank and Cashes Ledge. In spring, high-use areas exist in the Great South Channel, northern Georges Bank, the steeply sloping edge of Davis Bank and Cape Cod, southern Stellwagen Bank and the waters between Jeffreys Ledge and Platts Bank. In summer, there is a shift and expansion of habitat toward the east and northeast. High-use areas are identified along most of the northern edge of Georges Bank between the 50– and 200–m (164– and 656–ft) isobaths and northward from the Great South Channel along the slopes of Davis Bank and Cape Cod. High numbers of sightings are also recorded over Truxton Swell, Wilkinson Basin, Cashes Ledge and the bathymetrically complex area northeast of Platts Bank. High numbers of sightings of white-sided dolphin are recorded within SBNMS in all seasons, with highest density in summer and most widespread distributions in spring located mainly over the southern end of Stellwagen Bank. In winter, high numbers of sightings are recorded at the northern tip of Stellwagen Bank and Tillies Basin.

A comparison of spatial distribution patterns for all baleen whales (Mysticeti) and all porpoises and dolphins combined show that both groups have very similar spatial patterns of high- and low-use areas. The baleen whales, whether piscivorous or planktivorous, are more concentrated than the dolphins and porpoises. They utilize a corridor that extended broadly along the most linear and steeply sloping edges in the southern Gulf of Maine indicated broadly by the 100–m (328–ft) isobath. Stellwagen Bank and Jeffreys Ledge support a high abundance of baleen whales throughout the year. Species richness maps indicate that high-use areas for individual whales and dolphin species co-occur, resulting in similar patterns of species richness primarily along the southern portion of the 100–m (328–ft) isobath extending northeast and northwest from the Great South Channel. The southern edge of Stellwagen Bank and the waters around the northern tip of Cape Cod are also highlighted as supporting high cetacean species richness. Intermediate to high numbers of species are also calculated for the waters surrounding Jeffreys Ledge, the entire Stellwagen Bank, Platts Bank, Fippennies Ledge and Cashes Ledge. The best estimate of abundance for the western North Atlantic stock of white-sided dolphins is 48,819 (Waring *et al.,* 2016). A trend analysis has not been conducted for this species.

Killer Whale, Common Dolphin, Bottlenose Dolphin, Risso's Dolphin, and Harbor Porpoise

Although these five species are some of the most widely distributed small cetacean species in the world (Jefferson *et al.,* 1993), they are not commonly seen in the vicinity of the proposed project area in Massachusetts Bay (Wiley *et al.,* 1994; Northeast Gateway Marine Mammal Monitoring Weekly Reports 2007). The total number of killer whales off the eastern U.S. coast is unknown, and present data are insufficient to calculate a minimum population estimate or to determine the population trends for this stock (Blaylock *et al.,* 1995). The best estimate of abundance for the western North Atlantic stock of common dolphins is 173,486 animals, and a trend analysis has not been conducted for this species (Waring *et al.,* 2016). There are several stocks of bottlenose dolphins found along the eastern United States from Maine to Florida. The stock that may occur in the area of the Neptune Port is the western North Atlantic coastal northern migratory stock of bottlenose dolphins. The best estimate of abundance for this stock is 11,548 animals (Waring *et al.,* 2016). There are insufficient data to determine the population trend for this stock. The best estimate of abundance for the western North Atlantic stock of Risso's dolphins is 18,250 animals (Waring *et al.,* 2016). There are insufficient data to determine the population trend for this stock. The best estimate of abundance for the Gulf of Maine/Bay of Fundy stock of harbor porpoise is 79,833 animals (Waring *et al.,* 2016). A trend analysis has not been conducted for this species.

Harbor Seal and Gray Seal

In the U.S. waters of the western North Atlantic, both harbor and gray seals are usually found from the coast of Maine south to southern New England and New York (Waring *et al.,* 2010).

Along the southern New England and New York coasts, harbor seals occur seasonally from September through late May (Schneider and Payne 1983). In recent years, their seasonal interval along the southern New England to New Jersey coasts has increased (deHart 2002). In U.S. waters, harbor seal breeding and pupping normally occur in waters north of the New Hampshire/Maine border, although breeding has occurred as far south as Cape Cod in the early part of the 20th century (Temte *et al.,* 1991; Katona *et al.,* 1993). The best estimate of abundance for the western North Atlantic stock of harbor seals is 75,834 animals (Waring *et al.,* 2016). Although gray seals are often seen off the coast from New England to Labrador, within the U.S. waters, only small numbers of gray seals have been observed pupping on several isolated islands along the Maine coast and in Nantucket-Vineyard Sound, Massachusetts (Katona *et al.,* 1993; Rough, 1995). In the late 1990s, a year-

round breeding population of approximately 400 gray seals was documented on outer Cape Cod and Muskeget Island (Warring *et al.,* 2007). Depending on the model used, the minimum estimate for the Canadian gray seal population was estimated to range between 125,541 and 169,064 animals (Trzcinski *et al.,* 2005, cited in Waring *et al.,* 2009); however, present data are insufficient to calculate the minimum population estimate for U.S. waters. Waring *et al.* (2016) note that gray seal abundance in the U.S. Atlantic is likely increasing, but the rate of increase is unknown.

TABLE 1—MARINE MAMMAL SPECIES POTENTIALLY PRESENT IN REGION OF ACTIVITY

Species	ESA Status	MMPA Status	Abundance	Range	Occurrence
North Atlantic right whale	Endangered	Depleted	476	N. Atlantic	Occasional.
Humpback whale	Endangered	Depleted	823	N. Atlantic	Occasional.
Fin whale	Endangered	Depleted	1618	N. Atlantic	Occasional.
Sei whale	Endangered	Depleted	357	N. Atlantic	Occasional.
Minke whale	Not listed	Non-depleted	20741	N. Atlantic	Occasional.
Long-finned pilot whale	Not listed	Non-depleted	5636	N. Atlantic	Occasional.
Atlantic white-sided dolphin	Not listed	Non-depleted	48819	N. Atlantic	Occasional.
Bottlenose dolphin	Not listed	Non-depleted	11548	N. Atlantic	Uncommon.
Common dolphin	Not listed	Non-depleted	173486	N. Atlantic	Uncommon.
Killer whale	Not listed	Non-depleted	Unknown	N. Atlantic	Uncommon.
Risso's dolphin	Not listed	Non-depleted	18250	N. Atlantic	Uncommon.
Harbor porpoise	Not listed	Non-depleted	79833	N. Atlantic	Uncommon.
Harbor Seal	Not listed	Non-depleted	75834	N. Atlantic	Occasional.
Gray seal	Not listed	Non-depleted	Unknown	N. Atlantic	Occasional.

Potential Effects of the Specified Activity on Marine Mammals

This section includes a summary and discussion of the ways that the types of stressors associated with the specified activity (*e.g.,* pile removal and pile driving) have been observed to impact marine mammals. This discussion may also include reactions that we consider to rise to the level of a take and those that we do not consider to rise to the level of a take (for example, with acoustics, we may include a discussion of studies that showed animals not reacting at all to sound or exhibiting barely measurable avoidance). This section is intended as a background of potential effects and does not consider either the specific manner in which this activity will be carried out or the mitigation that will be implemented and how either of those will shape the anticipated impacts from this specific activity. The ''Estimated Take by Incidental Harassment'' section later in this document will include a quantitative analysis of the number of individuals that are expected to be taken by this activity. The ''Negligible Impact Analysis'' section will include the analysis of how this specific activity will impact marine mammals and will consider the content of this section, the ''Estimated Take by Incidental Harassment'' section, the ''Proposed Mitigation'' section, and the ''Anticipated Effects on Marine Mammal Habitat'' section to draw conclusions regarding the likely impacts of this activity on the reproductive success or survivorship of individuals and from that on the affected marine mammal populations or stocks.

When considering the influence of various kinds of sound on the marine environment, it is necessary to understand that different kinds of marine life are sensitive to different frequencies of sound. Based on available behavioral data, audiograms have been derived using auditory evoked potentials, anatomical modeling, and other data. NMFS (2016) designate ''marine mammal hearing groups'' for marine mammals and estimate the lower and upper frequencies of functional hearing of the groups. The marine mammal hearing groups and the associated frequencies are indicated below (though animals are less sensitive to sounds at the outer edge of their range and most sensitive to sounds of frequencies within a smaller range somewhere in the middle of their hearing range):

- Low frequency cetaceans (13 species of mysticetes): Functional hearing is estimated to occur between approximately 7 Hertz (Hz) and 35 kilo Hertz (kHz);
- Mid-frequency cetaceans (32 species of dolphins, six species of larger toothed whales, and 19 species of beaked and bottlenose whales): Functional hearing is estimated to occur between approximately 150 Hz and 160 kHz;
- High frequency cetaceans (eight species of true porpoises, six species of river dolphins, *Kogia,* the franciscana, and four species of cephalorhynchids): Functional hearing is estimated to occur between approximately 275 Hz and 160 kHz;
- Phocid pinnipeds (true seals): Functional hearing is estimated between 50 Hz to 86 kHz; and
- Otariid pinnipeds (sea lions and fur seals): Functional hearing is estimated between 60 Hz to 39 kHz.

Species found in the vicinity of the NEG Port and Pipeline Lateral operations and maintenance and repair area include five low-frequency cetacean species (North Atlantic right whale, humpback whale, fin whale, sei whale, and minke whale), six mid-frequency cetacean species (long-finned pilot whale, Atlantic white-sided dolphin, bottlenose dolphin, common dolphin, Risso's dolphin, and killer whale), one high-frequency cetacean species (harbor porpoise), and two pinniped species (harbor seal and gray seal) (Table 1).

The proposed NEG Port operations and maintenance and repair activities could adversely affect marine mammal species and stocks by exposing them to elevated noise levels in the vicinity of the activity area.

Marine mammals exposed to high intensity sound repeatedly or for prolonged periods can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Kastak *et al.,* 1999; Schlundt *et al.,* 2000; Finneran *et al.,* 2002; 2005). TS can be permanent (PTS), in which case the loss of hearing sensitivity is unrecoverable, or temporary (TTS), in which case the animal's hearing threshold will recover over time (Southall *et al.,* 2007). Since marine mammals depend on acoustic cues for vital biological functions, such as orientation, communication, finding

prey, and avoiding predators, marine mammals that suffer from PTS or TTS will have reduced fitness in survival and reproduction, either permanently or temporarily. Repeated noise exposure that leads to TTS could cause PTS.

In addition, chronic exposure to excessive, though not high-intensity, noise could cause masking at particular frequencies for marine mammals that utilize sound for vital biological functions (Clark *et al.,* 2009). Acoustic masking can interfere with detection of acoustic signals such as communication calls, echolocation sounds, and environmental sounds important to marine mammals. Therefore, under certain circumstances, marine mammals whose acoustical sensors or environment are being severely masked could also be impaired from maximizing their performance fitness in survival and reproduction.

Masking occurs at the frequency band which the animals utilize. Therefore, since noise generated from in-water vibratory pile driving and removal is mostly concentrated at low frequency ranges, it may have less effect on high frequency echolocation sounds by odontocetes (toothed whales). However, lower frequency man-made noises are more likely to affect detection of communication calls and other potentially important natural sounds such as surf and prey noise. It may also affect communication signals when they occur near the noise band and thus reduce the communication space of animals (*e.g.,* Clark *et al.,* 2009) and cause increased stress levels (*e.g.,* Foote *et al.,* 2004; Holt *et al.,* 2009).

Unlike TS, masking can potentially affect the species at population, community, or even ecosystem levels, as well as individual levels. Masking affects both senders and receivers of the signals and could have long-term chronic effects on marine mammal species and populations. Recent science suggests that low frequency ambient sound levels have increased by as much as 20 decibel (dB) (more than 3 times in terms of sound pressure level (SPL)) in the world's ocean from pre-industrial periods, and most of these increases are from distant shipping (Hildebrand 2009). All anthropogenic noise sources, such as those from vessel traffic, vessel docking, and stationing while operating DP thrusters, dredging and pipe laying associated with NEG Port and Pipeline Lateral maintenance and repair, and NEG regasification activities, contribute to the elevated ambient noise levels, thus increasing potential for or severity of masking.

Finally, exposure of marine mammals to certain sounds could lead to behavioral disturbance (Richardson *et al.,* 1995), such as: changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where noise sources are located; and/or flight responses (*e.g.,* pinnipeds flushing into water from haulouts or rookeries).

The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification are expected to be biologically significant if the change affects growth, survival, and/or reproduction.

The onset of behavioral disturbance from anthropogenic noise depends on both external factors (characteristics of noise sources and their paths) and the receiving animals (hearing, motivation, experience, demography) and is also difficult to predict (Southall *et al.,* 2007). Currently NMFS uses 160 dB re 1 microPascal (root-mean-square) (μPa (rms)) at received level for impulse noises (such as impact pile driving) as the onset of marine mammal behavioral harassment, and 120 dB re 1 μPa (rms) for non-impulse noises (such as operating DP thrusters, dredging, pipe laying, and NEG regasification). No impulse noise is expected from the NEG and Algonquin's proposed NEG Port and Pipeline Lateral operation, maintenance, and repair activities. For the NEG Port and Pipeline Lateral operations and maintenance and repair activities, only the 120 dB re 1 μPa (rms) threshold is considered because only non-impulse noise sources would be generated.

Potential Effects on Marine Mammal Habitat

The proposed action area is considered biologically important habitat for the North Atlantic right, fin, humpback, and minke whales during part of the seasons, and it is adjacent to the SBNMS. There is no critical habitat in the vicinity of the proposed action area.

NEG Port Operations

Operation of the NEG Port will not result in short-term effects, however, long-term effects on the marine environment, including alteration of the seafloor conditions, continued disturbance of the seafloor, regular withdrawal of sea water, and regular generation of underwater noise, will result from NEG Port operations. Specifically, a small area (0.14 acre) along the Pipeline Lateral has been permanently altered (armored) at two cable crossings. In addition, the structures associated with the NEG Port (flowlines, mooring wire rope and chain, suction anchors, and pipeline end manifolds) occupy 4.8 acres of seafloor. An additional area of the seafloor of up to 43 acres (worst case scenario based on severe 100-year storm with Energy Bridge Regasification Vehicle (EBRV) occupying both submerged turret loading (STL) buoys will be subject to disturbance due to chain sweep while the buoys are occupied. Given the relatively small size of the NEG Port area that will be directly affected by Port operations, NMFS does not anticipate that habitat loss will be significant.

EBRVs are currently authorized to withdraw an average of 4.97 million gallons per day (mgd) and 2.6 billion gallons per year of sea water for general ship operations during cargo delivery activities at the NEG Port. However, as we explained in the **Federal Register** notice for the 2015 IHA (78 FR 69049; November 18, 2013), during the operations of the NEG Port facility, it was revealed that significantly more water usage is needed than what was originally evaluated in the final USCG Environmental Impact Statement/Environmental Impact Report (EIS/EIR). The updates for the needed water intake and discharge temperature are:

- 11 billion gallons of total annual water use at the Port;
- Maximum daily intake volume of up to 56 mgd at a rate of 0.45 ft per second when an EBRV is not able to achieve the heat recovery system (HRS) it is the capability of reducing water use during the regasification process) mode of operation; and,
- Maximum daily change in discharge temperature of 12°C (53.6°F) from ambient from the vessel's main condenser cooling system.

Under the requested water-use scenario, Tetra Tech (2011) conducted an environmental analysis on the potential impacts to marine mammals and their prey. To evaluate impacts to phytoplankton under the increased water usage, the biomass of phytoplankton lost from the Massachusetts Bay ecosystem was estimated based on the method presented in the final EIS/EIR. Phytoplankton densities of 65,000 to 390,000 cells/gallon were multiplied by the annual planned activities of withdrawal rate of 11 billion gallons to estimate a loss of 7.15×10^{14} to $4.29 \times$

10^{15} cells per year. Assuming a dry-weight biomass of 10^{-10} to 10^{-11} gramper cell (g/cell), an estimated 7.2 kilograms (kg) to 429 kg of biomass would be lost from Massachusetts Bay under the proposed activity, up to approximately 4.2 times that estimated in the final EIS/EIR for the permitted operational scenario. An order of magnitude estimate of the effect of this annual biomass loss on the regional food web can be calculated assuming a 10 percent transfer of biomass from one trophic level to the next (Sumich 1988) following the method used in the final EIS/EIR. This suggests that the loss of 7.2 kg to 429 kg of phytoplankton will result in the loss of about 0.7 kg to 42.9 kg of zooplankton, less than 0.1 kg to 4.3 kg of small planktivorous fish, and up to 0.4 kg of large piscivorous fish (approximately equivalent to a single 1=pound striped bass). Relative to the biomass of these trophic levels in the project area, this biomass loss is minor and consistent with the findings in the final EIS/EIR.

In addition, zooplankton losses will also increase proportionally to the increase in water withdrawn. The final EIS/EIR used densities of zooplankton determined by the sampling conducted by the Massachusetts Water Resource Authority (MWRA) to characterize the area around its offshore outfall and assumed a mean zooplankton density of 34.9×10^3 organisms per m^3. Applying this density, the water withdrawal volume under the proposed activity would result in the entrainment of 2.2×10^{10} zooplankton individuals per trip or 1.5×10^{12} individuals per year. Assuming an average biomass of 0.63 $\times 10^{6}$ g per individual, this would result in the loss of 14.1 kg of zooplankton per shipment or 916.5 kg of zooplankton per year. As discussed for phytoplankton, biomass transfers from one trophic level to the next at a rate of about 10 percent. Therefore, this entrainment of zooplankton would result in loss of about 91.6 kg of planktivorous fish and 9.2 kg of large piscivorous fish (approximately equivalent to two 9-pound striped bass). These losses are minor relative to the total biomass of these trophic levels in Massachusetts Bay.

Finally, ichthyoplankton (fish eggs and larvae) losses and equivalent age one juvenile fish estimates under the proposed activity were made based on actual monthly ichthyoplankton data collected in the port area from October 2005 through December 2009 and the proposed activity withdrawal volume of 11 billion gallons per year evenly distributed among months (0.92 billion gallons per month) as a worst-case scenario, representing the maximum number of NEG Port deliveries during any given month. Similarly, the lower, upper, and mean annual entrainment estimates are based on the lower and upper 95 percent confidence limits, of the monthly mean ichthyoplankton densities, and the monthly mean estimates multiplied by the monthly withdrawal rate of 0.92 billion gallons per month. At this withdrawal rate approximately 106 million eggs and 67 million larvae are estimated to be lost (see Table 4.2–2 of the IHA application). The most abundant species and life stages estimated to be entrained under the proposed activity are cunner post yolk-sac larvae (33.3 million), yellowtail flounder/*Labridae* eggs (27.4 million) and hake species eggs (18.7 million). Together, these species and life stages accounted for approximately 46 percent of the total entrainment estimated. Entrainment was estimated to be highest in June through July when 97.4 million eggs and larvae (approximately 57 percent of the annual total) were estimated to be entrained. However, the demand for natural gas and corresponding NEG Port activities will likely be greatest during the winter heating season (November through March) when impacts from entrainment will likely be lower.

These estimated losses are not significant given the very high natural mortality of ichthyoplankton. This comparison was done in the final EIS/EIR where ichthyoplankton losses based on historic regional ichthyoplankton densities and a withdrawal rate of approximately 2.6 billion gallons per year were represented by the equivalent number of age-one fish. Under the final EIS/EIR withdrawal scenario, equivalent age-one losses due to entrainment ranged from 1 haddock to 43,431 sand lance (Tetra Tech 2010). Equivalent age-one losses under the conditions when no NEG Port operation occurrence were recalculated using Northeast Gateway monitoring data in order to facilitate comparisons between the permitted scenario and the updated scenario. Using Northeast Gateway monitoring data, withdrawal of 2.6 billion gallons per year would result in equivalent age-one losses ranging from less than 1 haddock to 5,602 American sand lance. By comparison, equivalent age one losses under the proposed activity withdrawal rate of 11 billion gallons per year ranged from less than 1 haddock to 23,701 sand lance and were generally similar to or less than those in the final EIS/EIR. Substantially more equivalent age-one Atlantic herring, pollock, and butterfish were estimated to be lost under the final EIS/EIR at a withdrawal rate of 2.6 billion gallons per year, while substantially more equivalent age-one Atlantic cod, silver hake and hake species, cunner, and Atlantic mackerel are estimated to be lost under the proposed activity.

Although no reliable annual food consumption rates of baleen whales are available for comparison, based on the calculated quantities of phytoplankton, zooplankton, and ichthyoplankton removal analyzed above, it is reasonable to conclude that baleen whale predation rates would dwarf any reasonable estimates of prey removals by NEG Port operations.

NEG Port Maintenance

As stated earlier, NEG Port will require scheduled maintenance inspections using either divers or remote operated vehicles (ROVs). The duration of these inspections are not anticipated to be more than two 8-hour working days. An EBRV will not be required to support these annual inspections. Water usage during the NEG Port maintenance would be limited to the standard requirements of NEG's normal support vessel. As with all vessels operating in Massachusetts Bay, sea water uptake and discharge is required to support engine cooling, typically using a once-through system. The rate of seawater uptake varies with the ship's horsepower and activity and therefore will differ between vessels and activity type. For example, the *Gateway Endeavor* is a 90-foot vessel powered with a 1,200-horsepower diesel engine with a four-pump seawater cooling system. This system requires seawater intake of about 68 gallons per minute (gpm) while idling and up to about 150 gpm at full power. Use of full power is required generally for transit. A conservatively high estimate of vessel activity for the Gateway Endeavor would be operation at idle for 75 percent of the time and full power for 25 percent of the time. During the routine activities this would equate to approximately 42,480 gallons of seawater per 8-hour work day. When compared to the engine cooling requirements of an EBRV over an 8-hour period (approximately 18 million gallons), the *Gateway Endeavour* uses about 0.2 percent of the EBRV requirement. To put this water use into context, potential effects from the water-use scenario of 56 mgd have been concluded to be orders of magnitude less than the natural fluctuations of Massachusetts Bay and Cape Cod Bay and not detectable. Water use by support vessels during routine port

activities would not materially add to the overall impacts.

Certain maintenance and repair activities may also require the presence of an EBRV at the NEG Port. Such instances may include maintenance and repair on the STL Buoy, vessel commissioning, and any onboard equipment malfunction or failure occurring while a vessel is present for cargo delivery. Because the requested water-use scenario allows for daily water use of up to 56 mgd to support standard EBRV requirements when not operating in the HRS mode, vessels would be able to remain at the NEG Port as necessary to support all such maintenance and repair scenarios. Therefore, NMFS considers that NEG Port maintenance and repair would have negligible impacts to marine mammal habitat in the proposed activity area.

Unanticipated Algonquin Pipeline Lateral Maintenance and Repair

As stated earlier, proper care and maintenance of the Pipeline Lateral should minimize the likelihood of an unanticipated maintenance and/or repair event. However, unanticipated activities may occur from time to time if facility components become damaged or malfunction. Unanticipated repairs may range from relatively minor activities requiring minimal equipment and one or two diver/ROV support vessels to major activities requiring larger construction-type vessels similar to those used to support the construction and installation of the facility.

Major repair activities, although unlikely, may include repairing or replacement of pipeline manifolds or sections of the Pipeline Lateral. This type of work would likely require the use of large specialty construction vessels such as those used during the construction and installation of the NEG Port and Pipeline Lateral. The duration of a major unplanned activity would depend upon the type of repair work involved and would require careful planning and coordination.

Turbidity would likely be a potential effect of Pipeline Lateral maintenance and repair activities on listed species. In addition, the possible removal of benthic or planktonic species, resulting from relatively minor construction vessel water use requirements, as measured in comparison to EBRV water use, is unlikely to affect in a measurable way the food sources available to marine mammals. Thus, any impacts to marine mammal habitat are not expected to cause significant or long-term consequences for individual marine mammals or their populations.

Proposed Mitigation Measures

In order to issue an incidental take authorization under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses. NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat.

For the proposed NEG's NEG Port operations and maintenance and repair activities, Excelerate and Tetra Tech worked with NMFS to develop mitigation measures to minimize the potential impacts to marine mammal populations in the project vicinity as a result of the NEG Port and Pipeline Lateral operations and maintenance and repair activities. The primary purpose of these proposed mitigation measures is to ensure that no marine mammal would be injured or killed by vessels transiting the NEG Port facility, and to minimize the intensity of noise exposure of marine mammals in the activity area. For the proposed NEG Port and Pipeline Lateral operations and maintenance and repair, the following mitigation measures are proposed.

(a) General Marine Mammal Avoidance Measures

All vessels shall utilize the International Maritime Organization (IMO)-approved Boston Traffic Separation Scheme (TSS) on their approach to and departure from the NEG Port and/or the repair/maintenance area at the earliest practicable point of transit in order to avoid the risk of whale strikes.

Upon entering the TSS and areas where North Atlantic right whales are known to occur, including the Great South Channel Seasonal Management Area (GSC–SMA) and the SBNMS, EBRVs shall go into ''Heightened Awareness'' as described below.

(1) Prior to entering and navigating the modified TSS, the Master of the vessel shall:

- Consult Navigational Telex (NAVTEX), NOAA Weather Radio, the NOAA Right Whale Sighting Advisory System (SAS) or other means to obtain current right whale sighting information as well as the most recent Cornell acoustic monitoring buoy data for the potential presence of marine mammals;
- Post a look-out to visually monitor for the presence of marine mammals;
- Provide the USCG required 96-hour notification of an arriving EBRV to allow the NEG Port manager to notify Cornell of vessel arrival.

(2) The look-out shall concentrate his/her observation efforts within the 2-mile radius ZOI from the maneuvering EBRV.

(3) If marine mammal detection was reported by NAVTEX, NOAA Weather Radio, SAS and/or an acoustic monitoring buoy, the look-out shall concentrate visual monitoring efforts towards the areas of the most recent detection.

(4) If the look-out (or any other member of the crew) visually detects a marine mammal within the 2-mile radius ZOI of a maneuvering EBRV, he/she will take the following actions:

- The Officer-of-the-Watch shall be notified immediately; who shall then relay the sighting information to the Master of the vessel to ensure action(s) can be taken to avoid physical contact with marine mammals; and
- The sighting shall be recorded in the sighting log by the designated look-out.

In accordance with 50 CFR 224.103(c), all vessels associated with NEG Port and Pipeline Lateral activities shall not approach closer than 500 yards (yd, 460 m) to a North Atlantic right whale and 100 yd (91 m) to other whales to the extent physically feasible given navigational constraints. In addition, when approaching and departing the project area, vessels shall be operated so as to remain at least 1 kilometer away from any visually-detected North Atlantic right whales.

In response to active right whale sightings and active acoustic detections, and taking into account exceptional circumstances, EBRVs as well as repair and maintenance vessels shall take appropriate actions to minimize the risk of striking whales. Specifically vessels shall:

(1) Respond to active right whale sightings and/or Dynamic Management Areas (DMAs) reported on the Mandatory Ship Reporting (MSR) or SAS by concentrating monitoring efforts towards the area of most recent detection and reducing speed to 10 knots or less if the vessel is within the boundaries of a DMA or within the circular area centered on an area 8 nautical miles (nmi) in radius from a sighting location;

(2) Respond to active acoustic detections by concentrating monitoring efforts towards the area of most recent detection and reducing speed to 10 knots or less within an area 5 nm in radius centered on the detecting auto-detection buoy (AB); and

(3) Respond to additional sightings made by the designated look-outs within a 2-mile radius of the vessel by slowing the vessel to 10 knots or less and concentrating monitoring efforts towards the area of most recent sighting.

All vessels operated under NEG and Algonquin must follow the established specific speed restrictions when calling at the NEG Port. The specific speed restrictions required for all vessels (*i.e.,* EBRVs and vessels associated with maintenance and repair) consist of the following:

(1) Vessels shall reduce their maximum transit speed while in the TSS from 12 knots or less to 10 knots or less from March 1 to April 30 in all waters bounded by straight lines connecting the following points in the order stated below unless an emergency situation dictates for an alternate speed. This area shall hereafter be referred to as the Off Race Point Seasonal Management Area (ORP–SMA) and tracks NMFS regulations at 50 CFR 224.105:

42°30′ N. 70°30′ W.	41°40′ N. 69°57′ W.
42°30′ N. 69°45′ W.	42°12′ N. 70°15′ W.
41°40′ N. 69°45′ W.	42°12′ N. 70°30′ W.
42°04.8′ N. 70°10′ W.	42°30′ N. 70°30′ W.;

(2) Vessels shall reduce their maximum transit speed while in the TSS to 10 knots or less unless an emergency situation dictates for an alternate speed from April 1 to July 31 in all waters bounded by straight lines connecting the following points in the order stated below. This area shall hereafter be referred to as the GSC–SMA and tracks NMFS regulations at 50 CFR 224.105:

42°30′ N. 69°45′ W.	41°40′ N. 69°45′ W.
42°30′ N. 67°27′ W.	42°30′ N. 69°45′ W.
42°09′ N. 67°08.4′ W.	41°00′ N. 69°05′ W.;

(3) Vessels are not expected to transit the Cape Cod Bay or the Cape Cod Canal; however, in the event that transit through the Cape Cod Bay or the Cape Cod Canal is required, vessels shall reduce maximum transit speed to 10 knots or less from January 1 to May 15 in all waters in Cape Cod Bay, extending to all shorelines of Cape Cod Bay, with a northern boundary of 42°12′ N. latitude and the Cape Cod Canal. This area shall hereafter be referred to as the Cape Cod Bay Seasonal Management Area (CCB–SMA);

(4) All Vessels transiting to and from the project area shall report their activities to the mandatory reporting Section of the USCG to remain apprised of North Atlantic right whale movements within the area. All vessels entering and exiting the MSRA shall report their activities to WHALESNORTH. Vessel operators shall contact the USCG by standard procedures promulgated through the Notice to Mariner system;

(5) All Vessels greater than or equal to 300 gross tons (GT) shall maintain a speed of 10 knots or less, unless an emergency situation requires speeds greater than 10 knots; and

(6) All Vessels less than 300 GT traveling between the shore and the project area that are not generally restricted to 10 knots will contact the Mandatory Ship Reporting (MSR) system, the USCG, or the project site before leaving shore for reports of active DMAs and/or recent right whale sightings and, consistent with navigation safety, restrict speeds to 10 knots or less within 5 miles (mi) (8 km) of any sighting location, when traveling in any of the seasonal management areas (SMAs) or when traveling in any active DMA.

(b) NEG Port-Specific Operations

In addition to the general marine mammal avoidance requirements identified above, vessels calling on the NEG Port must comply with the following additional requirements:

(1) EBRVs shall travel at 10 knots maximum speed when transiting to/from the TSS or to/from the NEG Port/Pipeline Lateral area. For EBRVs, at 1.86 mi (3 km) from the NEG Port, speed will be reduced to 3 knots and to less than 1 knot at 1,640 ft (500 m) from the NEG buoys, unless an emergency situation dictates the need for an alternate speed;

(2) EBRVs that are approaching or departing from the NEG Port and are within the Area to be Avoided (ATBA) surrounding the NEG Port, shall remain at least 1 km away from any visually-detected North Atlantic right whale and at least 100 yd (91 m) away from all other visually-detected whales unless an emergency situation requires that the vessel stay its course. During EBRV maneuvering, the Vessel Master shall designate at least one look-out to be exclusively and continuously monitoring for the presence of marine mammals at all times while the EBRV is approaching or departing from the NEG Port;

(3) During NEG Port operations, in the event that a whale is visually observed within 1 km of the NEG Port or a confirmed acoustic detection is reported on either of the two ABs closest to the NEG Port (western-most in the TSS array), departing EBRVs shall delay their departure from the NEG Port, unless an emergency situation requires that departure is not delayed. This departure delay shall continue until either the observed whale has been visually (during daylight hours) confirmed as more than 1 km from the NEG Port or 30 minutes have passed without another confirmed detection either acoustically within the acoustic detection range of the two ABs closest to the NEG Port, or visually within 1 km from the NEG Port.

Vessel captains shall focus on reducing DP thruster power to the maximum extent practicable, taking into account vessel and Port safety, during the operation activities. Vessel captains will shut down thrusters whenever they are not needed.

(c) Planned and Unplanned Maintenance and Repair Activities

NEG Port

(1) The Northeast Gateway shall conduct empirical source level measurements on all noise emitting from construction equipment and all vessels that are involved in maintenance/repair work.

(2) If DP systems are to be employed and/or activities will emit noise with a source level of 139 dB re 1 μPa at 1 m, activities shall be conducted in accordance with the requirements for DP systems listed above.

(3) Northeast Gateway shall provide the NMFS Headquarters Office of the Protected Resources, NMFS Northeast Region Ship Strike Coordinator, and SBNMS with a minimum of 30-days notice prior to any planned repair and/or maintenance activity. For any unplanned/emergency repair/maintenance activity, Northeast Gateway shall notify the agencies as soon as it determines that repair work must be conducted. Northeast Gateway shall continue to keep the agencies apprised of repair work plans as further details (*e.g.,* the time, location, and nature of the repair) become available. A final notification shall be provided to agencies 72 hours prior to crews being deployed into the field.

Pipeline Lateral

(1) Pipeline maintenance/repair vessels less than 300 GT traveling between the shore and the maintenance/repair area that are not generally

restricted to 10 knots shall contact the MSR system, the USCG, or the project site before leaving shore for reports of active DMAs and/or recent right whale sightings and, consistent with navigation safety, restrict speeds to 10 knots or less within 5 mi (8 km) of any sighting location, when travelling in any of the seasonal management areas (SMAs) as defined above.

(2) Maintenance/repair vessels greater than 300 GT shall not exceed 10 knots, unless an emergency situation that requires speeds greater than 10 knots.

(3) Planned maintenance and repair activities shall be restricted to the period between May 1 and November 30 when most of the majority of North Atlantic right whales are absent in the area.

(4) Unplanned/emergency maintenance and repair activities shall be conducted utilizing anchor-moored dive vessel whenever operationally possible.

(5) Algonquin shall also provide the NMFS Office of the Protected Resources, NMFS Northeast Region Ship Strike Coordinator, and SBNMS with a minimum of 30-day notice prior to any planned repair and/or maintenance activity. For any unplanned/emergency repair/maintenance activity, Northeast Gateway shall notify the agencies as soon as it determines that repair work must be conducted. Algonquin shall continue to keep the agencies apprised of repair work plans as further details (*e.g.,* the time, location, and nature of the repair) become available. A final notification shall be provided to agencies 72 hours prior to crews being deployed into the field.

(6) If DP systems are to be employed and/or activities will emit noise with a source level of 139 dB re 1 µPa at 1 m, activities shall be conducted in accordance with the requirements for DP systems listed in (5)(b)(ii).

(7) In the event that a whale is visually observed within 0.5 mi (0.8 km) of a repair or maintenance vessel, the vessel superintendent or on-deck supervisor shall be notified immediately. The vessel's crew shall be put on a heightened state of alert and the marine mammal shall be monitored constantly to determine if it is moving toward the repair or maintenance area.

(8) Repair/maintenance vessel(s) must cease any movement and/or cease all activities that emit noises with source level of 139 dB re 1 µPa @1 m or higher when a right whale is sighted within or approaching at 500 yd (457 meters) from the vessel. The source level of 139 dB corresponds to 120 dB received level at 500 yd (457 meters). Repair and maintenance work may resume after the marine mammal is positively reconfirmed outside the established zones (500 yd (457 meters)) or 30 minutes have passed without a redetection. Any vessels transiting the maintenance area, such as barges or tugs, must also maintain these separation distances.

(9) Repair/maintenance vessel(s) must cease any movement and/or cease all activities that emit noises with source level of 139 dB re 1 µPa @1 m or higher when a marine mammal other than a right whale is sighted within or approaching at 100 yd (91 m) from the vessel. Repair and maintenance work may resume after the marine mammal is positively reconfirmed outside the established zones (100 yd (91 meters)) or 30 minutes have passed without a redetection. Any vessels transiting the maintenance area, such as barges or tugs, must also maintain these separation distances.

(10) Algonquin and associated contractors shall also comply with the following:

• Operations involving excessively noisy equipment (source level exceeding 139 dB re 1µPa @1 m) shall ''ramp-up'' sound sources, allowing whales a chance to leave the area before sounds reach maximum levels. In addition, Northeast Gateway, Algonquin, and other associated contractors shall maintain equipment to manufacturers' specifications, including any sound-muffling devices or engine covers in order to minimize noise effects. Noisy construction equipment shall only be used as needed and equipment shall be turned off when not in operation;

• Any material that has the potential to entangle marine mammals (*e.g.,* anchor lines, cables, rope or other construction debris) shall only be deployed as needed and measures shall be taken to minimize the chance of entanglement;

• For any material that has the potential to entangle marine mammals, such material shall be removed from the water immediately unless such action jeopardizes the safety of the vessel and crew as determined by the Captain of the vessel; and

• In the event that a marine mammal becomes entangled, the marine mammal coordinator and/or protected species observer (PSO) will notify NMFS (if outside the SBNMS), and SBNMS staff (if inside the SBNMS) immediately so that a rescue effort may be initiated.

(11) All maintenance/repair activities shall be scheduled to occur between May 1 and November 30. However, in the event of unplanned/emergency repair work that cannot be scheduled during the preferred May through November work window, the following additional measures shall be followed for Pipeline Lateral maintenance and repair related activities between December and April:

• Between December 1 and April 30, if on-board PSOs do not have at least 0.5-mile visibility, they shall call for a shutdown. At the time of shutdown, the use of thrusters must be minimized. If there are potential safety problems due to the shutdown, the captain will decide what operations can safely be shut down;

• Prior to leaving the dock to begin transit, the barge shall contact one of the PSOs on watch to receive an update of sightings within the visual observation area. If the PSO has observed a North Atlantic right whale within 30 minutes of the transit start, the vessel shall hold for 30 minutes and again get a clearance to leave from the PSOs on board. PSOs shall assess whale activity and visual observation ability at the time of the transit request to clear the barge for release;

• Transit route, destination, sea conditions and any marine mammal sightings/mitigation actions during watch shall be recorded in the log book. Any whale sightings within 1,000 meters of the vessel shall result in a high alert and slow speed of 4 knots or less and a sighting within 750 m shall result in idle speed and/or ceasing all movement;

• The material barges and tugs used in repair and maintenance shall transit from the operations dock to the work sites during daylight hours when possible provided the safety of the vessels is not compromised. Should transit at night be required, the maximum speed of the tug shall be 5 knots; and

• All repair vessels must maintain a speed of 10 knots or less during daylight hours. All vessels shall operate at 5 knots or less at all times within 5 km of the repair area.

Acoustic Monitoring Related Activities

Vessels associated with maintaining the AB network operating as part of the mitigation/monitoring protocols shall adhere to the following speed restrictions and marine mammal monitoring requirements.

(1) In accordance with 50 CFR 224.103 (c), all vessels associated with NEG Port activities shall not approach closer than 500 yd (460 meters) to a North Atlantic right whale.

(2) All vessels shall obtain the latest DMA or right whale sighting information via the NAVTEX, MSR,

SAS, NOAA Weather Radio, or other available means prior to operations.

Mitigation Conclusions

NMFS has carefully evaluated the applicant's proposed mitigation measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and
- The practicability of the measure for applicant implementation.

Any mitigation measure(s) prescribed by NMFS should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

(1) Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal);

(2) A reduction in the numbers of marine mammals (total number or number at biologically important time or location) exposed to received levels of pile driving and pile removal or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only);

(3) A reduction in the intensity of exposures (either total number or number at biologically important time or location) to received levels of pile driving, or other activities expected to result in the take of marine mammals (this goal may contribute to a, above, or to reducing the severity of harassment takes only);

(4) Avoidance or minimization of adverse effects to marine mammal habitat, paying special attention to the food base, activities that block or limit passage to or from biologically important areas, permanent destruction of habitat, or temporary destruction/disturbance of habitat during a biologically important time and

(5) For monitoring directly related to mitigation—an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on our evaluation of the applicant's proposed measures that include vessel speed reduction, noise level related shutdown measures, and ramping up procedures, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on marine mammals species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth, ''requirements pertaining to the monitoring and reporting of such taking.'' The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for IHAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Tetra Tech submitted a marine mammal monitoring plan as part of the IHA application. It can be found at *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.* The plan may be modified or supplemented based on comments or new information received from the public during the public comment period.

Monitoring measures prescribed by NMFS should accomplish one or more of the following general goals:

(1) An increase in the probability of detecting marine mammals, both within the mitigation zone (thus allowing for more effective implementation of the mitigation) and in general to generate more data to contribute to the analyses mentioned below;

(2) An increase in our understanding of how many marine mammals are likely to be exposed to levels of pile driving that we associate with specific adverse effects, such as behavioral harassment, TTS, or PTS;

(3) An increase in our understanding of how marine mammals respond to stimuli expected to result in take and how anticipated adverse effects on individuals (in different ways and to varying degrees) may impact the population, species, or stock (specifically through effects on annual rates of recruitment or survival) through any of the following methods:

- Behavioral observations in the presence of stimuli compared to observations in the absence of stimuli (need to be able to accurately predict received level, distance from source, and other pertinent information);
- Physiological measurements in the presence of stimuli compared to observations in the absence of stimuli (need to be able to accurately predict received level, distance from source, and other pertinent information); and
- Distribution and/or abundance comparisons in times or areas with concentrated stimuli versus times or areas without stimuli;

(4) An increased knowledge of the affected species; and

(5) An increase in our understanding of the effectiveness of certain mitigation and monitoring measures.

Proposed Monitoring Measures

(a) Vessel-Based Visual Monitoring

Vessel-based monitoring for marine mammals shall be done by trained look-outs during NEG Port and Pipeline Lateral operations and maintenance and repair activities. The observers shall monitor the occurrence of marine mammals near the vessels during NEG Port and Pipeline Lateral related activities. Lookout duties include watching for and identifying marine mammals; recording their numbers, distances, and reactions to the activities; and documenting ''take by harassment.'' The vessel look-outs assigned to visually monitor for the presence of marine mammals shall be provided with the following:

(1) Recent NAVTEX, NOAA Weather Radio, SAS and/or acoustic monitoring buoy detection data;

(2) Binoculars to support observations;

(3) Marine mammal detection guide sheets; and

(4) Sighting log.

(b) NEG NEG Port Operations

All individuals onboard the EBRVs responsible for the navigation duties and any other personnel that could be assigned to monitor for marine mammals shall receive training on marine mammal sighting/reporting and vessel strike avoidance measures.

While an EBRV is navigating within the designated TSS, there shall be three people with look-out duties on or near the bridge of the ship including the Master, the Officer-of-the-Watch and the Helmsman-on-watch. In addition to the standard watch procedures, while the EBRV is transiting within the designated TSS, maneuvering within the ATBA, and/or while actively engaging in the use of thrusters, an additional look-out shall be designated to exclusively and continuously monitor for marine mammals.

All sightings of marine mammals by the designated look-out, individuals posted to navigational look-out duties, and/or any other crew member while the EBRV is transiting within the TSS, maneuvering within the ATBA and/or when actively engaging in the use of thrusters, shall be immediately reported to the Officer-of-the-Watch who shall then alert the Master. The Master or Officer-of-the-Watch shall ensure the required reporting procedures are followed and the designated marine mammal look-out records all pertinent information relevant to the sighting.

Visual sightings made by look-outs from the EBRVs shall be recorded using a standard sighting log form. Estimated locations shall be reported for each individual and/or group of individuals categorized by species when known. This data shall be entered into a database and a summary of monthly sighting activity shall be provided to NMFS. Estimates of take and copies of these log sheets shall also be included in the reports to NMFS.

(c) Planned and Unplanned Maintenance and Repair

Two qualified and NMFS-approved PSOs shall be assigned to each vessel that will use DP systems during maintenance and repair related activities. PSOs shall operate individually in designated shifts to accommodate adequate rest schedules. Additional PSOs shall be assigned to additional vessels if AB data indicates that sound levels exceed 120 dB re 1 μPa, further then 100 m (328 ft) from these vessels.

All PSOs shall receive NMFS-approved marine mammal observer training and be approved in advance by NMFS after review of their resume. All PSOs shall have direct field experience on marine mammal vessels and/or aerial surveys in the Atlantic Ocean/Gulf of Mexico.

PSOs (one primary and one secondary) shall be responsible for visually locating marine mammals at the ocean's surface and, to the extent possible, identifying the species. The primary PSO shall act as the identification specialist and the secondary PSO will serve as data recorder and also assist with identification. Both PSOs shall have responsibility for monitoring for the presence of marine mammals and sea turtles. Specifically PSO's shall:

(1) Monitor at all hours of the day, scanning the ocean surface by eye for a minimum of 40 minutes every hour;

(2) Monitor the area where maintenance and repair work is conducted beginning at daybreak using 25x power binoculars and/or hand-held binoculars. Night vision devices must be provided as standard equipment for monitoring during low-light hours and at night;

(3) Conduct general 360° visual monitoring during any given watch period and target scanning by the observer shall occur when alerted of a whale presence;

(4) Alert the vessel superintendent or construction crew supervisor of visual detections within 2 mi (3.31 km) immediately;and

(5) Record all sightings on marine mammal field sighting logs. Specifically, all data shall be entered at the time of observation, notes of activities will be kept, and a daily report prepared and attached to the daily field sighting log form. The basic reporting requirements include the following:

- Beaufort sea state;
- Wind speed;
- Wind direction;
- Temperature;
- Precipitation;
- Glare;
- Percent cloud cover;
- Number of animals;
- Species;
- Position;
- Distance;
- Behavior;
- Direction of movement; and
- Apparent reaction to construction activity.

In the event that a whale is visually observed within the 2-mi (3.31-km) ZOI of a DP vessel or other construction vessel that has shown to emit noise with source level in excess of 139 dB re 1 μPa @1 m, the PSO will notify the repair/maintenance construction crew to minimize the use of thrusters until the animal has moved away, unless there are divers in the water or an ROV is deployed.

(d) Acoustic Monitoring

Northeast Gateway shall deploy 10 ABs within the Separation Zone of the TSS for the operational life of the Project. The ABs shall be used to detect a calling North Atlantic right whale an average of 5 nmi from each AB. The AB system shall be the primary detection mechanism that alerts the EBRV Master to the occurrence of right whales, heightens EBRV awareness, and triggers necessary mitigation actions as described above. Northeast Gateway shall conduct short-term passive acoustic monitoring to document sound levels during:

(1) The initial operational events in the 2015–2016 winter heating season;

(2) Regular deliveries outside the winter heating season should such deliveries occur; and

(3) Scheduled and unscheduled maintenance and repair activities.

Northeast Gateway shall conduct long-term monitoring of the noise environment in Massachusetts Bay in the vicinity of the NEG Port and Pipeline Lateral using marine autonomous recording units (MARUs) when there is anticipated to be more than 5 NEG shipments in a 30-day period or over 20 shipments in a 6-month period.

The acoustic data collected shall be analyzed to document the seasonal occurrences and overall distributions of whales (primarily fin, humpback and right whales) within approximately 10 nmi of the NEG Port and shall measure and document the noise ''budget'' of Massachusetts Bay so as to eventually assist in determining whether or not an overall increase in noise in the Bay associated with the Project might be having a potentially negative impact on marine mammals.

Northeast Gateway shall make all acoustic data, including data previously collected by the MARUs during prior construction, operations, and maintenance and repair activities, available to NOAA. Data storage will be the responsibility of NOAA.

(e) Acoustic Whale Detection and Response Plan

NEG Port Operations

(1) Ten ABs that have been deployed since 2007 shall be used to continuously screen the low-frequency acoustic environment (less than 1,000 Hertz) for right whale contact calls occurring within an approximately 5-nm radius from each buoy (the AB's detection range).

(2) Once a confirmed detection is made, the Master of any EBRVs operating in the area will be alerted immediately.

NEG Port and Pipeline Lateral Planned and Unplanned/Emergency Repair and Maintenance Activities

(1) If the repair/maintenance work is located outside of the detectible range of the 10 project area ABs, Northeast Gateway and Algonquin shall consult with NOAA (NMFS and SBNMS) to determine if the work to be conducted warrants the temporary installation of an additional AB(s) to help detect and provide early warnings for potential occurrence of right whales in the vicinity of the repair area.

(2) The number of ABs installed around the activity site shall be commensurate with the type and spatial extent of maintenance/repair work required, but must be sufficient to detect

vocalizing right whales within the 120-dB impact zone.

(3) Should acoustic monitoring be deemed necessary during a planned or unplanned/emergency repair and/or maintenance event, active monitoring for right whale calls shall begin 24 hours prior to the start of activities.

(4) Source level data from the acoustic recording units deployed in the NEG Port and/or Pipeline Lateral maintenance and repair area shall be provided to NMFS.

Proposed Reporting Measures

(a) Throughout NEG Port and Pipeline Lateral operations, Northeast Gateway and Algonquin shall provide a monthly Monitoring Report. The Monitoring Report shall include:

- Both copies of the raw visual EBRV lookout sighting information of marine mammals that occurred within 2 miles of the EBRV while the vessel transits within the TSS, maneuvers within the ATBA, and/or when actively engaging in the use of thrusters, and a summary of the data collected by the look-outs over each reporting period;
- Copies of the raw PSO sightings information on marine mammals gathered during pipeline repair or maintenance activities. This visual sighting data shall then be correlated to periods of thruster activity to provide estimates of marine mammal takes (per species/species class) that took place during each reporting period; and
- Conclusion of any planned or unplanned/emergency repair and/or maintenance period, a report shall be submitted to NMFS summarizing the repair/maintenance activities, marine mammal sightings (both visual and acoustic), empirical source-level measurements taken during the repair work, and any mitigation measures taken.

(b) During the maintenance and repair of NEG Port and Pipeline Lateral components, weekly status reports shall be provided to NOAA (both NMFS and SBNMS) using standardized reporting forms. The weekly reports shall include data collected for each distinct marine mammal species observed in the repair/maintenance area during the period that maintenance and repair activities were taking place. The weekly reports shall include the following information:

- Location (in longitude and latitude coordinates), time, and the nature of the maintenance and repair activities;
- Indication of whether a DP system was operated, and if so, the number of thrusters being used and the time and duration of DP operation;
- Marine mammals observed in the area (number, species, age group, and initial behavior);
- The distance of observed marine mammals from the maintenance and repair activities;
- Changes, if any, in marine mammal behaviors during the observation;
- A description of any mitigation measures (power-down, shutdown, etc.) implemented;
- Weather condition (Beaufort sea state, wind speed, wind direction, ambient temperature, precipitation, and percent cloud cover etc.);
- Condition of the observation (visibility and glare); and
- Details of passive acoustic detections and any action taken in response to those detections.

(d) Injured/Dead Protected Species Reporting

In the unanticipated event that survey operations clearly cause the take of a marine mammal in a manner prohibited by the proposed IHA, such as an injury (Level A harassment), serious injury or mortality (*e.g.,* ship-strike, gear interaction, and/or entanglement), NEG and/or Algonquin shall immediately cease activities and immediately report the incident to the Supervisor of the Incidental Take Program, Permits and Conservation Division, Office of Protected Resources, NMFS and the Northeast Regional Stranding Coordinators. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- The name and type of vessel involved;
- The vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- The fate of the animal(s); and
- Photographs or video footage of the animal (if equipment is available).

Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS shall work with NEG and/or Algonquin to determine what is necessary to minimize the likelihood of further prohibited take and ensure Marine Mammal Protection Act (MMPA) compliance. NEG and/or Algonquin may not resume their activities until notified by NMFS via letter, email, or telephone.

In the event that NEG and/or Algonquin discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.,* in less than a moderate state of decomposition as described in the next paragraph), NEG and/or Algonquin will immediately (*i.e.,* within 24 hours of the discovery) report the incident to the Supervisor of the Incidental Take Program, Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Northeast Stranding Coordinators. The report must include the same information identified above. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with NEG and/or Algonquin to determine whether modifications in the activities are appropriate.

In the event that NEG or Algonquin discovers an injured or dead marine mammal, and the lead PSO determines that the injury or death is not associated with or related to the activities authorized (if the IHA is issued) (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), NEG and/or Algonquin shall report the incident to the Supervisor of the Incidental Take Program, Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Northeast Stranding Coordinators, within 24 hours of the discovery. NEG and/or Algonquin shall provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network. NEG and/or Algonquin can continue its operations under such a case.

Marine Mammal Monitoring Report From Previous IHA

Prior marine mammal monitoring during NEG Port and Pipeline Lateral operation, maintenance and repair activities and monthly marine mammal observation memorandums (NEG 2010; 2015; 2016) indicate that only a small number of marine mammals were observed during these activities. Only one NEG Port operation occurred within the dates of the current IHA (starting December 23, 2015) and only one unidentified small whale was observed at a distance of 2 nmi from the NEG vessel on January 17, 2016. No other NEG Port and Pipeline Lateral related activity occurred during this period.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment). Only take by Level B harassment is anticipated as a result of NEG's operation and maintenance and repair activities. Anticipated take of marine mammals is associated with operation of dynamic positioning during the docking of the NEG vessels and positioning of maintenance and dive vessels, and by operations of certain machinery during maintenance and repair activities. The regasification process itself is an activity that does not rise to the level of taking, as the modeled source level for this activity is 108 dB. Certain species may have a behavioral reaction to the sound emitted during the activities. Hearing impairment is not anticipated. Additionally, vessel strikes are not anticipated, especially because of the speed restriction measures that are proposed that were described earlier in this document.

The full suite of potential impacts to marine mammals was described in detail in the ''Potential Effects of the Specified Activity on Marine Mammals'' section found earlier in this document. The potential effects of sound from the proposed NEG Port and Pipeline Lateral operations, maintenance and repair activities might include one or more of the following: masking of natural sounds and behavioral disturbance (Richardson *et al.,* 1995). As discussed earlier in this document, the most common impact will likely be from behavioral disturbance, including avoidance of the ensonified area or changes in speed, direction, and/or diving profile of the animal. Hearing impairment (TTS and PTS) is highly unlikely to occur based on low noise source levels from the proposed activities that would preclude marine mammals from being exposed to noise levels high enough to cause hearing impairment.

For non-pulse sounds, such as those produced by operating DP thruster during vessel docking and supporting underwater construction and repair activities and the operations of various machineries that produces non-pulse noises, NMFS uses the 120 dB (rms) re 1 µPa isopleth to indicate the onset of Level B harassment.

The basis for Northeast Gateway and Algonquin's ''take'' estimate is the number of marine mammals that would be exposed to sound levels in excess of 120 dB, which is the threshold used by NMFS for non-pulse sounds. For the NEG Port and Pipeline Lateral operations and maintenance and repair activities, the take estimates are determined by multiplying the 120-dB ensonified area by local marine mammal density estimates, and then multiplying by the estimated number of days such activities would occur during a year-long period. For the NEG Port operations, the 120-dB ensonified area is 56.8 km^2 for a single visit during docking when running DP system. Although two EBRV docking with simultaneous DP system running was modeled, this situation would not occur in reality. For NEG Port and Pipeline Lateral maintenance and repair activities, modeling based on the empirical measurements showed that the distance of the 120-dB radius is expected to be 3.5 km, making a maximum 120-dB ZOI of approximately 40.7 km^2.

NEG Port and Algonquin Pipeline Lateral Activities Acoustic Footprints

I. NEG Port Operations

For the purposes of understanding the noise footprint of operations at the NEG Port, measurements taken to capture operational noise (docking, undocking, regasification, and EBRV thruster use) during the 2006 Gulf of Mexico field event were taken at the source. Measurements taken during EBRV transit were normalized to a distance of 328 ft (100 m) to serve as a basis for modeling sound propagation at the NEG Port site in Massachusetts Bay.

Sound propagation calculations for operational activities were then completed at two positions in Massachusetts Bay to determine site-specific distances to the 120/160/180 dB isopleths:

- Operations Position 1—Port (EBRV Operations): 70°36.261′ W. and 42°23.790′ N.; and
- Operations Position 2—Boston TSS (EBRV Transit): 70°17.621′ W. and 42°17.539′ N.

At each of these locations sound propagation calculations were performed to determine the noise footprint of the operation activity at each of the specified locations. Updated acoustic modeling was completed using Tetra Tech's underwater sound propagation program which utilizes a version of the publicly available Range Dependent Acoustic Model (RAM). Based on the U.S. Navy's Standard Split-Step Fourier Parabolic Equation, this modeling methodology considers range and depth along with a geo-referenced dataset to automatically retrieve the time of year information, bathymetry, and seafloor geoacoustic properties along the given propagation transects radiating from the sound source. The calculation methodology assumes that outgoing energy dominates over scattered energy, and computes the solution for the outgoing wave equation. An approximation is used to provide two-dimensional transmission loss values in range and depth, *i.e.,* computation of the transmission loss as a function of range and depth within a given radial plane is carried out independently of neighboring radials, reflecting the assumption that sound propagation is predominantly away from the source. Transects were run along compass points at angular directions ranging from 0 to 360° in 5 degree increments. The received underwater sound levels at any location within the region of interest are computed from the ⅓-octave band source levels by subtracting the numerically modelled transmission loss at each ⅓-octave band center frequency and summing across all frequencies to obtain a broadband value. The resultant underwater sound pressure levels to the 120 dB isopleth is presented in Table 2.

TABLE 2—RADII OF 120-dB SPL ISOPLETHS FROM NEG PORT AND ALGONQUIN PIPELINE LATERAL OPERATIONS, MAINTENANCE, AND REPAIR ACTIVITIES

Activities	Radius to 120-dB zone (m)	120-dB ensonified area (km^2)
One EBRV docking procedure with support vessel	4,250	56.8
Barge/tug (pulling & pushing)/construction vessel/barge @mid-pipeline	3,500	40.7

II. NEG Port Maintenance and Repair

Modeling analysis conducted for the construction of the NEG Port concluded that the only underwater noise of critical concern during NEG Port construction would be from vessel noises such as turning screws, engine noise, noise of operating machinery, and thruster use. To confirm these modeled results and better understand the noise footprint associated with construction activities at the NEG Port, field measurements were taken of various construction activities during the 2007 NEG Port and Pipeline Lateral Construction period. Measurements were taken and normalized as described to establish the ''loudest'' potential construction measurement event. One position within Massachusetts Bay was then used to determine site-specific distances to the 120/180 dB isopleths for NEG Port maintenance and repair activities:

Construction Position 1. Port: 70°36.261′ W. and 42°23.790′ N.

Sound propagation calculations were performed to determine the noise footprint of the construction activity. The results showed that the estimated distance from the loudest source involved in construction activities fell to 120 dB re 1 µPa at a distance of 3,500 m.

III. Algonquin Pipeline Lateral Operation and Maintenance Activities

Modeling analysis conducted during the NEG Port and Pipeline Lateral construction concluded that the only underwater noise of critical concern during such activities would be from vessel noises such as turning screws, engine noise, noise of operating machinery, and thruster use. As with construction noise at the NEG Port, to confirm modeled results and better understand the noise footprint associated with construction activities along the Pipeline Lateral, field measurements were taken of various construction activities during the 2007 NEG Port and Algonquin Pipeline Lateral construction period. Measurements were taken and normalized to establish the ''loudest'' potential construction measurement event. Two positions within Massachusetts Bay were then used to determine site-specific distances to the 120/160/180 dB isopleths:

- Construction Position 2. PLEM: 70°46.755′ W. and 42°28.764′ N.; and
- Construction Position 3. Mid-Pipeline: 70°40.842′ W. and 42°31.328′ N.

Sound propagation calculations were performed to determine the noise footprint of the construction activity. The results of the distances to the 120-dB are shown in Table 2.

Since the issuance of an IHA to NEG on December 22, 2015, there was only one NEG delivery at the NEG Port in January 2015. NEG expects that when the Port is under full operation, it will receive up to 65 NEG shipments per year, and would require 14 days for NEG Port maintenance and up to 40 days for planned and unplanned Algonquin Pipeline Lateral maintenance and repair.

Marine Mammal Densities

The density calculation methodology applied to take estimates for this application is derived from the model results produced by Roberts *et al.* (2016) for the east coast region. These files are available Duke University's Habitat-based Cetacean Density Models Web site: *http://http://seamap.env.duke.edu/models/Duke-EC-GOM-2015/*. The estimated mean monthly abundance for each species for each month was an average of each month. Monthly values were not modeled for some species (*e.g.* killer whale), therefore, only the single value was reported. Estimates provided by the models are based on a grid cell size of 100 km^2, therefore, model grid cell values were divided by 100 to determine animals per km^2. Gray seal and harbor seal densities are not provided in the Roberts *et al.* (2016) models. Seal densities were derived from the Strategic Environmental Research and Development Program (SERDP) using the Navy Oparea Density Estimate (NODE) model for the Northeast Opareas. (Best *et al.,* 2012). A summary of the each species density is provided in Table 3 below.

TABLE 3—ESTIMATED SPECIES DENSITIES

[Animals per km^2]

Species	Mean monthly densities
North Atlantic right whale	0.000838
Fin whale	0.00225
Humpback whale	0.00502
Minke whale	0.00354
Sei whale	0.000025
Long-finned Pilot whale	0.00135
Killer whale	0.0000089
Atlantic white-sided dolphin	0.0219
Bottlenose dolphin	0.0113
Common dolphin	0.0025
Risso's dolphin	0.00025
Harbor porpoise	0.0804
Gray seal	0.027
Harbor seal	0.097

Marine Mammal Take Calculation

Based on NEG Gateway's expectations of up to 65 NEG shipments per year, and up to 14 days for NEG Port maintenance and up to 40 days for planned and unplanned Algonquin Pipeline Lateral repair, the total estimated takes in a given year is calculated based on the following equation.

$$N = A_{NEG} * D * 65 + A_{Port} * D * 14 + A_{Pipeline} * D * 40$$

Where N is the take number for a given species with average density of D. A_{NEG}, A_{Port}, and $A_{Pipeline}$ are the 120-dB ZOI during EMRV vessel docking for regasification, NEG Port maintenance, and Algonquin Pipeline Lateral repair, respectively. A summary of expected takes is provided in Table 4. Since it is very likely that individual animals could be ''taken'' by harassment multiple times, the percentages are the upper boundary of the animal population that could be affected. The actual number of individual animals being exposed or taken would likely be less. Since no population/stock estimates for killer whale and gray seal is available, the percentage of estimated takes for these species is unknown. Nevertheless, since Massachusetts Bay represents only a small fraction of the western North Atlantic basin where these animals occur, NMFS has preliminarily determined that the takes of 10 killer whales and 30 gray seals represent a small fraction of the population and stocks of these species (Table 4). There is no danger of injury, death, or hearing impairment from the exposure to these noise levels.

TABLE 4—ESTIMATED ANNUAL TAKES OF MARINE MAMMALS FROM THE NEG PORT AND ALGONQUIN PIPELINE LATERAL OPERATIONS AND MAINTENANCE AND REPAIR ACTIVITIES IN MASSACHUSETTS BAY

Species	Population/stock	Number of takes	% Population
Right whale	Western Atlantic	5	1.36%.

TABLE 4—ESTIMATED ANNUAL TAKES OF MARINE MAMMALS FROM THE NEG PORT AND ALGONQUIN PIPELINE LATERAL OPERATIONS AND MAINTENANCE AND REPAIR ACTIVITIES IN MASSACHUSETTS BAY—Continued

Species	Population/stock	Number of takes	% Population
Fin whale	Western North Atlantic	13	0.82%.
Humpback whale	Gulf of Maine	30	3.59%.
Sei whale	Nova Scotia	1	0.04%.
Minke whale	Canadian East Coast	21	0.10%.
Long-finned pilot whale	Western North Atlantic	8	0.14%.
Killer whale	Western North Atlantic	1	Unknown.*
Atlantic white-sided dolphin	Western North Atlantic	129	0.26%.
Bottlenose dolphin	Western North Atlantic Southern Migratory	67	0.58%.
Short-beaked common dolphin	Western North Atlantic	15	0.01%.
Risso's dolphin	Western North Atlantic	2	0.01%.
Harbor porpoise	Gulf of Maine/Bay of Fundy	474	0.59%.
Harbor seal	Western North Atlantic	571	0.75%.
Gray seal	Western North Atlantic	159	Unknown.*

*Killer whale and gray seal abundance information is not available.

Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing

On August 4, 2016, NMFS released its Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Guidance). This new guidance established new thresholds for predicting auditory injury, which equates to Level A harassment under the MMPA. In the **Federal Register** notice (81 FR 51694), NMFS explained the approach it would take during a transition period, wherein we balance the need to consider this new best available science with the fact that some applicants have already committed time and resources to the development of analyses based on our previous guidance and have constraints that preclude the recalculation of take estimates, as well as where the action is in the agency's decision-making pipeline. In that Notice, we included a non-exhaustive list of factors that would inform the most appropriate approach for considering the new Guidance, including: The scope of effects; how far in the process the applicant has progressed; when the authorization is needed; the cost and complexity of the analysis; and the degree to which the guidance is expected to affect our analysis.

In this case, we performed an analysis using the new Guidance to calculate potential takes of marine mammal by Level A harassment. The results show that given the brief duration of the NEG operations, NEG Port maintenance, and Algonquin Pipeline Lateral repair activities, no marine mammals would be exposed to received noise levels that would cause auditory injury.

Analysis and Preliminary Determinations

Negligible Impact

Negligible impact is ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival'' (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of Level B harassment takes, alone, is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through behavioral harassment, NMFS must consider other factors, such as the likely nature of any responses (their intensity, duration, etc.), the context of any responses (critical reproductive time or location, migration, etc.), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, effects on habitat, and the status of the species.

To avoid repetition, this introductory discussion of our analyses applies to all the species listed in Table 4, given that the anticipated effects of NEG Port and Pipeline Lateral operations, maintenance, and repair activities on marine mammals (taking into account the proposed mitigation) are expected to be relatively similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, they are described separately in the analysis below.

No injuries or mortalities are anticipated to occur as a result of NEG Port and Pipeline Lateral operations, maintenance, and repair activities, and none are authorized. Additionally, animals in the area are not expected to incur hearing impairment (*i.e.,* TTS or PTS) or non-auditory physiological effects. The takes that are anticipated and authorized are expected to be limited to short-term Level B behavioral harassment. While NEG expects that when the Port is under full operation, it will receive up to 65 NEG shipments per year, and would require 14 days for NEG Port maintenance and up to 40 days for planned and unplanned Pipeline Lateral maintenance and repair, schedules of NEG delivery would occur throughout the year, which include seasons certain marine mammals may not be present in the area.

Effects on marine mammals are generally expected to be restricted to avoidance of a limited area around NEG's proposed activities and short-term changes in behavior, falling within the MMPA definition of ''Level B harassment.'' Mitigation measures, such as controlled vessel speed, dedicated marine mammal observers, and passive acoustic monitoring, will ensure that takes are within the level being analyzed. In all cases, the effects are expected to be short-term, with no lasting biological consequence.

Of the 14 marine mammal species likely to occur in the proposed marine survey area, North Atlantic right, humpback, fin, and sei whales are listed as endangered under the ESA. These species are also designated as ''depleted'' under the MMPA. None of the other species that may occur in the project area are listed as threatened or endangered under the ESA or

designated as depleted under the MMPA.

The project area of the NEG and Algonquin's proposed activities is a biologically important area (BIA) for feeding for the North Atlantic right whale in February to April, humpback whale in March to December, fin whale year-round, and minke whale in March to November (LaBrecque *et al.,* 2015). However, as stated earlier, the NEG and Algonquin's proposed action would only involve short duration of elevated noise levels. In addition, based on prior monitoring reports, on average NEG only had one NEG delivery event per year, and this trend is likely to continue. Therefore, the actual impacts to these species from the Northeast Gateway's proposed operations would likely be much less than what are analyzed here. There are no known important areas for other species within the action area.

Regarding adverse effect to marine mammal habitat, the major potential impact would be the loss of prey due to water intake for cooling during the NEG regasification process. Under the requested water-use scenario, it is estimated that a dry-weight biomass of 916.5 kg of zooplankton per year (translates to 9.2 kg of large piscivorous fish) would be lost per year. The amount of loss is minor relative to the total biomass of the trophic level in Massachusetts Bay.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from NEG and Algonquin's proposed NEG Port and Pipeline Lateral operation, maintenance, and repair activities in Masschusetts Bay are not expected to have adversely affect the affected species or stocks through impacts on annual rates of recruitment or survival, and therefore will have a negligible impact on the affected marine mammal species or stocks.

Small Numbers

The requested takes represent less than 3.6 percent of all populations or stocks potentially impacted (see Table 4 in this document). These take estimates represent the percentage of each species or stock that could be taken by Level B behavioral harassment and TTS (Level B harassment). The numbers of marine mammals estimated to be taken are small proportions of the total populations of the affected species or stocks. In addition, the mitigation and monitoring measures (described previously in this document) prescribed in the IHA are expected to reduce even further any potential disturbance to marine mammals.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, NMFS finds that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no subsistence uses of marine mammals in the proposed project area and, thus, no subsistence uses impacted by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

Our November 18, 2013, **Federal Register** notice of the proposed IHA described the history and status of Endangered Species Act (ESA) compliance for the NEG NEG facility (78 FR 69049). As explained in that notice, the biological opinions for construction and operation of the facility only analyzed impacts on ESA-listed species from activities under the initial construction period and during operations, and did not take into consideration potential impacts to marine mammals that could result from the subsequent NEG Port and Pipeline Lateral maintenance and repair activities. In addition, NEG also revealed that significantly more water usage and vessel operating air emissions are needed from what was originally evaluated for the NEG Port operation. NMFS PR1 initiated consultation with NMFS Greater Atlantic Region Fisheries Office under section 7 of the ESA on the proposed issuance of an IHA to NEG under section 101(a)(5)(D) of the MMPA for the proposed activities that include increased NEG Port and Pipeline Lateral maintenance and repair and water usage for the NEG Port operations this activity. A Biological Opinion was issued on November 21, 2014, and concluded that the proposed action may adversely affect but is not likely to jeopardize the continued existence of ESA-listed right, humpback, fin, and sei whales.

NMFS' Permits and Conservation Division has preliminarily determined that the activities described in here are the same as those analyzed in the November 21, 2014, Biological Opinion. Therefore, a new consultation is not required for issuance of this IHA.

National Environmental Policy Act

MARAD and the USCG released a Final EIS/Environmental Impact Report (EIR) for the proposed NEG Port and Pipeline Lateral. NMFS was a cooperating agency (as defined by the Council on Environmental Quality (40 CFR 1501.6)) in the preparation of the Draft and Final EISs. NMFS reviewed the Final EIS and adopted it on May 4, 2007. NMFS issued a separate Record of Decision for issuance of authorizations pursuant to section 101(a)(5) of the MMPA for the construction and operation of the NEG Port Facility in Massachusetts Bay.

We have reviewed the NEG's application for a renewed IHA for ongoing activities for 2015–16 and the 2014–15 monitoring report. Based on that review, we have determined that the proposed action is very similar to that considered in the previous IHA. In addition, no significant new circumstances or information relevant to environmental concerns have been identified. Thus, we have determined preliminarily that the preparation of a new or supplemental NEPA document is not necessary.

Proposed Incidental Harassment Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to Northeast Gateway and Algonquin for activities associated with Northeast Gateway's NEG Port and Algonquin's Pipeline Lateral operations and maintenance and repair activities in the Massachusetts Bay, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. The proposed IHA language is provided next.

(1) This Authorization is valid from December 22, 2015, through December 21, 2016.

(2) This Authorization is valid only for activities associated with Northeast Gateway's NEG Port and Algonquin's Pipeline Lateral operations and maintenance and repair activities in the Massachusetts Bay. The specific area of the activities is shown in Figure 2–1 of the Excelerate Energy, L.P. and Tetra Tech, Inc.'s IHA application.

(3)(a) The species authorized for incidental harassment takings, Level B harassment only, are: Right whales (*Eubalaena glacialis*); fin whales (*Balaenoptera physalus*); humpback whales (*Megaptera novaeangliae*); minke whales (*B. acutorostrata*); sei whales (*B. borealis*); long-finned pilot

whales (*Globicephala melas*); Atlantic white-sided dolphins (*Lagenorhynchus acutus*); bottlenose dolphins (*Tursiops truncatus*); short-beaked common dolphins (*Delphinus delphis*); Risso's dolphin (*Grampus griseus*); killer whales (*Orcinus orca*); harbor porpoises (*Phocoena phocoena*); harbor seals (*Phoca vitulina*); and gray seals (*Halichoerus grypus*).

(3)(b) The authorization for taking by harassment is limited to the following acoustic sources and from the following activities:

(i) NEG Port operations;

(ii) NEG Port maintenance and repair; and

(iii) Algonquin Pipeline Lateral operations and maintenance.

(3)(c) The taking of any marine mammal in a manner prohibited under this Authorization must be reported within 24 hours of the taking to the National Marine Fisheries Service (NMFS) Greater Atlantic Regional Administrator or his designee, NMFS Headquarters Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, at (301–427–8401), or her designee (301–427–8418).

(4) Prohibitions

(a) The taking, by incidental harassment only, is limited to the species listed under condition 3(a) above and by the numbers listed in Table 4. The taking by Level A harassment, injury or death of these species or the taking by harassment, injury or death of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation of this Authorization.

(5) Mitigation

The holder of this authorization is required to implement the following mitigation measures:

(a) General Marine Mammal Avoidance Measures

(i) All vessels shall utilize the International Maritime Organization (IMO)-approved Boston Traffic Separation Scheme (TSS) on their approach to and departure from the NEG Port and/or the repair/maintenance area at the earliest practicable point of transit in order to avoid the risk of whale strikes.

(ii) Upon entering the TSS and areas where North Atlantic right whales are known to occur, including the Great South Channel Seasonal Management Area (GSC–SMA) and the Stellwagen Bank National Marine Sanctuary (SBNMS), the Energy Bridge Regasification Vessel (EBRV) shall go into ''Heightened Awareness'' as described below.

(A) Prior to entering and navigating the modified TSS the Master of the vessel shall:

(I) Consult Navigational Telex (NAVTEX), NOAA Weather Radio, the NOAA Right Whale Sighting Advisory System (SAS) or other means to obtain current right whale sighting information as well as the most recent Cornell acoustic monitoring buoy data for the potential presence of marine mammals;

(II) Post a look-out to visually monitor for the presence of marine mammals;

(III) Provide the U.S. Coast Guard (USCG) the required 96-hour notification of an arriving EBRV to allow the NEG Port Manager to notify Cornell of vessel arrival.

(B) The look-out shall concentrate his/her observation efforts within the 2-mile radius zone of influence (ZOI) from the maneuvering EBRV.

(C) If marine mammal detection was reported by NAVTEX, NOAA Weather Radio, SAS and/or an acoustic monitoring buoy, the look-out shall concentrate visual monitoring efforts towards the areas of the most recent detection.

(D) If the look-out (or any other member of the crew) visually detects a marine mammal within the 2-mile radius ZOI of a maneuvering EBRV, he/she will take the following actions:

(I) The Officer-of-the-Watch shall be notified immediately; who shall then relay the sighting information to the Master of the vessel to ensure action(s) can be taken to avoid physical contact with marine mammals.

(II) The sighting shall be recorded in the sighting log by the designated look-out.

(III) In accordance with 50 CFR 224.103(c), all vessels associated with NEG Port and Pipeline Lateral activities shall not approach closer than 500 yd (460 m) to a North Atlantic right whale and 100 yd (91 m) to other whales to the extent physically feasible given navigational constraints. In addition, when approaching and departing the project area, vessels shall be operated so as to remain at least 1 km away from any visually-detected North Atlantic right whales.

(IV) In response to active right whale sightings and active acoustic detections, and taking into account exceptional circumstances, EBRVs, repair and maintenance vessels shall take appropriate actions to minimize the risk of striking whales. Specifically vessels shall:

(A) Respond to active right whale sightings and/or DMAs reported on the Mandatory Ship Reporting (MSR) or SAS by concentrating monitoring efforts towards the area of most recent detection and reducing speed to 10 knots or less if the vessel is within the boundaries of a DMA (50 CFR 224.105) or within the circular area centered on an area 8 nm in radius from a sighting location;

(B) Respond to active acoustic detections by concentrating monitoring efforts towards the area of most recent detection and reducing speed to 10 knots or less within an area 5 nm in radius centered on the detecting AB; and

(C) Respond to additional sightings made by the designated look-outs within a 2-mile radius of the vessel by slowing the vessel to 10 knots or less and concentrating monitoring efforts towards the area of most recent sighting.

(V) All vessels operated under NEG and Algonquin must follow the established specific speed restrictions when calling at the NEG Port. The specific speed restrictions required for all vessels (*i.e.,* EBRVs and vessels associated with maintenance and repair) consist of the following:

(A) Vessels shall reduce their maximum transit speed while in the TSS from 12 knots or less to 10 knots or less from March 1 to April 30 in all waters bounded by straight lines connecting the following points in the order stated below unless an emergency situation dictates for an alternate speed. This area shall hereafter be referred to as the Off Race Point Seasonal Management Area (ORP–SMA) and tracks NMFS regulations at 50 CFR 224.105:

42°30′ N. 70°30′ W. 41°40′ N. 69°57′ W. 42°30′ N. 69°45′ W. 42°12′ N. 70°15′ W. 41°40′ N. 69°45′ W. 42°12′ N. 70°30′ W. 42°04.8′ N. 70°10′ W. 42°30′ N. 70°30′ W.

(B) Vessels shall reduce their maximum transit speed while in the TSS to 10 knots or less unless an emergency situation dictates for an alternate speed from April 1 to July 31 in all waters bounded by straight lines connecting the following points in the order stated below. This area shall hereafter be referred to as the GSC–SMA and tracks NMFS regulations at 50 CFR 224.105:

42°30′ N. 69°45′ W. 41°40′ N. 69°45′ W. 42°30′ N. 67°27′ W. 42°30′ N. 69°45′ W. 42°09′ N. 67°08.4′ W. 41°00′ N. 69°05′ W.

(C) Vessels are not expected to transit the Cape Cod Bay or the Cape Cod Canal; however, in the event that transit through the Cape Cod Bay or the Cape Cod Canal is required, vessels shall

reduce maximum transit speed to 10 knots or less from January 1 to May 15 in all waters in Cape Cod Bay, extending to all shorelines of Cape Cod Bay, with a northern boundary of 42°12′ N latitude and the Cape Cod Canal. This area shall hereafter be referred to as the Cape Cod Bay Seasonal Management Area (CCB–SMA).

(D) All Vessels transiting to and from the project area shall report their activities to the mandatory reporting Section of the USCG to remain apprised of North Atlantic right whale movements within the area. All vessels entering and exiting the MSRA shall report their activities to WHALESNORTH. Vessel operators shall contact the USCG by standard procedures promulgated through the Notice to Mariner system.

(E) All Vessels greater than or equal to 300 gross tons (GT) shall maintain a speed of 10 knots or less, unless an emergency situation requires speeds greater than 10 knots.

(F) All Vessels less than 300 GT traveling between the shore and the project area that are not generally restricted to 10 knots will contact the Mandatory Ship Reporting (MSR) system, the USCG, or the project site before leaving shore for reports of active DMAs and/or recent right whale sightings and, consistent with navigation safety, restrict speeds to 10 knots or less within 5 miles (8 kilometers) of any sighting location, when traveling in any of the seasonal management areas (SMAs) or when traveling in any active dynamic management area (DMA).

(b) NEG Port-Specific Operations

(i) In addition to the general marine mammal avoidance requirements identified in (5)(a) above, vessels calling on the NEG Port must comply with the following additional requirements:

(A) EBRVs shall travel at 10 knots maximum speed when transiting to/from the TSS or to/from the NEG Port/Pipeline Lateral area. For EBRVs, at 1.86 miles (3 km) from the NEG Port, speed will be reduced to 3 knots and to less than 1 knot at 1,640 ft (500 m) from the NEG buoys, unless an emergency situation dictates the need for an alternate speed.

(B) EBRVs that are approaching or departing from the NEG Port and are within the ATBA5 surrounding the NEG Port, shall remain at least 1 km away from any visually-detected North Atlantic right whale and at least 100 yd (91 m) away from all other visually-detected whales unless an emergency situation requires that the vessel stay its course. During EBRV maneuvering, the Vessel Master shall designate at least one look-out to be exclusively and continuously monitoring for the presence of marine mammals at all times while the EBRV is approaching or departing from the NEG Port.

(C) During NEG Port operations, in the event that a whale is visually observed within 1 km of the NEG Port or a confirmed acoustic detection is reported on either of the two ABs closest to the NEG Port (western-most in the TSS array), departing EBRVs shall delay their departure from the NEG Port, unless an emergency situation requires that departure is not delayed. This departure delay shall continue until either the observed whale has been visually (during daylight hours) confirmed as more than 1 km from the NEG Port or 30 minutes have passed without another confirmed detection either acoustically within the acoustic detection range of the two ABs closest to the NEG Port, or visually within 1 km from the NEG Port.

(ii) Vessel captains shall focus on reducing dynamic positioning (DP) thruster power to the maximum extent practicable, taking into account vessel and Port safety, during the operation activities. Vessel captains will shut down thrusters whenever they are not needed.

(c) Planned and Unplanned Maintenance and Repair Activities

(i) NEG Port

(A) The Northeast Gateway shall conduct empirical source level measurements on all noise emitting construction equipment and all vessels that are involved in maintenance/repair work.

(B) If dynamic positioning (DP) systems are to be employed and/or activities will emit noise with a source level of 139 dB re 1 µPa at 1 m, activities shall be conducted in accordance with the requirements for DP systems listed in (5)(b)(ii).

(C) Northeast Gateway shall provide the NMFS Headquarters Office of the Protected Resources, NMFS Northeast Region Ship Strike Coordinator, and SBNMS with a minimum of 30 days notice prior to any planned repair and/or maintenance activity. For any unplanned/emergency repair/maintenance activity, Northeast Gateway shall notify the agencies as soon as it determines that repair work must be conducted. Northeast Gateway shall continue to keep the agencies apprised of repair work plans as further details (*e.g.,* the time, location, and nature of the repair) become available. A final notification shall be provided to agencies 72 hours prior to crews being deployed into the field.

(ii) Pipeline Lateral

(A) Pipeline maintenance/repair vessels less than 300 GT traveling between the shore and the maintenance/repair area that are not generally restricted to 10 knots shall contact the MSR system, the USCG, or the project site before leaving shore for reports of active DMAs and/or recent right whale sightings and, consistent with navigation safety, restrict speeds to 10 knots or less within 5 miles (8 km) of any sighting location, when travelling in any of the seasonal management areas (SMAs) as defined above.

(B) Maintenance/repair vessels greater than 300 GT shall not exceed 10 knots, unless an emergency situation that requires speeds greater than 10 knots.

(C) Planned maintenance and repair activities shall be restricted to the period between May 1 and November 30.

(D) Unplanned/emergency maintenance and repair activities shall be conducted utilizing anchor-moored dive vessel whenever operationally possible.

(E) Algonquin shall also provide the NMFS Office of the Protected Resources, NMFS Northeast Region Ship Strike Coordinator, and SBNMS with a minimum of 30-day notice prior to any planned repair and/or maintenance activity. For any unplanned/emergency repair/maintenance activity, Northeast Gateway shall notify the agencies as soon as it determines that repair work must be conducted. Algonquin shall continue to keep the agencies apprised of repair work plans as further details (*e.g.,* the time, location, and nature of the repair) become available. A final notification shall be provided to agencies 72 hours prior to crews being deployed into the field.

(F) If dynamic positioning (DP) systems are to be employed and/or activities will emit noise with a source level of 139 dB re 1 µPa at 1 m, activities shall be conducted in accordance with the requirements for DP systems listed in (5)(b)(ii).

(G) In the event that a whale is visually observed within 0.5 mile (0.8 kilometers) of a repair or maintenance vessel, the vessel superintendent or on-deck supervisor shall be notified immediately. The vessel's crew shall be put on a heightened state of alert and the marine mammal shall be monitored constantly to determine if it is moving toward the repair or maintenance area.

(H) Repair/maintenance vessel(s) must cease any movement and/or cease all activities that emit noises with

source level of 139 dB re 1 µPa @1 m or higher when a right whale is sighted within or approaching at 500 yd (457 m) from the vessel. Repair and maintenance work may resume after the marine mammal is positively reconfirmed outside the established zones (500 yd (457 m)) or 30 minutes have passed without a redetection. Any vessels transiting the maintenance area, such as barges or tugs, must also maintain these separation distances.

(I) Repair/maintenance vessel(s) must cease any movement and/or cease all activities that emit noises with source level of 139 dB re 1 µPa @1 m or higher when a marine mammal other than a right whale is sighted within or approaching at 100 yd (91 m) from the vessel. Repair and maintenance work may resume after the marine mammal is positively reconfirmed outside the established zones (100 yd (91 m)) or 30 minutes have passed without a redetection. Any vessels transiting the maintenance area, such as barges or tugs, must also maintain these separation distances.

(J) Algonquin and associated contractors shall also comply with the following:

(I) Operations involving excessively noisy equipment (source level exceeding 139 dB re 1µPa @1 m) shall ''ramp-up'' sound sources, allowing whales a chance to leave the area before sounds reach maximum levels. In addition, Northeast Gateway, Algonquin, and other associated contractors shall maintain equipment to manufacturers' specifications, including any sound-muffling devices or engine covers in order to minimize noise effects. Noisy construction equipment shall only be used as needed and equipment shall be turned off when not in operation.

(II) Any material that has the potential to entangle marine mammals (*e.g.,* anchor lines, cables, rope or other construction debris) shall only be deployed as needed and measures shall be taken to minimize the chance of entanglement.

(III) For any material that has the potential to entangle marine mammals, such material shall be removed from the water immediately unless such action jeopardizes the safety of the vessel and crew as determined by the Captain of the vessel.

(IV) In the event that a marine mammal becomes entangled, the marine mammal coordinator and/or PSO will notify NMFS (if outside the SBNMS), and SBNMS staff (if inside the SBNMS) immediately so that a rescue effort may be initiated.

(K) All maintenance/repair activities shall be scheduled to occur between May 1 and November 30. However, in the event of unplanned/emergency repair work that cannot be scheduled during the preferred May through November work window, the following additional measures shall be followed for Pipeline Lateral maintenance and repair related activities between December and April:

(I) Between December 1 and April 30, if on-board PSOs do not have at least 0.5-mile visibility, they shall call for a shutdown. At the time of shutdown, the use of thrusters must be minimized. If there are potential safety problems due to the shutdown, the captain will decide what operations can safely be shut down.

(II) Prior to leaving the dock to begin transit, the barge shall contact one of the PSOs on watch to receive an update of sightings within the visual observation area. If the PSO has observed a North Atlantic right whale within 30 minutes of the transit start, the vessel shall hold for 30 minutes and again get a clearance to leave from the PSOs on board. PSOs shall assess whale activity and visual observation ability at the time of the transit request to clear the barge for release.

(III) Transit route, destination, sea conditions and any marine mammal sightings/mitigation actions during watch shall be recorded in the log book. Any whale sightings within 1,000 m of the vessel shall result in a high alert and slow speed of 4 knots or less and a sighting within 750 m shall result in idle speed and/or ceasing all movement.

(IV) The material barges and tugs used in repair and maintenance shall transit from the operations dock to the work sites during daylight hours when possible provided the safety of the vessels is not compromised. Should transit at night be required, the maximum speed of the tug shall be 5 knots.

(V) All repair vessels must maintain a speed of 10 knots or less during daylight hours. All vessels shall operate at 5 knots or less at all times within 5 km of the repair area.

(d) Acoustic Monitoring Related Activities

(i) Vessels associated with maintaining the AB network operating as part of the mitigation/monitoring protocols shall adhere to the following speed restrictions and marine mammal monitoring requirements.

(A) In accordance with NOAA Regulation 50 CFR 224.103 (c), all vessels associated with NEG Port activities shall not approach closer than 500 yd (460 meters) to a North Atlantic right whale.

(B) All vessels shall obtain the latest DMA or right whale sighting information via the NAVTEX, MSR, SAS, NOAA Weather Radio, or other available means prior to operations to determine if there are right whales present in the operational area.

(6) Monitoring

(a) Vessel-Based Visual Monitoring

(i) Vessel-based monitoring for marine mammals shall be done by trained look-outs during NEG NEG Port and Pipeline Lateral operations and maintenance and repair activities. The observers shall monitor the occurrence of marine mammals near the vessels during NEG Port and Pipeline Lateral related activities. Lookout duties include watching for and identifying marine mammals; recording their numbers, distances, and reactions to the activities; and documenting ''take by harassment.''

(ii) The vessel look-outs assigned to visually monitor for the presence of marine mammals shall be provided with the following:

(A) Recent NAVTEX, NOAA Weather Radio, SAS and/or acoustic monitoring buoy detection data;

(B) Binoculars to support observations;

(C) Marine mammal detection guide sheets; and

(D) Sighting log.

(b) NEG NEG Port Operations

(i) All individuals onboard the EBRVs responsible for the navigation duties and any other personnel that could be assigned to monitor for marine mammals shall receive training on marine mammal sighting/reporting and vessel strike avoidance measures.

(ii) While an EBRV is navigating within the designated TSS, there shall be three people with look-out duties on or near the bridge of the ship including the Master, the Officer-of-the-Watch and the Helmsman-on-watch. In addition to the standard watch procedures, while the EBRV is transiting within the designated TSS, maneuvering within the Area to be Avoided (ATBA), and/or while actively engaging in the use of thrusters, an additional look-out shall be designated to exclusively and continuously monitor for marine mammals.

(iii) All sightings of marine mammals by the designated look-out, individuals posted to navigational look-out duties and/or any other crew member while the EBRV is transiting within the TSS, maneuvering within the ATBA and/or when actively engaging in the use of thrusters, shall be immediately reported

to the Officer-of-the-Watch who shall then alert the Master. The Master or Officer-of-the-Watch shall ensure the required reporting procedures are followed and the designated marine mammal look-out records all pertinent information relevant to the sighting.

(iv) Visual sightings made by look-outs from the EBRVs shall be recorded using a standard sighting log form. Estimated locations shall be reported for each individual and/or group of individuals categorized by species when known. This data shall be entered into a database and a summary of monthly sighting activity shall be provided to NMFS. Estimates of take and copies of these log sheets shall also be included in the reports to NMFS.

(c) Planned and Unplanned Maintenance and Repair

(i) Two (2) qualified and NMFS-approved protected species observers (PSOs) shall be assigned to each vessel that will use dynamic positioning (DP) systems during maintenance and repair related activities. PSOs shall operate individually in designated shifts to accommodate adequate rest schedules. Additional PSOs shall be assigned to additional vessels if auto-detection buoy (AB) data indicates that sound levels exceed 120 dB re 1 µPa, further then 100 meters (328 feet) from these vessels.

(ii) All PSOs shall receive NMFS-approved marine mammal observer training and be approved in advance by NMFS after review of their resume. All PSOs shall have direct field experience on marine mammal vessels and/or aerial surveys in the Atlantic Ocean/Gulf of Mexico.

(iii) PSOs (one primary and one secondary) shall be responsible for visually locating marine mammals at the ocean's surface and, to the extent possible, identifying the species. The primary PSO shall act as the identification specialist and the secondary PSO will serve as data recorder and also assist with identification. Both PSOs shall have responsibility for monitoring for the presence of marine mammals and sea turtles. Specifically PSO's shall:

(A) Monitor at all hours of the day, scanning the ocean surface by eye for a minimum of 40 minutes every hour.

(B) Monitor the area where maintenance and repair work is conducted beginning at daybreak using 25x power binoculars and/or hand-held binoculars. Night vision devices must be provided as standard equipment for monitoring during low-light hours and at night.

(C) Conduct general 360° visual monitoring during any given watch period and target scanning by the observer shall occur when alerted of a whale presence.

(D) Alert the vessel superintendent or construction crew supervisor of visual detections within 2 mi (3.31 km) immediately.

(E) Record all sightings on marine mammal field sighting logs. Specifically, all data shall be entered at the time of observation, notes of activities will be kept, and a daily report prepared and attached to the daily field sighting log form. The basic reporting requirements include the following:

- Beaufort sea state;
- Wind speed;
- Wind direction;
- Temperature;
- Precipitation;
- Glare;
- Percent cloud cover;
- Number of animals;
- Species;
- Position;
- Distance;
- Behavior;
- Direction of movement; and
- Apparent reaction to construction activity.

(iv) In the event that a whale is visually observed within the 2-mile (3.31-kilometers) zone of influence (ZOI) of a DP vessel or other construction vessel that has shown to emit noise with source level in excess of 139 dB re 1 µPa @1 m, the PSO will notify the repair/maintenance construction crew to minimize the use of thrusters until the animal has moved away, unless there are divers in the water or an ROV is deployed.

(d) Acoustic Monitoring

(i) Northeast Gateway shall deploy 10 ABs within the Separation Zone of the TSS for the operational life of the Project.

(ii) The ABs shall be used to detect a calling North Atlantic right whale an average of 5 nm from each AB. The AB system shall be the primary detection mechanism that alerts the EBRV Master to the occurrence of right whales, heightens EBRV awareness, and triggers necessary mitigation actions as described in section (5) above.

(iii) Northeast Gateway shall conduct short-term passive acoustic monitoring to document sound levels during the initial operational events in the 2015–2016 winter heating season, and during both regular deliveries outside the winter heating season should such deliveries occur, and during scheduled and unscheduled maintenance and repair activities.

(iv) Northeast Gateway shall conduct long-term monitoring of the noise environment in Massachusetts Bay in the vicinity of the NEG Port and Pipeline Lateral using marine autonomous recording units (MARUs) when there is anticipated to be more than 5 NEG shipments in a 30-day period or over 20 shipments in a six-month period.

(v) The acoustic data collected in 6(d)(ii) shall be analyzed to document the seasonal occurrences and overall distributions of whales (primarily fin, humpback and right whales) within approximately 10 nm of the NEG Port and shall measure and document the noise ''budget'' of Massachusetts Bay so as to eventually assist in determining whether or not an overall increase in noise in the Bay associated with the Project might be having a potentially negative impact on marine mammals.

(vi) Northeast Gateway shall make all acoustic data, including data previously collected by the MARUs during prior construction, operations, and maintenance and repair activities, available to NOAA. Data storage will be the responsibility of NOAA.

(e) Acoustic Whale Detection and Response Plan

(i) NEG Port Operations

(A) Ten (10) ABs that have been deployed since 2007 shall be used to continuously screen the low-frequency acoustic environment (less than 1,000 Hertz) for right whale contact calls occurring within an approximately 5-nm radius from each buoy (the AB's detection range).

(B) Once a confirmed detection is made, the Master of any EBRVs operating in the area will be alerted immediately.

(ii) NEG Port and Pipeline Lateral Planned and Unplanned/Emergency Repair and Maintenance Activities

(A) If the repair/maintenance work is located outside of the detectible range of the 10 project area ABs, Northeast Gateway and Algonquin shall consult with NOAA (NMFS and SBNMS) to determine if the work to be conducted warrants the temporary installation of an additional AB(s) to help detect and provide early warnings for potential occurrence of right whales in the vicinity of the repair area.

(B) The number of ABs installed around the activity site shall be commensurate with the type and spatial extent of maintenance/repair work required, but must be sufficient to detect vocalizing right whales within the 120-dB impact zone.

(C) Should acoustic monitoring be deemed necessary during a planned or

unplanned/emergency repair and/or maintenance event, active monitoring for right whale calls shall begin 24 hours prior to the start of activities.

(D) Revised noise level data from the acoustic recording units deployed in the NEG Port and/or Pipeline Lateral maintenance and repair area shall be provided to NMFS.

(7) Reporting

(a) Throughout NEG Port and Pipeline Lateral operations, Northeast Gateway and Algonquin shall provide a monthly Monitoring Report. The Monitoring Report shall include:

(i) Both copies of the raw visual EBRV lookout sighting information of marine mammals that occurred within 2 miles of the EBRV while the vessel transits within the TSS, maneuvers within the ATBA, and/or when actively engaging in the use of thrusters, and a summary of the data collected by the look-outs over each reporting period.

(ii) Copies of the raw PSO sightings information on marine mammals gathered during pipeline repair or maintenance activities. This visual sighting data shall then be correlated to periods of thruster activity to provide estimates of marine mammal takes (per species/species class) that took place during each reporting period.

(iii) Conclusion of any planned or unplanned/emergency repair and/or maintenance period, a report shall be submitted to NMFS summarizing the repair/maintenance activities, marine mammal sightings (both visual and acoustic), empirical source-level measurements taken during the repair work, and any mitigation measures taken.

(b) During the maintenance and repair of NEG Port components, weekly status reports shall be provided to NOAA (both NMFS and SBNMS) using standardized reporting forms. The weekly reports shall include data collected for each distinct marine mammal species observed in the repair/maintenance area during the period that maintenance and repair activities were taking place. The weekly reports shall include the following information:

(i) Location (in longitude and latitude coordinates), time, and the nature of the maintenance and repair activities;

(ii) Indication of whether a DP system was operated, and if so, the number of thrusters being used and the time and duration of DP operation;

(iii) Marine mammals observed in the area (number, species, age group, and initial behavior);

(iv) The distance of observed marine mammals from the maintenance and repair activities;

(v) Changes, if any, in marine mammal behaviors during the observation;

(vi) A description of any mitigation measures (power-down, shutdown, etc.) implemented;

(vii) Weather condition (Beaufort sea state, wind speed, wind direction, ambient temperature, precipitation, and percent cloud cover etc.);

(viii) Condition of the observation (visibility and glare); and

(ix) Details of passive acoustic detections and any action taken in response to those detections.

(d) Injured/Dead Protected Species Reporting

(i) In the unanticipated event that survey operations clearly cause the take of a marine mammal in a manner prohibited by the proposed IHA, such as an injury (Level A harassment), serious injury or mortality (*e.g.,* ship-strike, gear interaction, and/or entanglement), NEG and/or Algonquin shall immediately cease activities and immediately report the incident to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, and the Greater Atlantic Regional Stranding Coordinators. The report must include the following information:

(A) Time, date, and location (latitude/longitude) of the incident;

(B) The name and type of vessel involved;

(C) The vessel's speed during and leading up to the incident;

(D) Description of the incident;

(E) Status of all sound source use in the 24 hours preceding the incident;

(F) Water depth;

(G) Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);

(H) Description of marine mammal observations in the 24 hours preceding the incident;

(I) Species identification or description of the animal(s) involved;

(J) The fate of the animal(s); and

(K) Photographs or video footage of the animal (if equipment is available).

Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS shall work with NEG and/or Algonquin to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. NEG and/or Algonquin may not resume their activities until notified by NMFS via letter, email, or telephone.

(ii) In the event that NEG and/or Algonquin discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.,* in less than a moderate state of decomposition as described in the next paragraph), NEG and/or Algonquin will immediately report the incident to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Greater Atlantic Stranding Coordinators, within 24 hours of the discovery. The report must include the same information identified above. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with NEG and/or Algonquin to determine whether modifications in the activities are appropriate.

(iii) In the event that NEG or Algonquin discovers an injured or dead marine mammal, and the lead PSO determines that the injury or death is not associated with or related to the activities authorized (if the IHA is issued) (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), NEG and/or Algonquin shall report the incident to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Greater Atlantic Stranding Coordinators, within 24 hours of the discovery. NEG and/or Algonquin shall provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network. NEG and/or Algonquin can continue its operations under such a case.

(8) This Authorization may be modified, suspended, or withdrawn if the holder fails to abide by the conditions prescribed herein or if NMFS determines that the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals.

(9) A copy of this Authorization and the Incidental Take Statement must be in the possession of each survey vessel operator taking marine mammals under the authority of this Incidental Harassment Authorization.

(10) Northeast Gateway and Algonquin are required to comply with the Terms and Conditions of the Incidental Take Statement corresponding to NMFS' Biological Opinion.

Request for Public Comments

NMFS requests comment on our analysis, the draft authorization for an IHA, the receipt of notice for a rulemaking, and any other aspect of the Notice of Proposed IHA for Northeast Gateway and Algonquin's proposed NEG Port and Pipeline Lateral

operations, maintenance, and repair activities in the Massachusetts Bay. Please include with your comments any supporting data or literature citations to help inform our final decision on Northeast Gateway and Algonquin's request for an MMPA authorization.

Dated: November 7, 2016.

Donna Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–27383 Filed 11–14–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 161017970–6970–01]

RIN 0648–XE976

Fisheries of the Northeastern United States; Summer Flounder Fishery; 2017 and 2018 Summer Flounder Specifications

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

ACTION: Proposed specifications; request for comments.

SUMMARY: NMFS proposes revised summer flounder specifications for the 2017 and 2018 fishing years. Updated scientific information regarding the status of the summer flounder stock indicates that these proposed catch limits are necessary to constrain summer flounder harvest within scientifically sound recommendations to prevent overfishing. This action is intended to inform the public of proposed reductions for the 2017 and 2018 summer flounder fishing years.

DATES: Comments must be received on or before November 30, 2016.

ADDRESSES: A supplemental environmental assessment (SEA) was prepared for the specifications and describes the proposed action and other considered alternatives, and provides an analysis of the impacts of the proposed measures and alternatives. Copies of the Specifications Document, including the SEA, the Initial Regulatory Flexibility Analysis (IRFA), and the original environmental assessment for the 2016–2018 summer flounder, scup, and black sea bass specifications are available on request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. These documents are also accessible via the Internet at *http://www.mafmc.org.*

You may submit comments on this document, identified by NOAA–NMFS–2016–0138, by either of the following methods:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2016-0138,*

2. Click the ''Comment Now!'' icon, complete the required fields

3. Enter or attach your comments.

—or—

Mail: Submit written comments to John Bullard, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA, 01950. Mark the outside of the envelope, ''Comments on the Proposed Rule for Summer Flounder Specifications.''

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Emily Gilbert, Fishery Policy Analyst, (978) 281–9244.

SUPPLEMENTARY INFORMATION:

Background and Proposed Specifications

The Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission cooperatively manage the summer flounder, scup, and black sea bass fisheries. The Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) and its implementing regulations outline the Council's process for establishing specifications. Specifications in these fisheries include various catch and landing subdivisions, such as the commercial and recreational sector annual catch limits (ACLs), annual catch targets (ACTs), and sector-specific landing limits (*i.e.,* the commercial fishery quota and recreational harvest limit). Annual specifications may be established for three year periods, and, in interim years, specifications are reviewed by the Council to ensure previously established multi-year specifications remain appropriate. The FMP also contains formulas to divide the specification catch limits into commercial and recreational fishery allocations, state-by-state quotas, and quota periods, depending on the species in question. Rulemaking for measures used to manage the recreational fisheries (minimum fish sizes, open seasons, and bag limits) for these three species occurs separately, and typically takes place in the spring of each year.

On December 28, 2015, NMFS published a final rule implementing the Council's recommended specifications for the summer flounder, scup, and black sea bass fisheries (80 FR 80689) for fishing years 2016 through 2018. The Council intended to reconsider the specifications set for fishing years 2017 and 2018 after reviewing any updated information. Based on updated information on the status of the summer flounder stock, the Council is now recommending adjustments to the previously established summer flounder specifications for the 2017 and 2018 fishing years. An assessment update will be available next summer and notice will be provided in the **Federal Register** on whether the revised 2018 specifications will remain in place or be updated further based on any new information. The scup and black sea bass specifications implemented through previous rulemaking remain unchanged by this action.

When the Council previously recommended summer flounder specifications in 2015, available scientific information indicated that the summer flounder stock size was declining and that overfishing occurred in 2014. In order to minimize disruption to the industry as much as possible, given the necessary reduction in available catch to prevent further overfishing and to increase the stock size, the Council requested its Scientific and Statistical Committee (SSC) to deviate from the standard risk policy and to phase-in the summer flounder catch reductions over the 3-year specifications cycle. The SSC complied with this request, but requested a stock assessment update in July 2016 to determine if its recommended acceptable biological catches (ABCs) remain appropriate for 2017 and 2018.

The SSC met on July 21–22, 2016, to review the stock assessment update for summer flounder compiled by the Northeast Fisheries Science Center. This 2016 update was based on the peer-review approved model from the 2013 benchmark assessment, updated to include data through 2015. More specific information about the

assessment information (*e.g.,* biomass level, fishing mortality, etc.) can be found in section 6.0 of the SEA for this action. The assessment update noted that the consistent pattern in both underestimation of fishing mortality and overestimation of spawning stock biomass is continuing, even though catches have not substantially exceeded ABC levels. This downward trend in biomass is mainly due to below average recruitment in the last five years. As a result of this information, the assessment update recalculated the 2017 and 2018 overfishing limits (OFLs) for the stock. For 2017, the recalculated OFL is 16.76 million lb (7,600 mt) and for 2018, the recalculated OFL is 18.69 million lb (8,476 mt), representing approximately a 16-percent reduction from the previously established OFLs. To keep catch below these updated OFL estimates, the SSC recommended revisions to the previously adopted 2017 and 2018 ABCs. The SSC recommended revising the ABCs by abandoning the phased-in approach and instead following the Council's standard risk policy. The SSC cited among its reasons for departing from the previously approved phased-in approach the continual overestimation of biomass and recruitment and underestimation of fishing mortality, emphasizing that continuing to overfish in a period of consistently poor recruitment represents a substantial risk to the stock. The SSC recommended a revised 2017 ABC that is approximately 30 percent lower than both the previously established 2017 ABC and the current 2016 ABC. The SSC recommended a 2018 ABC that is 16 percent lower than the previously established 2018 ABC (Table 1).

The Council's Summer Flounder Monitoring Committee met July 25, 2016, to discuss specification-related recommendations for the summer flounder fishery, to recommend offsets from the ACL to account for management uncertainty, and to discuss commercial management measure recommendations, as appropriate. The Monitoring Committee determined that no additional reductions were necessary to account for management uncertainty because the recreational fishery has had only minor overages of the recreational harvest limit in recent years, and the commercial landings monitoring and fishery closure system is timely enough to prevent commercial overages. As a result, the Monitoring Committee recommended that ACTs for the commercial and recreational sectors should equal their respective ACLs and made no recommended changes to any other summer flounder management measures.

Following the SSC and Monitoring Committee meetings, the Council and the Commission's Summer Flounder, Scup, and Black Sea Bass Management Board met jointly on August 9, 2016, to consider the recommendations of the SSC, the Monitoring Committee, and public comments, and to make their specification recommendations. More complete details on the SSC, Monitoring Committee, and Council meeting deliberations can be found on the Council's Web site (*www.mafmc.org*). Ultimately, the Council recommended the summer flounder commercial quotas and recreational harvest limits shown in Table 1. The recommended catch limits for 2017 are nearly 30 percent lower than those previously established.

TABLE 1—COMPARISON OF RECOMMENDED MEASURES TO PREVIOUSLY ESTABLISHED CATCH AND LANDING LIMITS OF SUMMER FLOUNDER

	2016	2017			2018		
		Current	Proposed	Difference (%)	Current	Proposed	Difference (%)
Acceptable Biological Catch:							
million lb	16.26	15.86	11.30	−29	15.68	13.23	−16
Mt	7,374	7,193	5,125		7,111	5,999	
Commercial Quota:							
million lb	8.12	7.91	5.66	−28	7.89	6.63	−16
Mt	3,685	3,590	2,567		3,581	3,006	
Recreational Harvest Limit:							
million lb	5.42	5.28	3.77	−29	5.26	4.42	−16
Mt	2,457	2,393	1,711		2,387	2,004	

While the Board action was finalized at the August meeting, the Council's recommendations must be reviewed by NMFS to ensure that they comply with the FMP and applicable law. NMFS also must conduct notice-and-comment rulemaking to propose and implement the final specifications.

Proposed 2017 and 2018 Summer Flounder Specifications

Table 2 summarizes the Council's recommended summer flounder specifications that NMFS is proposing for 2017 and 2018, including the sector-specific estimated discards.

TABLE 2—PROPOSED 2017–2018 SUMMER FLOUNDER SPECIFICATIONS

	2016 (current)		2017		2018	
	million lb	mt	million lb	mt	million lb	mt
OFL	18.06	8,194	16.76	7,600	18.69	8,476
ABC	16.26	7,375	11.30	5,125	13.23	5,999
ABC Landings Portion	13.54	6,142	9.43	4,278	11.05	5,010
ABC Discards Portion	2.72	1,233	1.87	847	2.18	989
Commercial ACL	9.43	4,275	6.57	2,982	7.70	3,491
Commercial ACT	9.43	4,275	6.57	2,982	7.70	3,491
Projected Commercial Discards	1.30	590	0.92	415	1.07	485

TABLE 2—PROPOSED 2017–2018 SUMMER FLOUNDER SPECIFICATIONS—Continued

	2016 (current)		2017		2018	
	million lb	mt	million lb	mt	million lb	mt
Commercial Quota	8.12	3,685	5.66	2,567	6.63	3,006
Recreational ACL	6.84	3,100	4.72	2,143	5.53	2,508
Recreational ACT	6.84	3,100	4.72	2,143	5.53	2,508
Projected Recreational Discards	1.42	643	0.95	432	1.11	504
Recreational Harvest Limit	5.42	2,457	3.77	1,711	4.42	2,004

Consistent with the summer flounder regulations, the sum of the recreational and commercial sector ACLs is equal to the ABC for each fishing year. To derive the ACLs, the sum of the sector-specific projected discards are removed from the ABCs to derive the landing allowances. For summer flounder, 60 percent of the landing allowance for each fishing year is allocated to the commercial fishery and 40 percent to the recreational fishery. Using this method ensures that each sector is accountable for its respective discards, rather than simply apportioning the ABCs by the allocation percentages to derive the sector ACLs. Although the derived ACLs are not split exactly according to the allocations specified in the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP), the landing portions of the ACLs preserve the appropriate allocation split, consistent with the FMP.

Table 3 presents the proposed state summer flounder allocations for 2017–2018 using the commercial state quota allocations described in the FMP. Any commercial quota adjustments to account for overages will be published in the **Federal Register** prior to the start of the respective fishing year. The final rule for this action will include any necessary quota overage reductions for fishing year 2017.

TABLE 3—2017–2018 PROPOSED INITIAL SUMMER FLOUNDER STATE COMMERCIAL QUOTAS

State	FMP percent share	2017 Initial quota		2018 Initial quota	
		Lb	Kg	Lb	Kg
ME	0.04756	2,692	1,221	3,152	1,430
NH	0.00046	26	18	30	14
MA	6.82046	385,988	175,081	451,998	205,023
RI	15.68298	887,542	402,582	1,039,326	471,430
CT	2.25708	127,734	57,939	149,579	67,848
NY	7.64699	432,764	196,298	506,773	229,868
NJ	16.72499	946,512	429,331	1,108,381	502,753
DE	0.01779	1,007	457	1,179	535
MD	2.0391	115,398	52,344	135,133	61,295
VA	21.31676	1,206,372	547,201	1,412,682	640,782
NC	27.44584	1,553,233	704,535	1,818,862	825,022
Total	100	5,659,266	2,567,000	6,627,096	3,006,000

Note: Kilograms are as converted from pounds and do not sum to the converted total due to rounding. Rounding of quotas results in totals slightly exceeding 100 percent.

The Council and Commission will develop recreational management measures (*e.g.,* minimum fish sizes, open seasons, and bag limits) for summer flounder this fall and NMFS rulemaking will occur in early spring of 2017.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Summer Flounder, Scup, and Black Sea Bass FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

These proposed specifications are exempt from review under Executive Order 12866.

An IRFA was prepared by the Council, as required by section 603 of the Regulatory Flexibility Act (RFA), to examine the impacts of these proposed specifications on small business entities, if adopted. A description of the specifications, why they are being considered, and the legal basis for proposing and implementing specifications for the summer flounder fishery are contained in the preamble to this proposed rule. A copy of the detailed RFA analysis is available from NMFS or the Council (see **ADDRESSES**). The Council's analysis made use of quantitative approaches when possible. Where quantitative data on revenues or other business-related metrics that would provide insight to potential impacts were not available to inform the analyses, qualitative analyses were conducted. A summary of the 2017 and 2018 summer flounder specifications RFA analysis follows.

Description of the Reasons Why Action by the Agency Is Being Considered, and a Statement of the Objectives of, and Legal Basis for, This Proposed Rule

This action proposes management measures, including annual catch limits, for the summer flounder fishery in order to prevent overfishing and achieve optimum yield in the fishery. A complete description of the action, why it is being considered, and the legal basis for this action are contained in the specifications document, and elsewhere in the preamble to this proposed rule, and are not repeated here.

Description and Estimate of the Number of Small Entities To Which the Proposed Rule Would Apply

On December 29, 2015, NMFS issued a final rule establishing a small business size standard of $11 million in annual gross receipts for all businesses primarily engaged in the commercial fishing industry and $7 million in annual gross receipts for all businesses primarily engaged in for-hire fishing activity (NAICS 11411) for Regulatory Flexibility Act (RFA) compliance purposes only (80 FR 81194, December 29, 2015). The North American Industry Classification System (NAICS) is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy.

This proposed rule affects commercial and recreational fish harvesting entities engaged in the summer flounder fishery. Individually-permitted vessels may hold permits for several fisheries, harvesting species of fish that are regulated by several different FMPs, even beyond those impacted by the proposed action. Furthermore, multiple-permitted vessels and/or permits may be owned by entities affiliated by stock ownership, common management, identity of interest, contractual relationships, or economic dependency. For the purposes of the RFA analysis, the ownership entities, not the individual vessels, are considered to be the regulated entities.

Ownership entities are defined as those entities with common ownership personnel as listed on the permit application. Only permits with identical ownership personnel are categorized as an ownership entity. For example, if five permits have the same seven persons listed as co-owners on their permit applications, those seven persons would form one ownership entity that holds those five permits. If two of those seven owners also co-own additional vessels, that ownership arrangement would be considered a separate ownership entity for the purpose of this analysis.

The current ownership data set used for this analysis is based on calendar year 2015 (the most recent complete year available) and contains average gross sales associated with those permits for calendar years 2013 through 2015.

A description of the specific permits that are likely to be impacted by this action is provided below, along with a discussion of the impacted businesses, which can include multiple vessels and/or permit types.

According to the commercial ownership database, 553 affiliate firms landed summer flounder during the 2013–2015 period, with 547 of those businesses affiliates categorized as small businesses and 6 categorized as large businesses. The ownership data for the for-hire fleet indicate that there were 411 for-hire affiliate firms generating revenues from fishing recreationally for various species during the 2013–2015 period, all of which are categorized as small businesses. Although it is not possible to derive what proportion of the overall revenues came from specific fishing activities, given the popularity of summer flounder as a recreational species, it is likely that revenues generated from summer flounder recreational fishing is important for some, if not all, of these firms.

Description of the Projected Reporting, Record-Keeping, and Other Compliance Requirements of This Proposed Rule

There are no new reporting or recordkeeping requirements contained in any of the alternatives considered for this action.

Federal Rules Which May Duplicate, Overlap, or Conflict With This Proposed Rule

NMFS is not aware of any relevant Federal rules that may duplicate, overlap, or conflict with this proposed rule.

Description of Significant Alternatives to the Proposed Action Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact on Small Entities

This action proposes to set commercial quotas and recreational harvest limits for the summer flounder fishery for the 2017 and 2018 fishing years that are consistent with the best scientific information available and the most recent catch limit recommendations of the Council's SSC. The proposed landings limits for 2017 include a commercial quota of 5.66 million lb (2,567 mt) and a recreational harvest limit of 3.77 million lb (1,711 mt). For 2018, the proposed measures include a commercial quota of 6.63 million lb (3,006 mt) and a recreational harvest limit of 4.42 million lb (2,004 mt).

The only other alternatives considered in this document are status quo alternatives that are identical to the summer flounder landings limits implemented in December 2015. If these specifications remained in place, they would have greater positive socioeconomic impacts than the preferred alternatives. However, these alternatives were not selected as preferred given that they do not address the new scientific information regarding summer flounder stock status, and, therefore, would likely result in overfishing, which would be inconsistent with the FMP, National Standard 1 guidance under the Magnuson-Stevens Act, and the most recent advice of the Council's SSC. Because these alternatives are inconsistent with the purpose and need of this action, they are not considered further under this analysis.

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

Dated: November 7, 2016.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2016–27410 Filed 11–14–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF039

South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings of the South Atlantic Fishery Management Council.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold meetings of the: Advisory Panel Selection Committee (Partially Closed Session); Law Enforcement Committee; Scientific and Statistical Committee (SSC) Selection Committee; Protected Resources Committee; Habitat Protection and Ecosystem-Based Management Committee; Southeast Data, Assessment and Review (SEDAR) Committee (Partially Closed Session); Spiny Lobster Committee; Joint Dolphin Wahoo/Snapper Grouper and Mackerel Cobia Committees; Information and Education Committee; Executive Finance Committee; Snapper Grouper Committee; Personnel Committee (Closed Session); Highly Migratory Species Committee; Mackerel Cobia Committee; Citizen Science Committee; Data Collection Committee; and a meeting of the Full Council.

The Council will take action as necessary. The Council will also hold a formal public comment session. The

Atlantic States Marine Fisheries Commission (ASMFC) will also conduct a public hearing in conjunction with the Council meeting.

DATES: The Council meeting will be held from 8:30 a.m. on Monday, December 5, 2016 until 1 p.m. on Friday, December 9, 2016.

ADDRESSES:

Meeting address: The meeting will be held at the DoubleTree by Hilton Atlantic Beach Oceanfront, 2717 West Fort Macon Road, Atlantic Beach, NC 28512; phone: (800) 222–8733 or (252) 240–1155; fax: (252) 222–4065.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone (843) 571–4366 or toll free (866) SAFMC–10; fax (843) 769–4520; email: *kim.iverson@safmc.net.* Meeting information is available from the Council's Web site at: *http://safmc.net/meetings/council-meetings/.*

SUPPLEMENTARY INFORMATION:

Public comment: Written comments may be directed to Gregg Waugh, Executive Director, South Atlantic Fishery Management Council (see **ADDRESSES**) or electronically via the Council's Web site at: *https://goo.gl/forms/QAZYglsYhWIkQZNV2.* The public comment form is open for use when the briefing book is posted to the Web site on the Friday, two weeks prior to the Council meeting. Comments received by close of business the Monday before the meeting (November 28, 2016) will be compiled, posted to the Web site as part of the meeting materials, and included in the administrative record. For written comments received after the Monday before the meeting (after 11/28), individuals sending the comment must use the Council's online form available from the Web site. Comments will automatically be posted to the Web site and available for Council consideration. Comments received prior to noon on Thursday, December 8, 2016 will be a part of the meeting administrative record.

The items of discussion in the individual meeting agendas are as follows:

Advisory Panel Selection Committee (Partially Closed Session), Monday, December 5, 2016, 8:30 a.m. Until 9:30 a.m.

1. The Committee will review applications for the SEDAR Pool Advisory Panel and provide recommendations (Closed Session).

2. The Committee will review options for the structure of an advisory panel for the Council's System Management Plan addressing protected areas and provide guidance and timing for the advisory panel as necessary.

Law Enforcement Committee, Monday, December 5, 2016, 9:30 a.m. Until 10:30 a.m.

1. The Committee will receive a report on the level of commercial logbook reporting at the time of permit renewal, discuss compliance with logbook reporting requirements, and provide recommendations as appropriate.

2. The Committee will also follow up on items from the earlier joint meeting of the Law Enforcement Committee and Advisory panel provide recommendations as appropriate.

SSC Selection Committee, Monday, December 5, 2016, 10:30 a.m. Until 12 p.m.

The Committee will review the SSC Conflict of Interest Policy, the SSC Public Comment Policy, and the SSC Update on complex analysis review process. The Committee will provide guidance as needed.

Protected Resources Committee, Monday, December 5, 2016, 1:30 p.m. Until 2:30 p.m.

The Committee will receive an update from NOAA Fisheries' Protected Resources Office, review the Biological Opinion for Snapper Grouper, appoint a Council member to the Large Whale Take Reduction Team, and receive an update from the U.S. Fish & Wildlife Service.

Habitat Protection and Ecosystem-Based Management Committee, Monday, December 5, 2016, 2:30 p.m. Until 5 p.m.

1. The Committee will receive a report from the Habitat Protection and Ecosystem-Based Management Advisory Panel and provide recommendations as appropriate.

2. The Committee will review and approve the Council's Essential Fish Habitat Policy Statements for the Fishery Ecosystem Plan II.

3. The Committee will receive an update on the Habitat and Ecosystem Tools and Model Development, Council actions pertaining to Habitat, and a report from the Lenfest Ecosystem Task Force and proved recommendations as appropriate.

SEDAR Committee, Tuesday, December 6, 2016, 8:30 a.m. Until 10:30 a.m. (Partially Closed)

1. The Committee will discuss and provide recommendations for appointments for the following stock assessments: SEDAR 50 Blueline Tilefish; SEDAR 48 *Black Grouper,* SEDAR 56 Black Sea Bass, and the SEDAR Stock Identification and Meristics Workshop. (Closed Session)

2. The Committee will receive updates on SEDAR projects, review the SEDAR Steering Committee Report, and assessment priorities, including SSC prioritization recommendations and a long-term assessment plan. The Committee will provide recommendations as appropriate.

Spiny Lobster Committee, Tuesday, December 6, 2016, 10:30 a.m. Until 11:30 a.m.

1. The Committee will receive a presentation on Spiny Lobster regulations in Florida, review recommendations from the SSC for establishing Overfishing Levels and Acceptable Biological Catch for Spiny Lobster, and provide recommendations to staff.

2. The Committee will also receive an overview of a Discussion Document on action to restrict recreational traps in the South Atlantic Exclusive Economic Zone and provide direction to staff.

Joint Dolphin Wahoo/Snapper Grouper/Mackerel Cobia Committees, Tuesday, December 6, 2016, 1 p.m. Until 4 p.m.

1. The Committees will receive updates from NOAA Fisheries on commercial and recreational catches of Dolphin and Wahoo versus annual catch limits (ACLs), status of amendments, and the 2015 commercial landings for Yellowtail Snapper.

2. The Committee will review Dolphin Wahoo Amendment 10/Snapper Grouper Amendment 44 addressing allocations of Dolphin and Yellowtail Snapper, provide direction to staff, and recommend approval of the joint amendment for public hearings.

3. The Committees will receive an overview of draft options for a Limited Entry program for federal For-Hire Permits in the Snapper Grouper, Coastal Migratory Pelagic, and Dolphin Wahoo fisheries in the South Atlantic/Atlantic, review options, modify the document if necessary, and provide guidance as appropriate.

Information and Education Committee, Tuesday, December 6, 2016, 4 p.m. Until 5 p.m.

The Committee will receive a report from the Information and Education Advisory Panel meeting and provide guidance to staff.

Executive/Finance Committee, Tuesday, December 6, 2016, 5 p.m. Until 6 p.m. and Thursday, December 8, 2016, From 4:30 p.m. Until 5:30 p.m.

1. The Committee will receive a presentation on the Final Rule for National Standard 1 Guidelines, discuss and provide guidance to staff.

2. The Committee will receive an overview of Electronic Reporting Project Proposals, discuss and take action as necessary.

3. The Committee will receive an update on the status of expenditures for Calendar Year (CY) 2016; review the Draft CY 2017 Budget; review, modify, and approve the Council Follow-up and work priorities; and provide recommendations as appropriate.

3. The Committee will discuss standards and procedures for participating in Council webinar meetings and take action as appropriate.

Snapper Grouper Committee, Wednesday, December 7, 2016, 8 a.m. Until 4:30 p.m. and Thursday, December 8, 2016, 9 a.m. Until 10 a.m.

1. The Committee will receive updates from NOAA Fisheries on the status of commercial and recreational catches versus quotas for species under Annual Catch Limits (ACLs) and the status of amendments currently under Secretarial review.

2. The Committee will receive reports from the Snapper Grouper Advisory Panel meeting and the SSC meeting, discuss and provide recommendations as appropriate.

3. The Committee will receive presentations on the efficacy of descending devices for deepwater grouper and commercial logbook discard data for red grouper, discuss and take action as appropriate.

4. The Committee will review Snapper Grouper Amendment 41 addressing management measures for mutton snapper, modify the document as appropriate, and provide recommendations to approve/disapprove the amendment for formal Secretarial Review.

5. The Committee will receive the Annual Review of the Vision Blueprint for the Snapper Grouper Fishery addressing long-term management needs and provide recommendations as appropriate. The Committee will also review options for the Recreational Visioning Blueprint Amendment (Vision Blueprint Regulatory Amendment 26) and the Commercial Visioning Blueprint Amendment (Vision Blueprint Regulatory Amendment 27), modify the documents as appropriate, and approve for public scoping.

6. The Committee will receive a presentation of Red Snapper landings by County in Florida, receive an overview of management options for Red Snapper to be addressed in Snapper Grouper Amendment 43, modify the document as necessary, and provide recommendations to approve/disapprove the options paper for public scoping.

7. The Committee will consider an emergency rule for the 2017 season of Golden Tilefish and provide guidance to staff for amendment development.

Formal Public Comment, Wednesday, December 7, 2016, 4:30 p.m.—Public comment will be accepted on items on the Council agenda. Comment will be accepted first on items before the Council for Secretarial approval: (1) Snapper Grouper Amendment 41 (Mutton Snapper); (2) Coastal Migratory Pelagic Amendment 29 (Gulf of Mexico King Mackerel Allocations); (3) Coastal Migratory Pelagic Amendment 30 (Atlantic Cobia Fishing Year); and (4) Atlantic For-Hire Electronic Reporting Amendment. The Council Chair, based on the number of individuals wishing to comment, will determine the amount of time provided to each commenter.

Personnel Committee, Thursday, December 8, 2016, 8 a.m. Until 9 a.m. (Closed Session)

The Committee will conduct the Executive Director's Performance Review.

Highly Migratory Species (HMS) Committee, Thursday, December 8, 2016, 10 a.m. Until 11 a.m.

The Committee will receive a presentation from NOAA Fisheries HMS on draft Amendment 5b to the 2006 Consolidated Atlantic HMS Fishery Management Plan addressing management measures for *Dusky Shark* and provide guidance to staff.

Mackerel Cobia Committee, Thursday, December 8, 2016, 11 a.m. Until 12 p.m.

1. The Committees will receive status updates from NOAA Fisheries on commercial and recreational catches versus annual catch limits (ACLs) for species under ACLs and amendments currently under Secretarial review.

2. The Committee will receive an overview of Amendment 29 to the Coastal Migratory Pelagic (CMP) Fishery Management Plan for the Gulf of Mexico and South Atlantic Region addressing allocations of Gulf Group King Mackerel, modify as necessary, and provide recommendations to approve/disapprove the amendment for formal Secretarial Review.

3. The Committee will receive an overview of CMP Amendment 30 addressing modifications to the Fishing Year for Atlantic *Cobia,* review public hearing comments, modify the document as necessary, and recommend approval/disapproval of the amendment for formal Secretarial Review.

4. The Committee will review the ASMFC's Public Information Document for the Interstate Fishery Management Plan for Cobia and provide comments and guidance as appropriate.

Citizen Science Committee, Thursday, December 8, 2016, 1:30 p.m. Until 2:30 p.m.

The Committee will receive a program development update on the Council's Citizen Science Program, discuss and take action as necessary.

Data Collection Committee, Thursday, December 8, 2016, 2:30 p.m. Until 4:30 p.m.

1. The Committee will receive an update on the status of the Bycatch Reporting Amendment and the final Standardized Bycatch Reporting Methodology (SBRM) rule from NOAA Fisheries, discuss and provide direction to staff.

2. The Committee will receive an update on the status of voluntary commercial logbook electronic reporting, discuss and take action as necessary.

3. The Committee will receive an update on the status of the Pilot For-Hire Electronic Reporting Project being conducted jointly between the Council and the Atlantic Coastal Cooperative Statistics Program, review and take action as necessary.

4. The Committee will also receive a report on the status of the Headboat Electronic Reporting Program and associated outreach, an overview of the For-Hire Reporting Amendment, review the amendment and provide recommendations for approval/disapproval of the amendment for Secretarial Review.

Public Hearing—Atlantic States Marine Fisheries Commission (ASMFC)—Public Information Document for the Interstate Fishery Management Plan (FMP) for Cobia, Thursday, December 8, 2016, 6 p.m.—The ASMFC will hold a public hearing in conjunction with the Council meeting

to solicit comment on the Public Information Document addressing state management of *Cobia.* Stakeholders are asked to provide information about changes observed in the fishery and provide input on potential management measures as well as any additional issues that should be included in the draft FMP. The Public Information Document includes draft goals and objectives of the plan; commercial and recreational measures; coast-wide, regional, or state-by-state measures; and other issues.

Council Session: Friday, December 9, 2016, 8:30 a.m. until 1 p.m. (Partially Closed)

The Full Council will convene on Friday morning with a Call to Order, announcements and introductions, and approve the September 2016 meeting minutes. The Council will present the Law Enforcement Officer of the Year award and make other presentations as appropriate.

The Council will receive a Legal Briefing on Litigation from NOAA General Counsel (if needed) during Closed Session.

The Council will receive a report from the Snapper Grouper Committee and approve/disapprove Snapper Grouper Amendment 41 (Mutton Snapper) for Secretarial review and approve Snapper Grouper Amendment 43 (red snapper), the Recreational Visioning Amendment, and the Commercial Visioning Amendment for public scoping. The Council will consider other Committee recommendations and take action as appropriate.

The Council will receive a report from the Mackerel Cobia Committee, approve/disapprove Coastal Migratory Pelagic Amendment 29 (Gulf of Mexico King Mackerel Allocations) and Coastal Migratory Pelagic Amendment 30 (Atlantic Cobia Fishing Year) for Secretarial review, consider other Committee recommendations, and take action as appropriate.

The Council will receive a report from the Data Collection Committee and approve/disapprove the Atlantic For-Hire Amendment (Electronic Reporting) for Secretarial Review, consider other committee recommendations, and take action as appropriate.

The Council will receive a report from the Joint Dolphin Wahoo/Snapper Grouper/Mackerel Cobia Committee, approve/disapprove Joint Dolphin Wahoo Amendment 10/Snapper Grouper Amendment 44 (Allocations for Dolphin and Yellowtail Snapper) for public hearings, consider other recommendations, and take action as appropriate.

The Council will continue to receive committee reports from Information & Education, Protected Resources, Advisory Panel Selection, SSC Selection, SEDAR, Habitat and Ecosystem-Based Management, Law Enforcement, Spiny Lobster, HMS, Citizen Science, and Executive Finance Committees, review recommendations and take action as appropriate.

The Council will receive status reports from NOAA Fisheries Southeast Office and the Southeast Fisheries Science Center; review and develop recommendations on Experimental Fishing Permits as necessary; receive agency and liaison reports; and discuss other business and upcoming meetings.

Documents regarding these issues are available from the Council office (see **ADDRESSES**).

Although non-emergency issues not contained in this agenda may come before these groups for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: November 9, 2016.

Tracey L. Thompson,

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

[FR Doc. 2016–27434 Filed 11–14–16; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No.: CFPB–2016–0047]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Consumer Financial Protection (Bureau) is proposing a new information collection titled, ''Application Forms for Financial Empowerment Partnerships.''

DATES: Written comments are encouraged and must be received on or before December 15, 2016 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *OMB:* Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503 or fax to (202) 395–5806. Mailed or faxed comments to OMB should be to the attention of the OMB Desk Officer for the Bureau of Consumer Financial Protection.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.reginfo.gov* (this link becomes active on the day following publication of this notice). Select ''Information Collection Review,'' under ''Currently under review, use the dropdown menu ''Select Agency'' and select ''Consumer Financial Protection Bureau'' (recent submissions to OMB will be at the top of the list). The same documentation is also available at *http://www.regulations.gov.* Requests for additional information should be directed to the Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, (202) 435–9575, or email: *CFPB_PRA@cfpb.gov. Please do not submit comments to this email box.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Application Forms for Financial Empowerment Partnerships.

OMB Control Number: 3170–XXXX.

Type of Review: New collection (Request for a new OMB Control Number).

Affected Public: Private Sector (*e.g.,* community-based organizations and national non-profit organizations), State, Local, or Tribal Governments, and Federal Government.

Estimated Number of Respondents: 285.

Estimated Total Annual Burden Hours: 1,625.

Abstract: The Bureau's Office of Financial Empowerment (Empowerment) is responsible for developing strategies to improve the financial capability of low-income and economically vulnerable consumers, such as consumers who are unbanked or underbanked, those with thin or no credit file, and households with limited savings. To address the needs of these consumers, Empowerment has developed three initiatives that target intermediary organizations and provide tools, training, technical assistance, and other services to help them reach low-income and economically vulnerable consumers to provide them the financial empowerment tools and information that they need, when they need it, where they are. These initiatives: (1) Your Money, Your Goals, (2) Financial Coaching, and (3) Tax Time Savings all require Bureau to engage organizations to participate in our financial empowerment initiatives. The proposed information collection request consists of application forms that will be used by community-based organizations, local, State, or Federal government entities, and national non-profit organizations to indicate their desire and ability to participate in Empowerment's various initiatives. Empowerment will use the information provided in these applications to select the best qualified organizations for participation.

Request for Comments: The Bureau issued a 60-day **Federal Register** notice on August, 23, 2016, (81 FR 57569), Docket Number: CFPB–2016–0042. Comments were solicited and continue to be invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

Dated: November 9, 2016.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2016–27427 Filed 11–14–16; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2016–HQ–0036]

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to alter a System of Records.

SUMMARY: Pursuant to the Privacy Act of 1974 and Office of Management and Budget (OMB) Circular No. A–130, notice is hereby given that the Department of the Army proposes to alter a system of records, A0037–104–3 USMA, entitled ''USMA Cadet Account System,'' last published at 65 FR 3219, January 20, 2000. This system of records exists to enable Cadets to receive income (salary, scholarship, individual deposits, etc.) and pay for expenses (uniforms, books, a computer, activity fees, etc.) while attending the United States Military Academy (USMA) at West Point. The program is managed by the USMA Treasurer who is charged with ensuring all cadets meet their USMA financial obligations.

This revision reflects considerable administrative changes that in sum warrant an alteration to the system of records notice. There are two significant changes: The categories of records has been updated to provide additional details on the information collected; and the applicable DoD Routine Uses have been incorporated in the notice to provide clarity for the public. There are also modifications to the system name, authorities, purpose, storage, retrievability, safeguards, notification and record access procedures, contesting record procedures, and records source categories to improve readability and update the notice to meet current departmental standards.

DATES: Comments will be accepted on or before December 15, 2016. This proposed action will be effective the date following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.*

Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Tracy Rogers, Department of the Army, Privacy Office, U.S. Army Records Management and Declassification Agency, 7701 Telegraph Road, Casey Building, Suite 144, Alexandria, VA 22325–3905 or by calling (703) 428–7499.

SUPPLEMENTARY INFORMATION: The Department of the Army's notices for system of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or from the Defense Privacy, Civil Liberties, and Transparency Division Web site *http://dpcld.defense.gov/.*

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act, as amended, were submitted on October 20, 2016, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4 of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' revised November 28, 2000 (December 12, 2000 65 FR 77677).

Dated: November 9, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0037–104–3 USMA

SYSTEM NAME:

USMA Cadet Account System (January 20, 2000, 65 FR 3219)

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with: ''United States Military Academy (USMA) Cadet Account System''.

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Name, address, Social Security Number (SSN), cadet account number, personal bank account number, monthly deposit listings of Corps of Cadets members showing entitlements, financial statements and schedules, and activities pertaining to funds held in trust by the USMA Treasurer.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''10 U.S.C. 3013, Secretary of Army; 10 U.S.C. 4340, Quartermaster; 10 U.S.C. 4350, Cadets: Clothing and equipment; Title 7—Fiscal Guidance, General Accounting Office Policy and Procedures Manual for Guidance of Federal Agencies; Army Regulation 210–26, United States Military Academy; and E.O. 9397 (SSN), as amended.''

PURPOSE:

Delete entry and replace with ''To compute debits and credits posted against cadet account balances. Debits include charges to the cadet's account for uniforms, textbooks, computers and related supplies, academic supplies, various fees; credits include advance pay, monthly deposits from payroll, scholarships, initial deposits, interest accumulated on cadet account balances, and individual deposits.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete entry and replace with ''In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, the records contained herein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Law Enforcement Routine Use. If a system of records maintained by a DoD Component to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or by regulation, rule, or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the agency concerned, whether federal, state, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, rule, regulation, or order issued pursuant thereto.

Disclosure When Requesting Information Routine Use. A record from a system of records maintained by a DoD Component may be disclosed as a routine use to a federal, state, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a DoD Component decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

Disclosure of Requested Information Routine Use. A record from a system of records maintained by a DoD Component may be disclosed to a federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

Congressional Inquiries Disclosure Routine Use. Disclosure from a system of records maintained by a DoD Component may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Data Breach Remediation Purposes Routine Use. A record from a system of records maintained by a Component may be disclosed to appropriate agencies, entities, and persons when (1) The Component suspects or has confirmed that the security or confidentiality of the information in the system of records has been compromised; (2) the Component has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Component or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Components efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.''

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Delete entry and replace with ''Electronic storage media and microfiche.''

RETRIEVABILITY:

Delete entry and replace with ''By Cadet's account number, full name, or SSN.''

SAFEGUARDS:

Delete entry and replace with ''Records are maintained in office areas which are secured and accessible only to authorized personnel. Access to computerized data is restricted by use of Common Access Cards (CACs) and is accessible only by users with an authorized account. The system is maintained in a controlled facility that employs physical restrictions and safeguards such as security guards, identification badges, key cards, and locks.''

* * * * *

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Superintendent, U.S. Military Academy, ATTN: USMA Treasurer, West Point, NY 10996–1783.

Individual should provide full name, cadet account number, SSN, graduating class year, current address, telephone number, and signature.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: 'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).'

If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)' ''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves contained in this system should address written inquiries to the Superintendent, U.S. Military Academy, ATTN: USMA Treasurer, West Point, NY 10996–1783.

Individual should provide full name, cadet account number, SSN, graduating

class year, current address, telephone number, and signature.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: 'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).'

If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).'

Personal visits may be made to the Treasurer, U.S. Military Academy; individual must provide acceptable identification such as valid driver's license and information that can be verified with his/her payroll.''

CONTESTING RECORDS PROCEDURES:

Delete entry and replace with ''The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in 32 CFR part 505, Army Privacy Program or may be obtained from the system manager.''

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''From the individual, Department of Army, Department of the Treasurer, and financial institutions.''

* * * * *

[FR Doc. 2016–27404 Filed 11–14–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee on Women in the Services (DACOWITS); Notice of Federal Advisory Committee Meeting

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Advisory Committee on Women in the Services (DACOWITS) will take place. This meeting is open to the public.

DATES: Thursday, December 8, 2016, from 8:30 a.m. to 3:15 p.m.; Friday, December 9, 2016, from 8:30 a.m. to 11:30 a.m.

ADDRESSES: Association of the United States Army (AUSA) Conference Center, 2425 Wilson Boulevard, Arlington, VA 22201.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Bowling or DACOWITS Staff at 4800 Mark Center Drive, Suite 04J25–01, Alexandria, Virginia 22350–9000; *robert.d.bowling1.civ@mail.mil,* telephone (703) 697–2122, fax (703) 614–6233. Any updates to the agenda or any additional information can be found at *http://dacowits.defense.gov/.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b), and Section 10(a), Public Law 92–463, as amended, notice is hereby given of a forthcoming meeting of the DACOWITS.

The purpose of the meeting is for the Committee to receive briefings and updates relating to their current work. The Designated Federal Officer (DFO) will open the meeting and give a status update on the Committee's requests for information. This will be followed with four panel discussions on the following topics: Integrated Boxing Programs at the Military Service Academies; the Services' Retention Initiatives; the Services' Efforts to Increase Propensity; and the Services' Sexual Harassment/Sexual Assault Training. This will be followed with a public comment period. The second day of the meeting will open with an awards ceremony to recognize departing members. The Committee will then receive a briefing update on DoD's Childcare Programs and Initiatives. This will be followed by a panel discussion on the Services' Family Care Plan Policies.

Pursuant to 41 CFR 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, interested persons may submit a written statement for consideration by the DACOWITS. Individuals submitting a written statement must submit their statement to the point of contact listed at the address in **FOR FURTHER INFORMATION CONTACT** no later than 5:00 p.m., Wednesday, November 30, 2016. If a written statement is not received by Wednesday, November 30, 2016, prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the DACOWITS until its next open meeting. The DFO will review all timely submissions with the DACOWITS Chair and ensure they are provided to the members of the Committee. If members of the public are interested in making an oral statement, a written statement should be submitted. After reviewing the written comments, the Chair and the DFO will determine who of the requesting persons will be able to make an oral presentation of their issue during an open portion of this meeting or at a future meeting. Pursuant to 41 CFR 102–3.140(d), determination of who will be making an oral presentation is at the sole discretion of the Committee Chair and the DFO, and will depend on time available and if the topics are relevant to the Committee's activities. Five minutes will be allotted to persons desiring to make an oral presentation. Oral presentations by members of the public will be permitted only on Thursday, December 8, 2016 from 2:45 p.m. to 3:15 p.m. in front of the full Committee. The number of oral presentations to be made will depend on the number of requests received from members of the public.

Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public, subject to the availability of space.

Meeting Agenda

Thursday, December 8, 2016, From 8:30 a.m. to 3:15 p.m.

—Welcome, Introductions, Announcements

—Request for Information Status Update

—Panel Discussion—Integrated Boxing Programs at the Military Service Academies

—Panel Discussion—Services' Retention Initiatives

—Panel Discussion—Services' Efforts to Increase Propensity Panel Discussion

—Panel Discussion—Services' Sexual Harassment/Sexual Assault Training

—Public Comment Period

—Public Dismissed

Friday, December 9, 2016, From 8:30 a.m. to 11:30 a.m.

—Welcome and Announcements

—Awards Ceremony for Departing Members

—Briefing—DoD Childcare Programs and Initiatives Update

—Panel Discussion—Services' Family Care Plan Policies

—Public Dismissed

Dated: November 9, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–27413 Filed 11–14–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2015–OS–0133]

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 December 15, 2016.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: DoD Consolidations Facility Request for Records, CAF Form 3; OMB Control Number 0704–XXXX.

Type of Request: Existing Collection without an OMB Control Number.

Number of Respondents: 120.

Responses per Respondent: 1.

Annual Responses: 120.

Average Burden per Response: 5 minutes.

Annual Burden Hours: 10 hours.

Needs and Uses: The information collection requirement is necessary to ensure needed information is collected to positively identify individuals who request records regarding themselves that are maintained by the DoD Consolidated Adjudications Facility. These records will also be used in any Privacy Act appeals or related litigation. The Law Enforcement, Congressional Inquiries, Department of Justice for Litigation, National Archives and Records Administration, and Data Breach Remediation, and Routine Uses found at *http://dpcld.defense.gov/Privacy/SORNsIndex/BlanketRoutineUses.aspx.* The DoD Consolidated Adjudications Facility Request for Records form will also be used to refer records under the release authority of another Federal Agency.

Affected Public: Individuals or Households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, 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: November 9, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–27407 Filed 11–14–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0099]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Trends in International Mathematics and Science Study (TIMSS 2019) Field Test Recruitment and Pilot Test

AGENCY: National Center for Education Statistics (NCES), 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 December 15, 2016.

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–0099. 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 2E–347, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact NCES Information Collections at *NCES.Information.Collections@ed.gov.*

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: Trends in International Mathematics and Science Study (TIMSS 2019) Field Test Recruitment and Pilot Test.

OMB Control Number: 1850–0695.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 8,594.

Total Estimated Number of Annual Burden Hours: 2,190.

Abstract: The Trends in Mathematics and Science Study (TIMSS) is an

international assessment of fourth and eighth grade students' achievement in mathematics and science. Since its inception in 1995, TIMSS has continued to assess students every 4 years. The United States will participate in TIMSS 2019 to continue to monitor the progress of its students compared to that of other nations and to provide data on factors that may influence student achievement. New in 2019, TIMSS will be a technology-based assessment conducted in an electronic format. TIMSS is designed by the International Association for the Evaluation of Educational Achievement (IEA), and is conducted in the U.S. by the National Center for Education Statistics (NCES). In preparation for the TIMSS 2019 main study, in April 2017, U.S. will participate in a pilot study to assist in the development of eTIMSS and, in March through April 2018, in a field test to evaluate new assessment items and background questions. The TIMSS 2019 Main Study data collection will take place from April through May 2019. This submission is to conduct the TIMSS 2019 pilot test and to begin recruitment of schools, teachers, and students for the field test study. The pilot test data collection will begin in April 2017 and the recruitment for the field test in May 2017. Recruitment for the main study will begin in May of 2018 In May 2017, NCES will submit a request to conduct the 2018 field test and recruit schools for TIMSS 2019 Main Study.

Dated: November 9, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–27394 Filed 11–14–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0127]

Agency Information Collection Activities; Comment Request; Integrated Postsecondary Education Data System (IPEDS) 2016–2019

AGENCY: National Center for Education Statistics (NCES), 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 January 17, 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–0127. 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 2E–347, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact NCES Information Collections at *NCES.Information.Collections@ed.gov.*

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: Integrated Postsecondary Education Data System (IPEDS) 2016–2019.

OMB Control Number: 1850–0582.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 76,000.

Total Estimated Number of Annual Burden Hours: 1,030,893.

Abstract: The National Center for Education Statistics (NCES) seeks authorization from OMB to make a change to the Integrated Postsecondary Education Data System (IPEDS) data collection. Current authorization expires 08/31/2019 (OMB #1850–0582). NCES is requesting a new clearance for the 2017–18, 2018–19, and 2019–20 data collections to enable us to make a change to two of the IPEDS data collection components and to continue the IPEDS collection of postsecondary data over the next 3 years. IPEDS is a web-based data collection system designed to collect basic data from all postsecondary institutions in the United States and the other jurisdictions. IPEDS enables NCES to report on key dimensions of postsecondary education such as enrollments, degrees and other awards earned, tuition and fees, average net price, student financial aid, graduation rates, student outcomes, revenues and expenditures, faculty salaries, and staff employed. The IPEDS web-based data collection system was implemented in 2000–01, and it collects basic data from approximately 7,500 postsecondary institutions in the United States and the other jurisdictions that are eligible to participate in Title IV Federal financial aid programs. All Title IV institutions are required to respond to IPEDS (Section 490 of the Higher Education Amendments of 1992 [Pub. L. 102–325]). IPEDS allows other (non-title IV) institutions to participate on a voluntary basis. About 200 elect to respond. IPEDS data are available to the public through the College Navigator and IPEDS Data Center Web sites. This clearance package includes a number of proposed changes to the data collection.

Dated: November 9, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–27426 Filed 11–14–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0126]

Agency Information Collection Activities; Comment Request; Principal Follow-Up Survey (PFS 2016–17) to the National Teacher and Principal Survey (NTPS 2015–16)

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before January 17, 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–0126. 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 2E–347, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact NCES Information Collections at *NCES.Information.Collections@ed.gov.*

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: Principal Follow-Up Survey (PFS 2016–17) to the National Teacher and Principal Survey (NTPS 2015–16).

OMB Control Number: 1850–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 7,240.

Total Estimated Number of Annual Burden Hours: 603.

Abstract: This request is to conduct data collection for the 2016–17 Principal Follow-up Survey (PFS), a one-year follow up of principals who responded to the 2015–16 National Teacher and Principal Survey (NTPS). PFS is conducted by the National Center for Education Statistics (NCES), of the Institute of Education Sciences (IES), within the U.S. Department of Education (ED). The PFS has been conducted two times previously: beginning in 2008–09 as a follow up to the Schools and Staffing Survey (SASS) in 2007–08 (OMB #1850–0598 v.5) and, subsequently, as a follow-up to SASS in 2012–2013 (OMB #1850–0598 v.9). During the 2015–16 school year, NCES conducted the first NTPS (OMB #1850–0598 v.11), a redesign of SASS to improve the flexibility, efficiency, and timeliness of NCES data on the nation's K–12 schools, principals, and teachers. The 2016–17 PFS will be the first to launch from the redesigned NTPS. The PFS survey design and content remain highly consistent with earlier administrations. The 2016–17 PFS, like earlier PFS collections, will measure the one-year attrition rates of principals who leave the profession and will permit comparisons of stayers, movers, and leavers. ''Stayers'' are principals who remain in the same school between the NTPS year of data collection and the follow-up year; ''movers'' are principals who stay in the profession but change schools between the NTPS year and the follow-up year; and ''leavers'' are NTPS respondents who leave the principal profession between the NTPS year and the follow-up year. The data collected in the 2016–17 PFS will be combined with data collected in the 2015–16 NTPS on principal characteristics, qualifications, and perceptions of the school environment. Together, NTPS and PFS provide national data on turnover in the principal workforce, including rates of entry and attrition from principalship, sources and characteristics of newly hired principals, and characteristics and destinations of leavers. The cross-sectional repeated design of PFS allows for analyses of trends related to these topics.

Dated: November 9, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–27393 Filed 11–14–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Hydrogen and Fuel Cell Technical Advisory Committee (HTAC)

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an open meeting of the Hydrogen and Fuel Cell Technical Advisory Committee (HTAC). The Federal Advisory Committee Act requires notice of the meeting be announced in the **Federal Register**.

DATES: Tuesday, December 6, 2016 9:00 a.m.–5:45 p.m.

Wednesday, December 7, 2016 9:00 a.m.–1:15 p.m.

ADDRESSES: National Renewable Energy Laboratory, 901 D St SW., Suite 930, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: *Email: HTAC@nrel.gov* or at the mailing address: Erika Gupta, Designated Federal Officer, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, 15013 Denver West Parkway, Golden, CO 80401.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The Hydrogen and Fuel Cell Technical Advisory Committee (HTAC) was established under section 807 of the Energy Policy Act of 2005 (EPACT), Pub. L. 109–58; 119 Stat. 849.

Purpose of the Meeting: To provide advice and recommendations to the Secretary of Energy on the program authorized by Title VIII of EPACT.

Tentative Agenda: (updates will be posted on the web at: *http://hydrogen.energy.gov/advisory_htac.html*).

- HTAC Business (including public comment period)
- DOE Leadership Updates
- Program and Budget Updates
- Updates from Federal/State Governments and Industry
- HTAC Subcommittee Updates
- Open Discussion Period

Public Participation: The meeting is open to the public. Individuals who would like to attend and/or to make oral statements during the public comment period must register no later than 5:00 p.m. on Monday, November 28, 2016 by email at *HTAC@nrel.gov.* Entry to the meeting room will be restricted to those who have confirmed their attendance in advance. Please provide your name, organization, citizenship, and contact information. Anyone attending the meeting will be required to present government-issued identification. Those wishing to make a public comment are required to register. The public comment period will take place between 9:00 a.m. and 9:30 a.m. on December 6, 2016. Time allotted per speaker will depend on the number who wish to speak but will not exceed five minutes. Those not able to attend the meeting or have insufficient time to address the committee are invited to send a written statement to *HTAC@nrel.gov.*

Minutes: The minutes of the meeting will be available for public review at *http://hydrogen.energy.gov/advisory_htac.html.*

Issued in Washington, DC at November 8, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–27361 Filed 11–14–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Secretary of Energy Advisory Board

AGENCY: Department of Energy.

ACTION: Notice of cancellation of open meeting.

SUMMARY: On November 2, 2016, the Department of Energy (DOE) published a notice of open meeting scheduled for December 13, 2016, of the Secretary of Energy Advisory Board. This notice announces the cancellation of this meeting. The meeting is being cancelled because the board will not have a quorum due to scheduling conflicts by members. The next regular meeting will be held at a date to be determined.

DATES: The meeting scheduled for December 13, 2016, announced in the November 2, 2016, issue of the **Federal Register** (FR Doc. 2016–26419, 81 FR 212), is cancelled.

FOR FURTHER INFORMATION CONTACT: Karen Gibson, Designated Federal Officer, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585; *seab@hq.doe.gov.*

Issued at Washington, DC, on November 8, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–27362 Filed 11–14–16; 8:45 am]

BILLING CODE 6405–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration

DEPARTMENT OF STATE

DEPARTMENT OF COMMERCE

Amendment to Procedures Established Pursuant to the Nuclear Non-Proliferation Act of 1978

AGENCY: National Nuclear Security Administration, Department of Energy; Department of State, Department of Commerce.

ACTION: Notice.

SUMMARY: Section 3136 of the National Defense Authorization Act for Fiscal Year 2016 (NDAA) mandates that the Office of the Director of National Intelligence (ODNI) also be consulted with respect to each authorization under section 57b.(2) of the Atomic Energy Act of 1954, as amended (AEA), to a covered foreign country as defined in section 3136(i)(2) of the NDAA. This amendment to the Procedures Established Pursuant to the Nuclear Non-Proliferation Act of 1978 implements this consultation requirement.

DATES: *Effective:* November 15, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Goorevich, Senior Policy Advisor, Office of Nonproliferation and Arms Control (NPAC), National Nuclear Security Administration (NNSA), Department of Energy (DOE), 1000 Independence Avenue SW., Washington, DC 20585, *Richard.Goorevich@nnsa.doe.gov,* telephone 202–586–0589; or Mr. Dick Stratford, Director, Office of Nuclear Energy, Safety, and Security, Department of State (DOS), 2201 C St. NW., Room 3320, Washington, DC 20520, *StratfordRJ@state.gov,* telephone 202–647–4413; or Mr. Steven Clagett, Director, Nuclear and Missile Technology Division, Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, *Steven.clagett@bis.doc.gov,* telephone 202–482–1641.

SUPPLEMENTARY INFORMATION:

Background

Section 57b.(2) of the Atomic Energy Act of 1954, as amended (AEA), is implemented through the DOE/NNSA regulations under Title 10 of the Code of Federal Regulations (CPR) Part 810 (Part 810) governing exports of unclassified nuclear technology and assistance. On February 23, 2015, DOE/NNSA published its final rule (80 FR 9359) revising Part 810. The final rule came into effect on March 25, 2015. Before the Secretary of Energy authorizes certain transfers of civil nuclear technology and assistance, DOE/NNSA is required to consult with the Nuclear Regulatory Commission (NRC), the Department of Commerce (DOC), and the Department of Defense (DoD), and obtain the concurrence of the Department of State (DOS). These reviews are accomplished in a manner consistent with Part D of the Procedures Established Pursuant to the Nuclear Non-Proliferation Act of 1978 (the ''Procedures''), as published in the **Federal Register** on June 7, 1978 (43 FR 25326), and amended by publication in the **Federal Register** on May 16, 1984 (49 FR 20780), and February 19, 1991 (56 FR 6701). This amendment addresses only Section 12 of Part D of the Procedures to implement the new requirements of Section 3136 of the NDAA, which mandates that the Director, ODNI, also be consulted with respect to each authorization under section 57b. of the AEA to a covered foreign country as defined in section 3136(i)(2) of the NDAA.

Amended Procedure

To provide for consultation with the ODNI on applications for specific authorization under section 57b.(2) of the AEA, as implemented by DOE/NNSA regulations at 10 CFR Part 810, Section 12 of Part D of the Procedures is amended as follows:

1. Within 10 days of receipt of an application for specific authorization for a transfer of technology controlled under 10 CFR Part 810, DOE/NNSA conducts a technical review of the application to determine whether the application is properly submitted and falls within the scope of the regulation.

1.a. Concurrent with the internal DOE/NNSA technical review, for

packages involving covered foreign countries as defined in section 3136(i)(2) of the NDAA, DOE/NNSA sends the end user, equipment, supplier information, and any other relevant information to ODNI. ODNI notifies Intelligence Community (IC) elements of the application for transfer of technology as soon as possible.

1.b. Within 10 business days of initial notification, ODNI identifies, based on the details of the transfer application and availability, an IC point of contact (POC) to provide a response. DOE/NNSA provides ODNI with any technical reviews or assessments conducted by DOE/NNSA relevant to the technology transfer.

1.c. Within 30 business days of receiving the end user, equipment, and supplier information from DOE/NNSA, ODNI makes its coordinated response available to: DOE/NNSA; DOS; and NRC, DOC, and DoD (collectively herein referred to as the ''Consulting Agencies'').

2. After the DOE/NNSA technical review is complete, with expected timelines of not more than 60 days for covered foreign countries and 30 days for other destinations, DOE/NNSA transmits through appropriate means the application and DOE/NNSA analysis to DoD, DOC, DOS, and NRC for review. Within 30 days after receipt, DOS and the Consulting Agencies provide their views on the application and analysis. If DOS or a Consulting Agency notifies DOE/NNSA NPAC in writing that additional information is required, NPAC will provide appropriate time for all Consulting Agencies to consider the application and a new time line will be established for reviews based on individual circumstances. Note that the U.S. Government, through DOS, requests foreign government assurances for specific authorizations, and it is the foreign government's control over how long it may take to deliver these assurances, which may lengthen the time line for interagency review beyond the expected 30 days.

3. Within 100 days following the completion of the interagency consultations, NPAC provides the Secretary of Energy with a recommendation for action on the application, including the views of DOS, the Consulting Agencies, and ODNI, if applicable. In the event that any such agencies recommend further consideration this timeline may be extended.

Information provided to DOE in connection with these procedures may be marked or otherwise identified as business proprietary and/or personally identifiable information and would be subject to protection in accordance with applicable law and Executive Orders. Such information would be made available within the respective agencies only to those personnel who have a need to know for the purpose of reviewing applications for exports of unclassified nuclear technology and assistance under section 57b.(2) of the Atomic Energy Act of 1954, as amended, and otherwise disclosed only with the express consent of DOE/NNSA or when such disclosure is required by law.

Dated: November 2, 2016.

Kasia Mendelsohn,

Associate Deputy, Administrator, Office of Nonproliferation and Arms Control, National Nuclear Security Administration. Department of Energy.

Richard J.K. Stratford,

Director, Office of Nuclear Energy, Safety and Security, Bureau of International Security and Nonproliferation, Department of State.

Matthew Borman,

Deputy Assistant Secretary, Office of Export Administration, Bureau of lndustry and Security, Department of Commerce.

[FR Doc. 2016–27409 Filed 11–14–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2850–023]

Hampshire Paper Company, Inc., KE Emeryville, LLC; Notice of Application for Transfer of License and Soliciting Comments, Motions To Intervene, and Protests

On October 24, 2016, Hampshire Paper Company, Inc. (transferor) and KE Emeryville, LLC (transferee) filed an application for the transfer of license of the Emeryville Hydroelectric Project No. 2850. The project is located on the Oswegatchie River in St. Lawrence County, New York. The project does not occupy Federal lands.

The applicants seek Commission approval to transfer the license for the Emeryville Hydroelectric Project from Hampshire Paper Company, Inc. to KE Emeryville, LLC.

Applicants Contact: For transferor: Mr. Charles Wemyss, Hampshire Paper Company, Inc., c/o Pierce Atwood, LLP, 254 Commercial Street, Portland, ME 04101, Email: *cwemyss@oswpower.com* and Mr. Christopher Howard, Pierce Atwood, LLP, Merrill's Wharf, 245 Commercial Street, Portland, ME 04101, Email: *choward@pierceatwood.com.* For transferee: Mr. Frédéric Boucher, KE Emeryville, LLC, 37 Alfred A. Plourde Parkway, Suite 2, Lewiston, ME 04240, Email: *Frederic.boucher@kruger.com* and Ms. Heather J. Haney, Kaplan Kirsch & Rockwell, 1675 Broadway, Suite 2300, Denver, CO 80202, Email: *hhaney@kaplankirsch.com.*

FERC Contact: Patricia W. Gillis, (202) 502–8735, *patricia.gillis@ferc.gov.*

Deadline for filing comments, motions to intervene, and protests: 30 days from the date that the Commission issues this notice. The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov*, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–2850–023.

Dated: November 7, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–27381 Filed 11–14–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL17–15–000]

Big Rivers Electric Corporation v. Midcontinent Independent System Operator, Inc.; Notice of Complaint

Take notice that on November 4, 2016, pursuant to section 206 of the Federal Power Act, 16 U.S.C. 824e, and Rules 206 and 212 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 and 385.212 (2016), Big Rivers Electric Corporation (Complainant) filed a formal complaint against Midcontinent Independent System Operator, Inc. (Respondent) alleging that Respondent's application of the relevant Open Access Transmission, Energy and Operating Reserves Markets Tariff provisions to Complainant is not just and reasonable, all as more fully explained in the complaint.

Complainant certifies that a copy of the complaint has been served on MISO and on the Kentucky Public Service Commission.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

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

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

Comment Date: 5:00 p.m. Eastern Time on November 24, 2016.

Dated: November 7, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–27379 Filed 11–14–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP17–5–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on October 28, 2016, Columbia Gas Transmission, LLC (Columbia), located at 5151 San Felipe, Suite 2500, Houston, Texas 77056, filed in Docket No. CP17–5–000, a prior notice request pursuant to sections 157.205, and 157.208(b) of the Federal Energy Regulatory Commission's regulations under the Natural Gas Act (NGA), seeking authorization to abandon and construct certain natural gas facilities in Gallia, Jackson and Lawrence Counties, Ohio, all as more fully set forth in the application, which is on file with the Commission and open to public inspection. The filing may also be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding the Request should be directed to Richard D. Bralow, Counsel, Columbia Gas Transmission, LLC, 700 Louisiana Street, Houston, Texas 77002, by telephone at: 832–320–5177, or by email at *richard_bralow@transcanada.com.*

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenter's will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and ill not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*www.ferc.gov*) under the ''e-Filing'' link. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: November 7, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–27382 Filed 11–14–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL17–17–000; QF11–516–001]

Western Water and Power Production Limited LLC; Notice of Petition for Enforcement

Take notice that on November 7, 2016, pursuant to section 210(h)(2)(B) of the Public Utility Regulatory Policies Act of 1978 (PURPA), Western Water and Power Production Limited LLC (Petitioner) filed a Petition for Enforcement, requesting the Federal Energy Regulatory Commission (Commission) to exercise its authority and initiate enforcement action against

the New Mexico Public Regulation Commission to remedy its alleged improper implementation of PURPA, all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Petitioner.

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

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

Comment Date: 5:00 p.m. Eastern Time on November 28, 2016.

Dated: November 7, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–27380 Filed 11–14–16; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0698]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 17, 2017. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Approval Number: 3060–0698.

Title: Section 25.203(i) and 73.1030(a)(2), Radio Astronomy Coordination Zone in Puerto Rico.

Form No: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and State, local, or tribal Government.

Number of Respondents and Responses: 450 respondents, 4,000 responses.

Estimated Time per Response: 5–40 minutes (.0833 hours to .667 hours).

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained 47 U.S.C. 154(i), 303(f), 303(r), and 309(j)(13).

Total Annual Burden: 602 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this 60 day comment period to obtain the three-year clearance from them.

On October 15, 1997, the FCC released a Report and Order, ET Docket No. 96–2, RM–8165, FCC 97–347, that established a Coordination Zone for new and modified radio facilities in various communications services that cover the islands of Puerto Rico, Desecheo, Mona, Vieques, and Culebra within the Commonwealth of Puerto Rico. The coordination zone and notification procedures enable the Arecibo Radio Astronomy Observatory to receive information needed to assess whether an applicant's proposed operations will cause harmful interference to the Arecibo Observatory's operations, which also promotes efficient resolution of coordination problems between the applicants and the Arecibo Observatory.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–27331 Filed 11–14–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general

public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid 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 Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before January 17, 2017. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–XXXX.

Title: Improving Reporting for Submarine Cables and Enhanced Submarine Outage Data.

Form Number: FCC Form 5623.

Type of Review: New collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 63 respondents; 50 responses.

Estimated Time per Response: 2 hours.

Frequency of Response: Recurring reporting requirement if reporting thresholds are met, we estimate each respondent will file 0.79 reports per year.

Obligation To Respond: Mandatory. Statutory authority for this information collection is contained in 47 U.S.C. 1, 4(j), 4(o), 34–39, 151, 154(i)–(j), 3 U.S.C. 301, and Executive Order No. 10530.

Total Annual Burden: 100 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: Outage reports filed with the Commission pursuant to part 4 are presumed confidential. The information in those filings may be shared with the Department of Homeland Security only under appropriate confidential disclosure protections. Other persons seeking disclosure must follow the procedures delineated in 47 CFR 0.457 and 0.459 of the Commission's rules for requests for and disclosure of information. The information collection discussed here does not affect the confidential treatment of information provided to the FCC through NORS reports.

Needs and Uses: Section 151 of the Communications Act of 1934 (Act), as amended, requires the Commission to promote the safety of life and property through the use of wire and radio communications. Additionally, the Cable Landing License Act, Cable Landing License Act (47 U.S.C. 34–39), and Executive Order 10530, provide the Commission with authority to grant, withhold, condition and revoke submarine cable landing licenses. In concert, the Cable Landing License Act and Executive Order provide that the Commission may place conditions on the grant of a submarine cable landing license in order to assure just and reasonable rates and service in the operation and use of cables so licensed. ''Just and reasonable service'' entails assurance that the cable infrastructure will be reasonably available. Availability of submarine cables is also critically important for national security, and the economy, because submarine cables carry approximately 95 percent of international communications traffic, and are the primary means of connectivity for numerous U.S. states and territories. The data collection requires all submarine cable licensees to report outages through the network outage reporting system (NORS). The general purpose of NORS reporting is to gather sufficient information regarding disruptions to telecommunications to facilitate FCC monitoring, analysis, and investigation of the reliability and security of networks, and to identify and act on potential threats to our Nation's telecommunications infrastructure. The FCC uses this information collection to identify the duration, magnitude, root causes, contributing factors, and preventive measures taken with respect to significant outages, and to take swift remedial action as required in appropriate circumstances. The Commission also maintains an ongoing dialogue with reporting entities, as well as with the industry at large, generally regarding lessons learned from the information collection in order to foster better understanding of the root causes of significant outages, and to explore preventive measures in the future so as to mitigate the potential impact of such outages on the Nation and the American public.

The data will provide the Commission with greater visibility into the availability and health of these networks, allowing it to better track and analyze submarine cable resiliency, and suggest or take appropriate actions when the data so indicate, *i.e.* before there is a significant problem. Thus, the data will ensure that submarine cable service is just and reasonable, and that critical communications carried across submarine cables continue to promote the safety of life and property, fulfilling the aforementioned statutory obligations.

The NORS information collection (OMB Control No. 3060–0484) is administered by the FCC's Public Safety and Homeland Security Bureau (PSHSB), which maintains an Internet portal for the electronic submission of NORS reports. This electronic filing requirement entails entering the required information using Commission-approved Web-based outage report templates that are available online at the NORS Internet Web portal. The completion of these online templates results in the information being electronically entered into the Commission's NORS reporting data base in real-time.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–27332 Filed 11–14–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: November 17, 2016—10 a.m.

PLACE: 800 North Capitol Street NW., First Floor Hearing Room, Washington, DC.

STATUS: The first portion of the meeting will be held in Open Session and will be streamed live at

http://fmc.capitolconnection.org/; the second portion in closed session.

MATTERS TO BE CONSIDERED:

Open Session

1. Briefing by the Chairman on the World Shipping Summit
2. Staff Briefing on OTI License Renewals

Closed Session

1. Staff Briefing on Hanjin Bankruptcy and Shipping Disruptions
2. Update on the PierPASS Third-party Audit and Extended Gate Workshop
3. Empirical Analysis of Changing Alliance Structures in the Transpacific Trade

CONTACT PERSON FOR MORE INFORMATION: Rachel E. Dickon, Assistant Secretary, (202) 523–5725.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–27474 Filed 11–10–16; 11:15 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than November 30, 2016.

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. *Edwin W. Orr and James S. Orr, individually as members of a family control group that also includes Edwin S. Orr and Cheryl L. Orr, all of Columbia, Missouri;* to retain control of Montgomery Bancshares, Inc., Jonesburg, Missouri, and thereby retain shares of Jonesburg State Bank, Jonesburg Missouri.

Board of Governors of the Federal Reserve System, November 9, 2016.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2016–27412 Filed 11–14–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 151 0236]

Valeant Pharmaceuticals International, Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before December 7, 2016.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/valeantparagonpelicanconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''In the Matter of Valeant Pharmaceuticals International, Inc., File No. 1510236'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/valeantparagonpelicanconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''In the Matter of Valeant Pharmaceuticals International, Inc., File No. 1510236'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Charles Harwood, FTC Northwest Regional Office, 915 Second Ave., Room 2896, Seattle, WA 98174 (206–220–4480).

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for November 7, 2016), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 7, 2016. Write ''In the Matter of Valeant Pharmaceuticals International, Inc., File No. 1510236'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR

4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/valeantparagonpelicanconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''In the Matter of Valeant Pharmaceuticals International, Inc., File No. 1510236'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 7, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Agreement Containing Consent Order To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted for public comment an Agreement Containing Consent Order (''Consent Order'') with Valeant Pharmaceuticals International, Inc. (''Valeant'') to remedy the alleged anticompetitive effects resulting from Valeant's acquisition of Paragon Holdings I, Inc., including wholly-owned subsidiaries Paragon Vision Sciences, Inc. and CRT Technology, Inc. (''Paragon'').

The Complaint alleges that the acquisition violated Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening competition in the markets for polymer discs, or ''buttons,'' used to make three different types of rigid gas permeable (''GP'') contact lenses: Orthokeratology contact lenses, large-diameter scleral contact lenses, and general vision correction contact lenses. The Consent Order would remedy the alleged violations by restoring competition in these GP button markets.

Under the terms of the Consent Order, Valeant is required to divest Paragon in its entirety, including the assets of Pelican Products LLC (''Pelican''), a manufacturer of contact lens packaging.

The proposed Consent Order has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed Consent Order and any comments received, and decide whether the Consent Order should be withdrawn, modified, or made final.

1. The Parties

Valeant is a Canadian conglomerate that develops and markets prescription and non-prescription pharmaceutical products. Through its subsidiary Bausch + Lomb, Valeant is a leading producer of GP buttons used to make GP contact lenses. Prior to its acquisition by Valeant in May 2015, Paragon was a United States corporation with its principal place of business in Arizona. Paragon produces GP buttons used to make GP contact lenses and also produces finished GP lenses.

After the Paragon acquisition, Valeant also purchased Pelican, a manufacturer of contact lens packaging, and the only producer of FDA-approved vials for wet-shipping finished orthokeratology lenses. Pelican became a subsidiary of Paragon. This acquisition ensured Valeant's access to the vials, after Pelican's owner announced plans to exit the market.

2. The Relevant Market

Both parties engage in developing, manufacturing, and selling GP buttons in the United States. The relevant product markets in which to analyze the effects of the acquisition are the manufacture and sale of FDA-approved GP buttons for: Orthokeratology GP lenses, which are worn to reshape the cornea; large-diameter scleral GP lenses, which cover the white of the eye and are used post-surgery, for transplants, and to treat eye disease; and general vision correction GP lenses. Each type of GP lens requires a GP button with parameters unique to that lens type.

GP lenses are used, and in some cases are medically necessary, to address a variety of vision problems, including dry eyes, abnormal curvatures of the eye, corneal disease, post-eye surgery complications, and eye trauma. Optical labs use GP buttons to make GP contact lenses to fulfill prescriptions from eye care professionals. Prescriptions typically specify a particular product and brand of button, and eye care professionals invest significant capital in fitting equipment for the brands they prescribe.

The FDA requires that GP lenses must be made from FDA-approved GP buttons. Thus, there are no alternatives to FDA-approved GP buttons for making each of the types of GP lenses and the relevant geographic market is the United States.

Prior to the acquisition, Valeant and Paragon independently produced buttons for all three types of GP lenses. In the market for orthokeratology GP buttons, the combination of Valeant and Paragon was a merger to monopoly. In the market for scleral GP buttons, the combined company accounted for 70–80 percent of the market. In the market for general vision correction GP buttons, the combined company's market share was approximately 65–75 percent.

3. Effects of Acquisitions

The acquisition likely caused significant competitive harm in the relevant markets. Specifically, the acquisition of Paragon eliminated actual, direct, and substantial competition between Valeant and Paragon in the relevant markets for GP buttons and allowed Valeant to unilaterally exercise market power. For instance, following the acquisition, Valeant increased prices in all three GP button markets.

Prior to the acquisition, Valeant and Paragon also competed on innovation, with the incentive to develop new GP lens buttons and improve button materials by investing in research, development, and adoption. This innovation led to broader product lines, improvements to button materials, and marketing and education funding for optical labs. The acquisition also eliminated this innovation competition between Valeant and Paragon.

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

4. Entry and Efficiencies

Entry into the relevant market has not been, and would not be, timely, likely, or sufficient to deter or counteract the anticompetitive effects of the acquisition. Optical labs have limited short-term ability to switch from Valeant and Paragon, which supply the majority of their GP scleral buttons and GP general vision correction buttons, and 100 percent of their GP orthokeratology buttons. Optical labs might try to persuade eye care professionals to switch to a different material and brand, but ultimately the decision is made by the eye care professional, for whom such a change is costly and time-consuming.

Considerable entry barriers also arise from the FDA approval process. For GP orthokeratology buttons, the FDA premarket approval process takes several years because finished orthokeratology lenses worn overnight are Class III medical devices. For GP scleral and general vision buttons, the FDA premarket notification process likely requires at least one year, as the finished lenses incorporating such buttons are Class II medical devices.

We did not find any evidence of efficiencies that would outweigh the competitive concerns arising from the Paragon acquisition.

5. Consent Order

The proposed Consent Order requires Valeant to divest Paragon in its entirety no later than ten (10) days after the order date, to remedy the concerns raised by the acquisition and restore competition in the relevant markets by instituting Paragon as an independent, viable competitor to Valeant. The proposed Consent Order also requires Valeant to divest Pelican with Paragon to ensure continued access to FDA-approved vials for shipping its finished lenses.

The proposed Consent Order requires that Valeant must divest Paragon and Pelican to Paragon Companies LLC in an upfront transaction. Paragon Companies LLC is a newly created entity owned by Joe Sicari. Mr. Sicari was the president of Paragon prior to its acquisition by Valeant in May 2015.

The Commission may, at any time, appoint a Monitor with the power and authority to ensure that Valeant fulfills all obligations and responsibilities under the Consent Order and Divestiture Agreement.

The Consent Order will remain in effect for ten (10) years, and contains standard compliance and reporting requirements.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–27440 Filed 11–14–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–17–16AOW]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

CDC I–Catalyst Program—New—Office of the Associate Director for Science, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC Office of Technology and Innovation (OTI) within Office of the Associate Director for Science (OADS) is seeking approval for a new CDC generic clearance. OTI fosters innovative science and promotes the testing and implementation of innovative ideas that improve CDC's ability to have public health impact. To arm CDC staff with an expanded skill-set and tools to evaluate and translate their insights and ideas into solutions, CDC developed an experiential innovation curriculum called I-Catalyst based on the NSF I-Corp program. The program was created with the belief that innovation should be customer driven, be based on user research, and is something people at all levels of an organization can engage in.

The purpose of the I-Catalyst program is to teach CDC teams a process of discovering the issues and problems faced by their customers before considerable time and money is spent on a solution that may not be used. Each participating I-Catalyst project team will present with a unique customer problem for which they have a proposed solution. Participating project teams will go through a hypothesis-testing, scientific method of discovery to gather important insights about their customers and their needs.

Each individual collection will be a different problem for which a CDC team is designing a solution. The types of customers or stakeholders teams' interview will be detailed in each collection. For example, teams may interview government employees if the solution is intended to improve how government employees do their work. On the other hand, teams may interview individuals who work in industry and businesses if the problem is one experienced by external customers. This data collection covers qualitative information to be obtained through on-site, unstructured interviews with individuals who represent the customers or stakeholders CDC teams are attempting to serve or benefit.

It is expected that the program will help CDC teams generate information about their customers to help them make the case for key innovation investments to advance important public health solutions and innovations. The ultimate goal of the I-Catalyst program is to give CDC staff skills to successfully transfer knowledge into

value-based solutions that benefit society and broaden the agency's impact. Participation in the I-Catalyst interviews is completely voluntary. A three-year approval is requested. There is no cost to respondents other than their time.

CDC anticipates 30 projects over the next three years. Each project team will interview their customers/stakeholders for an average of 30 minutes and maximum of 2 responses per respondent. Each team will interview approximately 50 respondents. Approximately 1500 respondents will be interviewed. Of these respondents, approximately 40% of individuals will be internal CDC/ATSDR staff and 60% will be external partners, stakeholders, or customers. Annualized burden will be 500 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden (in hrs)
External + Internal stakeholder/customers ...	Sample Interview Guide	500	2	30/60	500

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–27421 Filed 11–14–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–17CX; Docket No. CDC–2016–0108]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed project entitled ''Reframing How We Talk About Alcohol: Public Perceptions of Excessive Alcohol Use Among Multiple Audiences.'' CDC will seek a one-year approval for a new information collection request to assess the public's perceptions and frames regarding alcohol use and its related harms, gain insights on the language the public uses when talking about excessive alcohol use, examine patient-provider communication about alcohol use, and evaluate the influence of other sources of information on the public's understanding of excessive alcohol use.

DATES: Written comments must be received on or before January 17, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0108, by any of the following methods:

- *Federal eRulemaking portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses); and (e) Assess information collection costs. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and use technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information, search data sources, and complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Reframing How We Talk About Alcohol: Public Perceptions of Excessive Alcohol Use and Related Harms—NEW—National Center on Birth Defects and Developmental Disabilities (NCBDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Excessive alcohol consumption leads to a variety of negative health and social consequences. Those who drink heavily have an increased risk for certain chronic diseases, such as hypertension, psychological disorders, and various forms of cancer. Excessive alcohol use also can result in societal harms, such as unintentional injuries, violence, and high economic costs.

Fortunately effective prevention strategies are available to reduce excessive alcohol use and its related harms. However, it is difficult to craft public health messages and communication strategies to change alcohol-related attitudes and behaviors because the range of knowledge and beliefs about excessive alcohol use and its risks is not well understood. Despite the fact that public health experts recommend that alcohol screening and brief counseling be provided to adults in primary care settings, data indicate that only one of six U.S. adults reported ever discussing alcohol use with a health professional. To develop an effective, consistent messaging strategy, a deeper understanding of how the public thinks and talks about alcohol is required. The research will be used to inform the development of patient and provider materials and messages about excessive alcohol use and related harms.

The one-year study proposes a series of individual in-depth interviews and triads (small group discussions with three participants) with 54 participants identified by contractor staff and professional recruiting firms. Data will be collected through one-time, 90-minute in-depth interviews or triads. Up to 300 individuals will be screened to obtain 54 individuals who will participate in 90-minute in-depth interviews or triads. All data will be collected only one time. Respondents who will participate in these interviews and triads will be selected purposively to inform the development of a messaging strategy. Topics addressed may include alcohol and its related harms, language used when talking about alcohol, how people talk about alcohol with their health care providers, and sources of information about alcohol.

The information gathered through this data collection will allow CDC to develop an effective messaging strategy that reframes the way the public thinks and communicates about excessive alcohol use. Participation is voluntary, and there is no cost to respondents other than their time.

The total estimated annualized burden hours are 132.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Persons aged 21–55	Study screener	300	1	10/60	50
	In-depth interviews				
	Phase 1 (Descriptive)	9	1	1.5	14
	Phase 2 (Prescriptive)	9	1	1.5	14
	Triads				
	Phase 1 (Descriptive)	18	1	1.5	27
	Phase 2 (Prescriptive)	18	1	1.5	27
Total					132

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–27395 Filed 11–14–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8062–N]

RIN 0938–AS70

Medicare Program; CY 2017 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year (CY) 2017 under Medicare's Hospital Insurance Program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts. For CY 2017, the inpatient hospital deductible will be $1,316. The daily coinsurance amounts for CY 2017 will be: (1) $329 for the 61st through 90th day of hospitalization in a benefit period; (2) $658 for lifetime reserve days; and (3) $164.50 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

DATES: *Effective Date:* This notice is effective on January 1, 2017.

FOR FURTHER INFORMATION CONTACT:

Clare McFarland, (410) 786–6390 for general information.

Gregory J. Savord, (410) 786–1521 for case-mix analysis.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires us to determine and publish each year the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following calendar year (CY).

II. Computing the Inpatient Hospital Deductible for CY 2017

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding CY, adjusted by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act) used for updating the payment rates to hospitals for discharges in the fiscal year (FY) that begins on October 1 of the same preceding CY, and adjusted to reflect changes in real case-mix. The adjustment to reflect real case-mix is determined on the basis of the most recent case-mix data available. The amount determined under this formula is rounded to the nearest multiple of $4 (or, if midway between two multiples of $4, to the next higher multiple of $4).

Under section 1886(b)(3)(B)(i)(XX) of the Act, the percentage increase used to update the payment rates for FY 2017 for hospitals paid under the inpatient prospective payment system is the market basket percentage increase, otherwise known as the market basket update, reduced by 0.75 percentage points (see section 1886(b)(3)(B)(xii)(V) of the Act), and an adjustment based on changes in the economy-wide productivity (the multifactor productivity (MFP) adjustment) (see section 1886(b)(3)(B)(xi)(II) of the Act). Under section 1886(b)(3)(B)(viii) of the Act, for FY 2017, the applicable percentage increase for hospitals that do not submit quality data as specified by the Secretary of the Department of Health and Human Services (the Secretary) is reduced by one quarter of the market basket update. We are estimating that after accounting for those hospitals receiving the lower market basket update in the payment-weighted average update, the calculated deductible will not be affected, since the majority of hospitals submit quality data and receive the full market basket update. Section 1886(b)(3)(B)(ix) of the Act requires that any hospital that is not a meaningful electronic health record (EHR) user (as defined in section 1886(n)(3) of the Act) will have three-quarters of the market basket update reduced by 66⅔ percent for FY 2016, 100 percent for FY 2017, and 100 percent for FY 2018 and each subsequent fiscal year. We are estimating that after accounting for these hospitals receiving the lower market basket update, the calculated deductible will not be affected, since the majority of hospitals are meaningful EHR users and are expected to receive the full market basket update.

Under section 1886 of the Act, the percentage increase used to update the payment rates for FY 2017 for hospitals excluded from the inpatient prospective payment system is as follows:

- The percentage increase for long term care hospitals is the market basket percentage increase reduced by 0.75 percentage points and the MFP adjustment (see sections 1886(m)(3)(A) and 1886(m)(4)(F) of the Act). In addition, these hospitals may also be impacted by the quality reporting adjustments and the site-neutral payment rates (see sections 1886(m)(5) and 1886(m)(6) of the Act).
- The percentage increase for inpatient rehabilitation facilities is the market basket percentage increase reduced by 0.75 percentage points and the MFP adjustment (see sections 1886(j)(3)(C) and 1886(j)(3)(D)(v) of the Act). In addition, these hospitals may also be impacted by the quality reporting adjustments (see section 1886(j)(7) of the Act).
- The percentage increase used to update the payment rate for inpatient psychiatric facilities is the market basket percentage increase reduced by 0.2 percentage points and the MFP adjustment (see sections 1886(s)(2)(A)(i), 1886(s)(2)(A)(ii), and 1886(s)(3)(E) of the Act). In addition, these hospitals may also be impacted by the quality reporting adjustments (see section 1886(s)(4) of the Act).
- The percentage increase for other types of hospitals excluded from the inpatient hospital prospective payment system (cancer hospitals, children's hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico) is the market basket percentage increase (see section 1886(b)(3)(B)(ii)(VIII) of the Act).

The Inpatient Prospective Payment System market basket percentage increase for FY 2017 is 2.7 percent and the MFP adjustment is −0.3 percentage point, as announced in the final rule that appeared in the **Federal Register** on August 22, 2016 entitled, ''Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2017 Rates'' (81 FR 56762). Therefore, the percentage increase for hospitals paid under the inpatient prospective payment system that submit quality data and are meaningful EHR users is 1.65 percent (that is, the FY 2017 market basket update of 2.7 percent less the MFP adjustment of 0.3 percentage point and less 0.75 percentage point). The average payment percentage increase for hospitals excluded from the inpatient prospective payment system is 2.0 percent. This average includes long term care hospitals, inpatient rehabilitation facilities, and other hospitals excluded from the inpatient hospital prospective payment system. Weighting these percentages in accordance with payment volume, our best estimate of the payment-weighted average of the increases in the payment rates for FY 2017 is 1.70 percent.

To develop the adjustment to reflect changes in real case-mix, we first calculated an average case-mix for each hospital that reflects the relative costliness of that hospital's mix of cases compared to those of other hospitals. We then computed the change in average case-mix for hospitals paid under the Medicare prospective payment system in FY 2016 compared to FY 2015. (We excluded from this calculation hospitals whose payments are not based on the inpatient prospective payment system because their payments are based on alternate prospective payment systems or reasonable costs.) We used Medicare bills from prospective payment hospitals that we received as of July 2016. These bills represent a total of about 7.4 million Medicare discharges for FY 2016 and provide the most recent case-mix data available at this time. Based on these bills, the change in average case-mix in FY 2016 is 2.61 percent. Based on these bills and past experience, we expect the overall case mix change to be 2.7 percent as the year progresses and more FY 2016 data become available.

Section 1813 of the Act requires that the inpatient hospital deductible be adjusted only by that portion of the case-mix change that is determined to

be real. Real case-mix is that portion of case-mix that is due to changes in the mix of cases in the hospital and not due to coding optimization. Over the past several years, we have seen case mix increases of about 0.5 percent per year. (In some years there were larger increases in case mix due to much lower discharges for that year.) For 2016, we expect the increase in real case mix to continue to be 0.5 percent. Most of the observed FY 2016 case mix increase is likely due to artifacts of the implementation of ICD–10 which affects the calculated case mix level, but does not measure the actual increase in real case mix. Therefore, we expect that much of the change in average case-mix will not be real and estimate that this real change will be 0.5 percent.

Thus as stated above, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 1.70 percent, and the real case-mix adjustment factor for the deductible is 0.5 percent. Therefore, using the statutory formula as stated in section 1813(b) of the Act, we calculate the inpatient hospital deductible for services furnished in CY 2017 to be $1,316. This deductible amount is determined by multiplying $1,288 (the inpatient hospital deductible for CY 2016 (81 FR 56762)) by the payment-weighted average increase in the payment rates of 1.017 multiplied by the increase in real case-mix of 1.005, which equals $1,316.45 and is rounded to $1,316.

III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for CY 2017

The coinsurance amounts provided for in section 1813 of the Act are defined as fixed percentages of the inpatient hospital deductible for services furnished in the same CY. The increase in the deductible generates increases in the coinsurance amounts. For inpatient hospital and extended care services furnished in CY 2017, in accordance with the fixed percentages defined in the law, the daily coinsurance for the 61st through 90th day of hospitalization in a benefit period will be $329 (one-fourth of the inpatient hospital deductible as stated in section 1813(a)(1)(A) of the Act); the daily coinsurance for lifetime reserve days will be $658 (one-half of the inpatient hospital deductible as stated in section 1813(a)(1)(B) of the Act); and the daily coinsurance for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period will be $164.50 (one-eighth of the inpatient hospital deductible as stated in section 1813(a)(3) of the Act).

IV. Cost to Medicare Beneficiaries

Table 1 below summarizes the deductible and coinsurance amounts for CYs 2016 and 2017, as well as the number of each that is estimated to be paid.

TABLE 1—PART A DEDUCTIBLE AND COINSURANCE AMOUNTS FOR CALENDAR YEARS 2016 AND 2017 TYPE OF COST SHARING

	Value		Number paid (in millions)	
	2016	2017	2016	2017
Inpatient hospital deductible	$1288	$1316	7.15	7.26
Daily coinsurance for 61st–90th Day	322	329	1.77	1.80
Daily coinsurance for lifetime reserve days	644	658	0.87	0.88
SNF coinsurance	161	164.50	40.56	41.83

The estimated total increase in costs to beneficiaries is about $740 million (rounded to the nearest $10 million) due to: (1) The increase in the deductible and coinsurance amounts; and (2) the increase in the number of deductibles and daily coinsurance amounts paid. We determine the increase in cost to beneficiaries by calculating the difference between the 2016 and 2017 deductible and coinsurance amounts multiplied by the estimated increase in the number of deductible and coinsurance amounts paid.

V. Waiver of Proposed Notice and Comment Period

Section 1813(b)(2) of the Act requires publication of the inpatient hospital deductible and all coinsurance amounts—the hospital and extended care services coinsurance amounts—between September 1 and September 15 of the year preceding the year to which they will apply. These amounts are determined according to the statute as discussed above. As has been our custom, we use general notices, rather than notice and comment rulemaking procedures, to make the announcements. In doing so, we acknowledge that under the Administrative Procedure Act (APA), interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find good cause that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. We find that the procedure for notice and comment is unnecessary here, because the formulae used to calculate the inpatient hospital deductible and hospital and extended care services coinsurance amounts are statutorily directed, and we can exercise no discretion in following the formulae. Moreover, the statute establishes the time period for which the deductible and coinsurance amounts will apply and delaying publication would be contrary to the public interest. Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. Regulatory Impact Analysis

A. Statement of Need

Section 1813(b)(2) of the Act requires the Secretary to publish, between September 1 and September 15 of each year, the amounts of the inpatient hospital deductible and hospital and extended care services coinsurance applicable for services furnished in the following CY.

B. Overall Impact

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C., Part I, Ch. 8).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major notices with economically significant effects ($100 million or more in any 1 year). As stated in section IV of this notice, we estimate that the total increase in costs to beneficiaries associated with this notice is about $740 million due to: (1) The increase in the deductible and coinsurance amounts; and (2) the increase in the number of deductibles and daily coinsurance amounts paid. As a result, this notice is economically significant under section 3(f)(1) of Executive Order 12866 and is a major action under the Congressional Review Act. In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year (for details, see the Small Business Administration's Web site at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*). Individuals and states are not included in the definition of a small entity. As discussed above, this annual notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in CY 2017 under Medicare's Hospital Insurance Program (Medicare Part A). As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. As discussed above, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. For 2016, that threshold accounting for inflation is approximately $146 million. This notice does not impose mandates that will have a consequential effect of $146 million or more on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this notice does not impose any costs on state or local governments, preempt state law, or have Federalism implications, the requirements of Executive Order 13132 are not applicable.

Dated: September 23, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 8, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–27389 Filed 11–10–16; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8064–N]

RIN 0938–AS72

Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Beginning January 1, 2017

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) beneficiaries enrolled in Part B of the Medicare Supplementary Medical Insurance (SMI) program beginning January 1, 2017. In addition, this notice announces the monthly premium for aged and disabled beneficiaries, the deductible for 2017, and the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. The monthly actuarial rates for 2017 are $261.90 for aged enrollees and $254.20 for disabled enrollees. The standard monthly Part B premium rate for all enrollees for 2017 is $134.00, which is equal to 50 percent of the monthly actuarial rate for aged enrollees (or approximately 25 percent of the expected average total cost of Part B coverage for aged enrollees) plus $3.00. (The 2016 standard premium rate was $121.80, which includes the $3.00 repayment amount.) The Part B deductible for 2017 is $183.00 for all Part B beneficiaries. If a beneficiary has to pay an income-related monthly adjustment, they will have to pay a total monthly premium of about 35, 50, 65, or 80 percent of the total cost of Part B coverage plus $4.20, $6.00, $7.80, or $9.60.

DATES: *Effective Date:* January 1, 2017.

FOR FURTHER INFORMATION CONTACT: M. Kent Clemens, (410) 786–6391.

SUPPLEMENTARY INFORMATION:

I. Background

Part B is the voluntary portion of the Medicare program that pays all or part of the costs for physicians' services, outpatient hospital services, certain home health services, services furnished by rural health clinics, ambulatory surgical centers, comprehensive outpatient rehabilitation facilities, and certain other medical and health services not covered by Medicare Part A, Hospital Insurance. Medicare Part B

is available to individuals who are entitled to Medicare Part A, as well as to U.S. residents who have attained age 65 and are citizens, and aliens who were lawfully admitted for permanent residence and have resided in the United States for 5 consecutive years. Part B requires enrollment and payment of monthly premiums, as described in 42 CFR part 407, subpart B, and part 408, respectively. The premiums paid by (or on behalf of) all enrollees fund approximately one-fourth of the total incurred costs, and transfers from the general fund of the Treasury pay approximately three-fourths of these costs.

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1839 of the Social Security Act (the Act) to announce the Part B monthly actuarial rates for aged and disabled beneficiaries as well as the monthly Part B premium. The Part B annual deductible is included because its determination is directly linked to the aged actuarial rate.

The monthly actuarial rates for aged and disabled enrollees are used to determine the correct amount of general revenue financing per beneficiary each month. These amounts, according to actuarial estimates, will equal, respectively, one-half of the expected average monthly cost of Part B for each aged enrollee (age 65 or over) and one-half of the expected average monthly cost of Part B for each disabled enrollee (under age 65).

The Part B deductible to be paid by enrollees is also announced. Prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), the Part B deductible was set in statute. After setting the 2005 deductible amount at $110, section 629 of the MMA (amending section 1833(b) of the Act) requires that the Part B deductible be indexed beginning in 2006. The inflation factor to be used each year is the annual percentage increase in the Part B actuarial rate for enrollees age 65 and over. Specifically, the 2017 Part B deductible is calculated by multiplying the 2016 deductible by the ratio of the 2017 aged actuarial rate to the 2016 aged actuarial rate. The amount determined under this formula is then rounded to the nearest $1.

The monthly Part B premium rate to be paid by aged and disabled enrollees is also announced. (Although the costs to the program per disabled enrollee are different than for the aged, the statute provides that they pay the same premium amount.) Beginning with the passage of section 203 of the Social Security Amendments of 1972 (Pub. L. 92–603), the premium rate, which was determined on a fiscal year basis, was limited to the lesser of the actuarial rate for aged enrollees, or the current monthly premium rate increased by the same percentage as the most recent general increase in monthly Title II social security benefits.

However, the passage of section 124 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) suspended this premium determination process. Section 124 of TEFRA changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). Section 606 of the Social Security Amendments of 1983 (Pub. L. 98–21), section 2302 of the Deficit Reduction Act of 1984 (DEFRA 84) (Pub. L. 98–369), section 9313 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA 85) (Pub. L. 99–272), section 4080 of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87) (Pub. L. 100–203), and section 6301 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) (Pub. L. 101–239) extended the provision that the premium be based on 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). This extension expired at the end of 1990.

The premium rate for 1991 through 1995 was legislated by section 1839(e)(1)(B) of the Act, as added by section 4301 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) (Pub. L. 101–508). In January 1996, the premium determination basis would have reverted to the method established by the 1972 Social Security Act Amendments. However, section 13571 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93) (Pub. L. 103–66) changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees) for 1996 through 1998.

Section 4571 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) permanently extended the provision that the premium be based on 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees).

The BBA included a further provision affecting the calculation of the Part B actuarial rates and premiums for 1998 through 2003. Section 4611 of the BBA modified the home health benefit payable under Part A for individuals enrolled in Part B. Under this section, beginning in 1998, expenditures for home health services not considered ''post-institutional'' are payable under Part B rather than Part A. However, section 4611(e)(1) of the BBA required that there be a transition from 1998 through 2002 for the aggregate amount of the expenditures transferred from Part A to Part B. Section 4611(e)(2) of the BBA also provided a specific yearly proportion for the transferred funds. The proportions were 1/6 for 1998, 1/3 for 1999, 1/2 for 2000, 2/3 for 2001, and 5/6 for 2002. For the purpose of determining the correct amount of financing from general revenues of the Federal Government, it was necessary to include only these transitional amounts in the monthly actuarial rates for both aged and disabled enrollees, rather than the total cost of the home health services being transferred.

Section 4611(e)(3) of the BBA also specified, for the purpose of determining the premium, that the monthly actuarial rate for enrollees age 65 and over be computed as though the transition would occur for 1998 through 2003 and that 1/7 of the cost be transferred in 1998, 2/7 in 1999, 3/7 in 2000, 4/7 in 2001, 5/7 in 2002, and 6/7 in 2003. Therefore, the transition period for incorporating this home health transfer into the premium was 7 years while the transition period for including these services in the actuarial rate was 6 years.

Section 811 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, also known as the Medicare Modernization Act, or MMA), which amended section 1839 of the Act, requires that, starting on January 1, 2007, the Part B premium a beneficiary pays each month be based on their annual income. Specifically, if a beneficiary's ''modified adjusted gross income'' is greater than the legislated threshold amounts (for 2017, $85,000 for a beneficiary filing an individual income tax return, and $170,000 for a beneficiary filing a joint tax return) the beneficiary is responsible for a larger portion of the estimated total cost of Part B benefit coverage. In addition to the standard 25 percent premium, these beneficiaries now have to pay an income-related monthly adjustment amount. The MMA made no change to the actuarial rate calculation, and the standard premium, which will continue to be paid by beneficiaries whose modified adjusted gross income is below the applicable thresholds, still represents 25 percent of the estimated total cost to the program of Part B coverage for an aged enrollee. However, depending on income and tax filing status, a beneficiary can now be responsible for 35, 50, 65, or 80 percent of the estimated total cost of Part B

coverage, rather than 25 percent. (For 2018 and subsequent years, the income thresholds are lower for the two highest income ranges, as a result of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10).) The end result of the higher premium is that the Part B premium subsidy is reduced and less general revenue financing is required for beneficiaries with higher income because they are paying a larger share of the total cost with their premium. That is, the premium subsidy continues to be approximately 75 percent for beneficiaries with income below the applicable income thresholds, but will be reduced for beneficiaries with income above these thresholds. The MMA specified that there be a 5-year transition to full implementation of this provision. However, section 5111 of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) modified the transition to a 3-year period.

Section 4732(c) of the BBA added section 1933(c) of the Act, which required the Secretary to allocate money from the Part B trust fund to the state Medicaid programs for the purpose of providing Medicare Part B premium assistance from 1998 through 2002 for the low-income Medicaid beneficiaries who qualify under section 1933 of the Act. This allocation, while not a benefit expenditure, was an expenditure of the trust fund and was included in calculating the Part B actuarial rates through 2002. For 2003 through 2015, the expenditure was made from the trust fund because the allocation was temporarily extended. However, because the extension occurred after the financing was determined, the allocation was not included in the calculation of the financing rates for these years. Section 211 of MACRA permanently extended this expenditure, which is included in the calculation of the Part B actuarial rates for 2016 and subsequent years.

Another provision affecting the calculation of the Part B premium is section 1839(f) of the Act, as amended by section 211 of the Medicare Catastrophic Coverage Act of 1988 (MCCA 88) (Pub. L. 100–360). (The Medicare Catastrophic Coverage Repeal Act of 1989 (Pub. L. 101–234) did not repeal the revisions to section 1839(f) of the Act made by MCCA 88.) Section 1839(f) of the Act, referred to as the ''hold-harmless'' provision, provides that if an individual is entitled to benefits under section 202 or 223 of the Act (the Old-Age and Survivors Insurance Benefit and the Disability Insurance Benefit, respectively) and has the Part B premium deducted from these benefit payments, the premium increase will be reduced, if necessary, to avoid causing a decrease in the individual's net monthly payment. This decrease in payment occurs if the increase in the individual's social security benefit due to the cost-of-living adjustment under section 215(i) of the Act is less than the increase in the premium. Specifically, the reduction in the premium amount applies if the individual is entitled to benefits under section 202 or 223 of the Act for November and December of a particular year and the individual's Part B premiums for December and the following January are deducted from the respective month's section 202 or 223 benefits. The ''hold-harmless'' provision does not apply to beneficiaries who are required to pay an income-related monthly adjustment amount.

A check for benefits under section 202 or 223 of the Act is received in the month following the month for which the benefits are due. The Part B premium that is deducted from a particular check is the Part B payment for the month in which the check is received. Therefore, a benefit check for November is not received until December, but has December's Part B premium deducted from it.

Generally, if a beneficiary qualifies for hold-harmless protection, the reduced premium for the individual for that January and for each of the succeeding 11 months is the greater of either—

- The monthly premium for January reduced as necessary to make the December monthly benefits, after the deduction of the Part B premium for January, at least equal to the preceding November's monthly benefits, after the deduction of the Part B premium for December; or
- The monthly premium for that individual for that December.

In determining the premium limitations under section 1839(f) of the Act, the monthly benefits to which an individual is entitled under section 202 or 223 of the Act do not include retroactive adjustments or payments and deductions on account of work. Also, once the monthly premium amount is established under section 1839(f) of the Act, it will not be changed during the year even if there are retroactive adjustments or payments and deductions on account of work that apply to the individual's monthly benefits.

Individuals who have enrolled in Part B late or who have re-enrolled after the termination of a coverage period are subject to an increased premium under section 1839(b) of the Act. The increase is a percentage of the premium and is based on the new premium rate before any reductions under section 1839(f) of the Act are made.

Section 1839 of the Act, as amended by section 601(a) of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), specified that the 2016 actuarial rate for enrollees age 65 and older be determined as if the hold-harmless provision did not apply. The premium revenue that was lost by using the resulting lower premium (excluding the foregone income-related premium revenue) was replaced by a transfer of general revenue from the Treasury, which will be repaid over time to the general fund.

Starting in 2016, in order to repay the balance due (which includes the transfer amount and the foregone income-related premium revenue), the Part B premium otherwise determined will be increased by $3.00. These repayment amounts will be added to the Part B premium otherwise determined each year and paid back to the general fund of the Treasury and will continue until the balance due is paid back.

High-income enrollees pay an additional $1.20, $3.00, $4.80, or $6.60 as part of the income-related monthly adjustment amount (IRMAA) premium dollars, which reduce (dollar for dollar) the amount of general revenue received by Part B from the general fund of the Treasury. Because of this general revenue offset, the repayment IRMAA premium dollars are not included in the direct repayments made to the general fund of the Treasury from Part B in order to avoid a double repayment. (Only the $3.00 monthly repayment amounts are included in the direct repayments).

These repayment amounts will continue until the total amount collected is equal to the beginning balance due. (In the final year of the repayment, the additional amounts may be modified in order to avoid an overpayment.) The repayment amounts (excluding the repayment amounts for high-income enrollees) are subject to the hold harmless provision. The beginning balance due was $9,066,409,000, consisting of $1,625,761,000 in forgone income-related premium revenue plus a transfer amount of $7,440,648,000. It is estimated that $701,088,000 will have been collected for repayment to the general fund by the end of 2016.

II. Provisions of the Notice

A. Notice of Medicare Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible

The Medicare Part B monthly actuarial rates applicable for 2017 are $261.90 for enrollees age 65 and over

and $254.20 for disabled enrollees under age 65. In section II.B. of this notice, we present the actuarial assumptions and bases from which these rates are derived. The Part B standard monthly premium rate for all enrollees for 2017 is $134.00.

Section 1839 of the Act requires the Secretary to determine the monthly actuarial rates, including an appropriate amount for a contingency margin, and the Part B premium each year. For 2017, the Secretary made the determination that a 13 percent target reserve ratio by the end of 2017 is appropriate and reasonable to balance both the level of premium increase necessary for the incurred expenditures and the reserve ratio. With the selected target reserve ratio, the Part B premium in 2017 is a 10 percent increase from 2016.

The following are the 2017 Part B monthly premium rates to be paid by (or on behalf of) beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return.

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	Less than or equal to $170,000	$0.00	$134.00
Greater than $85,000 and less than or equal to $107,000	Greater than $170,000 and less than or equal to $214,000.	53.50	187.50
Greater than $107,000 and less than or equal to $160,000.	Greater than $214,000 and less than or equal to $320,000.	133.90	267.90
Greater than $160,000 and less than or equal to $214,000.	Greater than $320,000 and less than or equal to $428,000.	214.30	348.30
Greater than $214,000	Greater than $428,000	294.60	428.60

In addition, the monthly premium rates to be paid by (or on behalf of) beneficiaries who are married and lived with their spouse at any time during the taxable year, but file a separate tax return from their spouse, are as follows:

Beneficiaries who are married and lived with their spouse at any time during the year, but file a separate tax return from their spouse:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	$0.00	$134.00
Greater than $85,000 and less than or equal to $129,000	214.30	348.30
Greater than $129,000	294.60	428.60

The Part B annual deductible for 2017 is $183.00 for all beneficiaries.

B. Statement of Actuarial Assumptions and Bases Employed in Determining the Monthly Actuarial Rates and the Monthly Premium Rate for Part B Beginning January 2017

Except where noted, the actuarial assumptions and bases used to determine the monthly actuarial rates and the monthly premium rates for Part B are established by the Centers for Medicare & Medicaid Services Office of the Actuary. The estimates underlying these determinations are prepared by actuaries meeting the qualification standards and following the actuarial standards of practice established by the Actuarial Standards Board.

1. Actuarial Status of the Part B Account in the Supplementary Medical Insurance Trust Fund

Under section 1839 of the Act, the starting point for determining the standard monthly premium is the amount that would be necessary to finance Part B on an incurred basis. This is the amount of income that would be sufficient to pay for services furnished during that year (including associated administrative costs) even though payment for some of these services will not be made until after the close of the year. The portion of income required to cover benefits not paid until after the close of the year is added to the trust fund and used when needed.

The premium rates are established prospectively and are, therefore, subject to projection error. Additionally, legislation enacted after the financing was established, but effective for the period in which the financing is set, may affect program costs. As a result, the income to the program may not equal incurred costs. Therefore, trust fund assets must be maintained at a level that is adequate to cover an appropriate degree of variation between actual and projected costs, and the amount of incurred, but unpaid, expenses. Numerous factors determine what level of assets is appropriate to cover variation between actual and projected costs. The three most important of these factors are the: (1) Difference from prior years between the actual performance of the program and estimates made at the time financing was established; (2) likelihood and potential magnitude of expenditure changes resulting from enactment of legislation affecting Part B costs in a year subsequent to the establishment of financing for that year; and (3) expected relationship between incurred and cash expenditures. These factors are analyzed on an ongoing basis, as the trends can vary over time.

Table 1 summarizes the estimated actuarial status of the trust fund as of the end of the financing period for 2015 and 2016.

TABLE 1—ESTIMATED ACTUARIAL STATUS OF THE PART B ACCOUNT IN THE SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND AS OF THE END OF THE FINANCING PERIOD

Financing period ending	Assets ($ in millions)	Liabilities ($ in millions)	Assets less liabilities ($ in millions)
December 31, 2015	68,157	24,712	43,445
December 31, 2016	85,169	26,487	58,682

2. Monthly Actuarial Rate for Enrollees Age 65 and Older

The monthly actuarial rate for enrollees age 65 and older is one-half of the sum of monthly amounts for: (1) The projected cost of benefits; and (2) administrative expenses for each enrollee age 65 and older, after adjustments to this sum to allow for interest earnings on assets in the trust fund and an adequate contingency margin. The contingency margin is an amount appropriate to provide for possible variation between actual and projected costs and to amortize any surplus assets or unfunded liabilities.

The monthly actuarial rate for enrollees age 65 and older for 2017 is determined by first establishing per-enrollee cost by type of service from program data through 2016 and then projecting these costs for subsequent years. The projection factors used for financing periods from January 1, 2014 through December 31, 2017 are shown in Table 2.

As indicated in Table 3, the projected per-enrollee amount required to pay for one-half of the total of benefits and administrative costs for enrollees age 65 and over for 2017 is $238.61. Based on current estimates, the assets associated with the aged Medicare beneficiaries at the end of 2016 are not sufficient to cover the amount of incurred, but unpaid, expenses and to provide for a significant degree of variation between actual and projected costs. Thus, a positive contingency margin is needed. The monthly actuarial rate of $261.90 provides an adjustment of $25.07 for a contingency margin and −$1.78 for interest earnings.

The contingency margin for 2017 is affected by several factors. As noted previously, for most Part B beneficiaries the hold-harmless provision prevents their benefits under Section 202 or 223 of the Act from decreasing as a result of an increase in the Part B premium. For 2016, social security benefits received no cost-of-living adjustment and therefore the majority of Part B enrollees were held harmless and paid a premium of $104.90, rather than the 2016 premium of $121.80. On October 18, 2016, the Social Security Administration announced that the increase in the benefits under Section 202 and 223 of the Act will be 0.3 percent for 2017. As a result, the average 2017 social security benefit increase will be about $4.00 and the average 2017 premium paid by Part B enrollees who are held harmless will be about $109.00. Consequently, a minority of Part B enrollees will pay (or have paid on their behalf) a larger-than-normal premium, resulting from an increased contingency margin. The Part B premium of $134.00 for 2017 will be paid by (or on behalf of) approximately 30 percent of beneficiaries (those not subject to the hold-harmless provision). (As noted previously, individuals with higher incomes would not be held harmless and would pay a 2017 premium that is higher than $134.00.)

Two other factors affect the contingency margin for 2017. Starting in 2011, manufacturers and importers of brand-name prescription drugs have paid a fee that is allocated to the Part B account of the SMI trust. For 2017, the total of these brand-name drug fees is estimated to be $3.9 billion. The contingency margin has been reduced to account for this additional revenue.

Another factor impacting the contingency margin comes from the requirement that certain payment incentives, to encourage the development and use of health information technology (HIT) by Medicare physicians, are to be excluded from the premium determination. HIT positive incentive payments or penalties will be directly offset through transfers with the general fund of the Treasury. The monthly actuarial rate includes an adjustment of −$0.13 for HIT incentive payments in 2017.

The traditional goal for the Part B reserve has been that assets minus liabilities at the end of a year should represent between 15 and 20 percent of the following year's total incurred expenditures. To accomplish this goal, a 17 percent reserve ratio has been the normal target used to calculate the Part B premium. The Secretary, who determines the Part B premium each year under section 1839 of the Act, directed the Office of the Actuary to use a target reserve ratio for the Part B premium determination of 13 percent by the end of 2017. This targets a 2017 reserve ratio that is lower than the reserve ratio expected for the end of 2016. The Office of the Actuary has estimated that a target reserve ratio of 14 percent is the minimally financially adequate level for the Part B premium determination. The target reserve ratio of 13 percent is below this level resulting in a non-trivial risk of Part B income and trust fund assets being inadequate to cover Part B costs, which would occur if experience is significantly worse than current estimates. Financing rates in future years will likely need to be increased to restore the contingency reserve to an adequate level.

The actuarial rate of $261.90 per month for aged beneficiaries, as announced in this notice for 2017, reflects that combined effect of the factors previously described and the projected assumptions listed in Table 2.

3. Monthly Actuarial Rate for Disabled Enrollees

Disabled enrollees are those persons under age 65 who are enrolled in Part B because of entitlement to Social Security disability benefits for more than 24 months or because of entitlement to Medicare under the end-stage renal disease (ESRD) program. Projected monthly costs for disabled enrollees (other than those with ESRD) are prepared in a fashion parallel to the projection for the aged using appropriate actuarial assumptions (see Table 2). Costs for the ESRD program are projected differently because of the different nature of services offered by the program.

As shown in Table 4, the projected per-enrollee amount required to pay for one-half of the total of benefits and administrative costs for disabled enrollees for 2017 is $285.21. The monthly actuarial rate of $254.20 also provides an adjustment of −$2.67 for interest earnings and −$28.34 for a contingency margin, reflecting the same factors described previously for the aged actuarial rate at magnitudes appropriate to the disabled rate determination. Based on current estimates, the assets associated with the disabled Medicare beneficiaries at the end of 2016 are more-than sufficient to cover the amount of incurred, but unpaid, expenses and to provide for a significant

degree of variation between actual and projected costs. Thus, a negative contingency margin is needed to decrease assets to an appropriate level.

The actuarial rate of $254.20 per month for disabled beneficiaries, as announced in this notice for 2017, reflects the combined net effect of the factors described previously for aged beneficiaries and the projection assumptions listed in Table 2.

4. Sensitivity Testing

Several factors contribute to uncertainty about future trends in medical care costs. It is appropriate to test the adequacy of the rates using alternative cost growth rate assumptions. The results of those assumptions are shown in Table 5. One set represents increases that are higher and, therefore, more pessimistic than the current estimate. The other set represents increases that are lower and, therefore, more optimistic than the current estimate. The values for the alternative assumptions were determined from a statistical analysis of the historical variation in the respective increase factors.

As indicated in Table 5, the monthly actuarial rates would result in an excess of assets over liabilities of $45,497 million by the end of December 2017 under the cost growth rate assumptions shown in Table 2 and assuming that the provisions of current law are fully implemented. This amounts to 13.7 percent of the estimated total incurred expenditures for the following year.

Assumptions that are somewhat more pessimistic (and that therefore test the adequacy of the assets to accommodate projection errors) produce a surplus of −$1,387 million by the end of December 2017 under current law, which amounts to −0.4 percent of the estimated total incurred expenditures for the following year. Under fairly optimistic assumptions, the monthly actuarial rates would result in a surplus of $89,869 million by the end of December 2017, or 31.0 percent of the estimated total incurred expenditures for the following year.

The sensitivity analysis indicates that the premium and general revenue financing established for 2017, together with existing Part B account assets would not be adequate to cover estimated Part B costs for 2017 under current law if actual costs prove to be somewhat greater than expected.

5. Premium Rates and Deductible

As determined in accordance with section 1839 of the Act, listed are the 2017 Part B monthly premium rates to be paid by beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return.

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	Less than or equal to $170,000	$0.00	$134.00
Greater than $85,000 and less than or equal to $107,000	Greater than $170,000 and less than or equal to $214,000.	53.50	187.50
Greater than $107,000 and less than or equal to $160,000.	Greater than $214,000 and less than or equal to $320,000.	133.90	267.90
Greater than $160,000 and less than or equal to $214,000.	Greater than $320,000 and less than or equal to $428,000.	214.30	348.30
Greater than $214,000	Greater than $428,000	294.60	428.60

In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouse at any time during the taxable year, but file a separate tax return from their spouse, are listed as follows:

Beneficiaries who are married and lived with their spouse at any time during the year, but file a separate tax return from their spouse:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	$0.00	$134.00
Greater than $85,000 and less than or equal to $129,000	214.30	348.30
Greater than $129,000	294.60	428.60

TABLE 2—PROJECTION FACTORS [1] 12-MONTH PERIODS ENDING DECEMBER 31 OF 2014–2017

[In percent]

Calendar year	Physicians' services		Durable medical equipment	Carrier lab [4]	Other carrier services [5]	Outpatient hospital	Home health agency	Hospital lab [6]	Other intermediary services [7]	Managed care
	Fees [2]	Residual [3]								
Aged:										
2014	0.5	0.6	−14.3	6.5	2.7	12.6	−0.6	−29.1	4.5	6.4
2015	−0.4	0.6	6.7	2.6	4.4	6.8	−1.4	2.4	5.0	2.1
2016	−0.4	0.1	−5.1	−1.6	6.3	5.4	0.4	3.1	4.4	3.7
2017	0.4	1.2	0.6	5.8	2.8	7.5	2.1	2.9	5.3	4.8
Disabled:										
2014	0.5	1.9	−11.0	13.6	4.2	13.6	−1.3	−35.9	7.3	9.4
2015	−0.4	0.6	7.6	6.6	6.7	7.0	−1.0	0.6	9.9	1.4
2016	−0.4	0.8	−4.6	−12.9	6.7	5.5	0.5	4.4	8.7	4.5
2017	0.4	1.2	0.5	5.8	3.1	7.4	2.4	2.8	5.4	4.8

[1] All values for services other than managed care are per fee-for-service enrollee. Managed care values are per managed care enrollee.
[2] As recognized for payment under the program.
[3] Increase in the number of services received per enrollee and greater relative use of more expensive services.
[4] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[5] Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[6] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[7] Includes services furnished in dialysis facilities, rural health clinics, federally qualified health centers, rehabilitation, and psychiatric hospitals, etc.

TABLE 3—DERIVATION OF MONTHLY ACTUARIAL RATE FOR ENROLLEES AGE 65 AND OVER FOR FINANCING PERIODS ENDING DECEMBER 31, 2014 THROUGH DECEMBER 31, 2017

[in dollars]

	CY 2014	CY 2015	CY 2016	CY 2017
Covered services (at level recognized):				
Physician fee schedule	76.97	75.48	74.34	74.57
Durable medical equipment	6.07	6.34	5.95	5.90
Carrier lab [1]	4.36	4.38	4.26	4.45
Other carrier services [2]	22.05	22.53	23.66	24.01
Outpatient hospital	41.35	43.20	45.00	47.78
Home health	9.70	9.36	9.28	9.36
Hospital lab [3]	2.25	2.25	2.29	2.33
Other intermediary services [4]	16.79	17.25	17.80	18.51
Managed care	73.65	78.38	83.02	88.95
Total services	253.19	259.17	265.59	275.85
Cost sharing:				
Deductible	−5.63	−5.64	−6.36	−7.00
Coinsurance	−28.18	−28.02	−28.14	−28.48
Sequestration of benefits	−4.39	−4.51	−4.62	−4.81
HIT payment incentives	−2.38	−1.08	−0.59	−0.13
Total benefits	212.61	219.92	225.88	235.42
Administrative expenses	3.24	2.82	3.00	3.19
Incurred expenditures	215.84	222.74	228.88	238.61
Value of interest	−1.93	−1.86	−1.75	−1.78
Contingency margin for projection error and to amortize the surplus or deficit	−4.11	−11.08	10.47	25.07
Monthly actuarial rate	209.80	209.80	237.60	261.90

[1] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[2] Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[3] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[4] Includes services furnished in dialysis facilities, rural health clinics, federally qualified health centers, rehabilitation and psychiatric hospitals, etc.

TABLE 4—DERIVATION OF MONTHLY ACTUARIAL RATE FOR DISABLED ENROLLEES FOR FINANCING PERIODS ENDING DECEMBER 31, 2014 THROUGH DECEMBER 31, 2017

[in dollars]

	CY 2014	CY 2015	CY 2016	CY 2017
Covered services (at level recognized):				
Physician fee schedule	83.44	81.07	79.87	79.59
Durable medical equipment	11.96	12.44	11.65	11.48
Carrier lab [1]	7.18	7.41	6.34	6.58
Other carrier services [2]	25.33	25.70	26.56	26.83
Outpatient hospital	59.58	61.51	63.56	66.98
Home health	8.28	7.92	7.79	7.82
Hospital lab [3]	2.85	2.79	2.86	2.89
Other intermediary services [4]	44.96	45.19	46.82	48.21
Managed care	65.16	72.59	79.66	87.19
Total services	308.74	316.61	325.13	337.55
Cost sharing:				
Deductible	−5.29	−5.30	−5.97	−6.57
Coinsurance	−43.12	−42.78	−43.11	−43.70
Sequestration of benefits	−5.20	−5.37	−5.52	−5.74
HIT payment incentives	−2.55	−1.14	−0.63	−0.14
Total benefits	252.57	262.02	269.91	281.40
Administrative expenses	3.84	3.36	3.58	3.81
Incurred expenditures	256.41	265.38	273.49	285.21
Value of interest	−2.49	−2.22	−2.25	−2.67
Contingency margin for projection error and to amortize the surplus or deficit	−35.02	−8.36	11.36	−28.34
Monthly actuarial rate	218.90	254.80	282.60	254.20

[1] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[2] Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[3] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[4] Includes services furnished in dialysis facilities, rural health clinics, federally qualified health centers, rehabilitation and psychiatric hospitals, etc.

TABLE 5—ACTUARIAL STATUS OF THE PART B ACCOUNT IN THE SMI TRUST FUND UNDER THREE SETS OF ASSUMPTIONS FOR FINANCING PERIODS THROUGH DECEMBER 31, 2017

As of December 31,	2015	2016	2017
Actuarial status (in $ millions):			
Assets	68,157	85,169	73,296
Liabilities	24,712	26,487	27,798
Assets less liabilities	43,445	58,682	45,497
Ratio (in percent) [1]	14.7	18.6	13.7
Low cost projection:			
Actuarial status (in $ millions):			
Assets	68,157	100,826	116,438
Liabilities	24,712	24,748	26,569
Assets less liabilities	43,445	76,078	89,869
Ratio (in percent) [1]	15.7	26.6	31.0
High cost projection:			
Actuarial status (in $ millions):			
Assets	68,157	69,173	27,830
Liabilities	24,712	28,265	29,217
Assets less liabilities	43,445	40,908	−1,387
Ratio (in percent) [1]	13.9	11.8	−0.4

[1] Ratio of assets less liabilities at the end of the year to the total incurred expenditures during the following year, expressed as a percent.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Regulatory Impact Analysis

A. Statement of Need

Section 1839 of the Act requires us to annually announce (that is by September 30th of each year) the Part B monthly actuarial rates for aged and disabled beneficiaries as well as the monthly Part B premium. We also announce the Part B annual deductible because its determination is directly linked to the aged actuarial rate.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major notices with economically significant effects ($100 million or more in any 1 year). For 2017 approximately 70 percent of Part B enrollees will be held harmless from the full increase in the Part B premium but will pay a small increase in their Part B premium. However, all Part B enrollees will experience a deductible that increases from $166 in 2016 to $183 in 2017. In addition, the standard Part B premium rate and the Part B income-related premium rates are higher than the respective amounts for 2016. All of these changes together have an annual effect on the economy of $100 million or more. As a result, this notice is economically significant under section 3(f)(1) of Executive Order 12866 and is a major action as defined under the Congressional Review Act (5 U.S.C. 804(2)).

As discussed earlier, this notice announces that the monthly actuarial rates applicable for 2017 are $261.90 for enrollees age 65 and over and $254.20 for disabled enrollees under age 65. It also announces the 2017 monthly Part B premium rates to be paid by beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with a dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return.

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	Less than or equal to $170,000	$0.00	$134.00
Greater than $85,000 and less than or equal to $107,000	Greater than $170,000 and less than or equal to $214,000.	53.50	187.50
Greater than $107,000 and less than or equal to $160,000.	Greater than $214,000 and less than or equal to $320,000.	133.90	267.90
Greater than $160,000 and less than or equal to $214,000.	Greater than $320,000 and less than or equal to $428,000.	214.30	348.30
Greater than $214,000	Greater than $428,000	294.60	428.60

In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouse at any time during the taxable year, but file a separate tax return from their spouse, are also announced and listed in the following chart:

Beneficiaries who are married and lived with their spouse at any time during the year, but file a separate tax return from their spouse:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	$0.00	$134.00
Greater than $85,000 and less than or equal to $129,000	214.30	348.30
Greater than $129,000	294.60	428.60

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under 65) beneficiaries enrolled in Part B of the Medicare SMI program beginning January 1, 2017. Also, this notice announces the monthly premium for aged and disabled beneficiaries as well as the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As we discussed previously, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this notice will not have a significant effect on a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1-year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. Part B enrollees who are also enrolled in Medicaid have their monthly Part B premiums paid by Medicaid. The 2017 premium increase is estimated to be a cost to each state Medicaid program that is less than the threshold. This notice does not impose mandates that will have a consequential effect of the threshold amount or more on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have determined that this notice does not significantly affect the rights, roles, and responsibilities of states. Accordingly, the requirements of Executive Order 13132 do not apply to this notice.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

V. Waiver of Proposed Notice

The Medicare statute requires the publication of the monthly actuarial rates and the Part B premium amounts in September. We ordinarily use general notices, rather than notice and comment rulemaking procedures, to make such announcements. In doing so, we note that, under the Administrative Procedure Act, interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find, for good cause, that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. The statute establishes the time period for which the premium rates will apply, and delaying publication of the Part B premium rate such that it would not be published before that time would be contrary to the public interest. Moreover, we find that notice and comment are unnecessary because the formulas used to calculate the Part B premiums are statutorily directed. Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

Dated: November 8, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 8, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–27425 Filed 11–10–16; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8063–N]

RIN 0938–AS71

Medicare Program; CY 2017 Part A Premiums for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This annual notice announces Medicare's Hospital Insurance (Part A) premium for uninsured enrollees in calendar year (CY) 2017. This premium is paid by enrollees age 65 and over who are not otherwise eligible for benefits under Medicare Part A (hereafter known as the ''uninsured aged'') and by certain disabled individuals who have exhausted other entitlement. The monthly Part A premium for the 12 months beginning January 1, 2017, for these individuals will be $413. The premium for certain other individuals as described in this notice will be $227.

DATES: *Effective Date:* This notice is effective on January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Clare McFarland, (410) 786–6390.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1818 of the Social Security Act (the Act) provides for voluntary enrollment in the Medicare Hospital Insurance Program (Medicare Part A), subject to payment of a monthly premium, of certain persons aged 65 and older who are uninsured under the Old-Age, Survivors, and Disability Insurance (OASDI) program or the Railroad Retirement Act and do not otherwise meet the requirements for entitlement to Medicare Part A. These ''uninsured aged'' individuals are uninsured under the OASDI program or the Railroad Retirement Act, because they do not have 40 quarters of coverage under Title II of the Act (or are/were not married to someone who did). (Persons insured under the OASDI program or the Railroad Retirement Act and certain others do not have to pay premiums for Medicare Part A.)

Section 1818A of the Act provides for voluntary enrollment in Medicare Part A, subject to payment of a monthly premium for certain disabled individuals who have exhausted other entitlement. These are individuals who were entitled to coverage due to a disabling impairment under section 226(b) of the Act, but who are no longer entitled to disability benefits and free Medicare Part A coverage because they have gone back to work and their earnings exceed the statutorily defined ''substantial gainful activity'' amount (section 223(d)(4) of the Act).

Section 1818A(d)(2) of the Act specifies that the provisions relating to premiums under section 1818(d) through section 1818(f) of the Act for the aged will also apply to certain disabled individuals as described above.

Section 1818(d)(1) of the Act requires us to estimate, on an average per capita basis, the amount to be paid from the Federal Hospital Insurance Trust Fund for services incurred in the upcoming calendar year (CY) (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A. We must then determine the monthly actuarial rate for the following year (the per capita amount estimated above divided by 12) and publish the dollar amount for the monthly premium in the succeeding CY. If the premium is not a multiple of $1, the premium is rounded to the nearest multiple of $1 (or, if it is a multiple of 50 cents but not of $1, it is rounded to the next highest $1).

Section 13508 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) amended section 1818(d) of the Act to provide for a reduction in the premium amount for certain voluntary enrollees (section 1818 and section 1818A of the Act). The reduction applies to an individual who is eligible to buy into the Medicare Part A program and who, as of the last day of the previous month:

- Had at least 30 quarters of coverage under Title II of the Act;
- Was married, and had been married for the previous 1-year period, to a person who had at least 30 quarters of coverage;
- Had been married to a person for at least 1 year at the time of the person's death if, at the time of death, the person had at least 30 quarters of coverage; or
- Is divorced from a person and had been married to the person for at least 10 years at the time of the divorce if, at the time of the divorce, the person had at least 30 quarters of coverage.

Section 1818(d)(4)(A) of the Act specifies that the premium that these individuals will pay for CY 2017 will be equal to the premium for uninsured aged enrollees reduced by 45 percent.

II. Monthly Premium Amount for CY 2017

The monthly premium for the uninsured aged and certain disabled individuals who have exhausted other entitlement for the 12 months beginning January 1, 2017, is $413.

The monthly premium for the individuals eligible under section 1818(d)(4)(B) of the Act, and therefore, subject to the 45 percent reduction in the monthly premium, is $227.

III. Monthly Premium Rate Calculation

As discussed in section I of this notice, the monthly Medicare Part A premium is equal to the estimated monthly actuarial rate for CY 2017 rounded to the nearest multiple of $1 and equals one-twelfth of the average per capita amount, which is determined by projecting the number of Medicare Part A enrollees aged 65 years and over as well as the benefits and administrative costs that will be incurred on their behalf.

The steps involved in projecting these future costs to the Federal Hospital Insurance Trust Fund are:

- Establishing the present cost of services furnished to beneficiaries, by type of service, to serve as a projection base;
- Projecting increases in payment amounts for each of the service types; and
- Projecting increases in administrative costs.

We base our projections for CY 2017 on—(1) current historical data; and (2) projection assumptions derived from current law and the Mid-Session Review of the President's Fiscal Year 2017 Budget.

We estimate that in CY 2017, 48,634,512 people aged 65 years and over will be entitled to (enrolled in) benefits (without premium payment) and that they will incur about $240.891 billion in benefits and related administrative costs. Thus, the estimated monthly average per capita amount is $412.76 and the monthly premium is $413. Subsequently, the full monthly premium reduced by 45 percent is $227.

IV. Costs to Beneficiaries

The CY 2017 premium of $413 is approximately 0.5 percent higher than the CY 2016 premium of $411. We estimate that approximately 654,000 enrollees will voluntarily enroll in Medicare Part A, by paying the full premium. Note that states pay Part A premiums for persons who are enrolled in the Qualified Medicare Beneficiary Program (a Medicaid program which helps certain low-income individuals with Medicare premium and cost-sharing liability). Furthermore, the CY 2017 reduced premium of $227 is approximately 0.5 percent higher than the CY 2016 premium of $226. We estimate an additional 67,000 enrollees will pay the reduced premium. Therefore, we estimate that the total aggregate cost to enrollees paying these premiums in CY 2017, compared to the amount that they paid in CY 2016, will be about $17 million.

V. Waiver of Proposed Notice and Comment Period

We use general notices, rather than notice and comment rulemaking procedures, to make announcements such as this premium notice. In doing so, we acknowledge that, under the Administrative Procedure Act (APA), interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking. The agency may also waive notice and comment if there is ''good cause,'' as defined by the statute. We considered publishing a proposed notice to provide a period for public comment. However, under the APA, we may waive that procedure if we find good cause that prior notice and comment are impracticable, unnecessary, or contrary to the public interest.

We are not using notice and comment rulemaking in this notification of Medicare Part A premiums for CY 2017 as that procedure is unnecessary because of the lack of discretion in the statutory formula that is used to calculate the premium and the solely ministerial function that this notice serves. The APA permits agencies to waive notice and comment rulemaking when notice and public comment thereon are unnecessary. On this basis, we waive publication of a proposed notice and a solicitation of public comments.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. Regulatory Impact Analysis

A. Statement of Need

Section 1818(d) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) during September of each year to determine and publish the amount to be paid, on an average per capita basis, from the Federal Hospital Insurance Trust Fund for services incurred in the impending CY (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A.

B. Overall Impact

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. Part I, Ch. 8).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major notices with economically significant effects ($100 million or more in any 1 year). As stated in section IV of this notice, we estimate that the overall effect of the changes in the Part A premium will be a cost to voluntary enrollees (section 1818 and section 1818A of the Act) of about $17 million. As a result, this notice is non-economically significant under section 3(f)(1) of Executive Order 12866 and is not a major action under the Congressional Review Act. In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year (for details, see the Small Business Administration's Web site at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*).

Individuals and states are not included in the definition of a small entity. As discussed above, this annual notice announces Medicare's Hospital Insurance (Part A) premium for uninsured enrollees in CY 2017. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. As discussed above, we are not preparing an analysis for section 1102(b) of the Act, because the Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. This notice does not impose mandates that will have a consequential effect of $146 million or more on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this notice does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Dated: September 23, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 8, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–27388 Filed 11–10–16; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1311]

Paul S. Singh: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Paul S. Singh from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Singh was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Singh was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Singh failed to request a hearing. Dr. Singh's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective November 15, 2016.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs (ELEM–4144), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On July 31, 2015, the U.S. District Court for the Eastern District of California entered judgment against Dr. Singh for one count of mail fraud, in violation of 18 U.S.C. 1341.

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: Dr. Singh was the President and Secretary of Paul S. Singh, DO, Inc., and provided obstetric and gynecological services to women. Beginning on or about May 2008, and continuing to at least on or about June 2012, within the Eastern District of California and elsewhere, Dr. Singh devised a scheme and artifice to defraud health care benefit programs, patients, and others of money and property by means of materially false and fraudulent pretenses, representations, and promises.

During the time period described, Dr. Singh provided his patients forms of birth control, including the insertion of an intrauterine device (''IUD''). IUDs are regulated by FDA. At the relevant time, FDA had only approved one IUD, which used copper as its active ingredient, the ParaGard T–380A IUD. ParaGard T–380A was sold only by its manufacturer and was not available on third-party Web sites.

The insertion of a non-FDA approved copper IUD risks a patient's health and safety. Dr. Singh knew of this risk and knew that inserting a non-FDA approved copper IUD was prohibited by FDA. Despite this, Dr. Singh obtained non-FDA approved copper IUDs by purchasing them on the Internet and inserted them in his patients. Dr. Singh failed to inform his patients that he had inserted a non-FDA approved copper IUD, and none of his patients consented to the insertion of one. On or about August 17, 2010, FDA agents met with Dr. Singh and warned him that he could not insert non-FDA approved copper IUDs, and he agreed that he would stop doing so. Notwithstanding this warning, Dr. Singh continued to insert non-FDA approved copper IUDs in his patients and falsely claimed to his patients that he was inserting FDA-approved copper IUDs.

Dr. Singh billed at least 10 different health care benefit programs for payment for the insertion of non-FDA approved copper IUDs in his patients. In submitting these claims, Dr. Singh knowingly misrepresented the type of IUD he had inserted. Dr. Singh caused the U.S. mails to be used to carry out an essential part of his scheme. At all relevant times, Dr. Singh acted with the intent to defraud. As a result of Dr. Singh's conduct, he made false claims of over $83,000 to health care benefit programs, his patients, and others.

As a result of this conviction, FDA sent Dr. Singh by certified mail on August 17, 2016, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Dr. Singh was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. FDA determined that Dr. Singh's felony conviction was related to the regulation of drug products because the conduct underlying his conviction undermined FDA's regulatory oversight over drug products marketed in the United States—it involved using and misrepresenting as approved unapproved IUDs that presented health risks to patients. The proposal also offered Dr. Singh an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on August 23, 2016. Dr. Singh did not request a hearing and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under sections 306(a)(2)(B) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Paul S. Singh has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Section 306(c)(2)(A)(ii) of the FD&C Act requires that Dr. Singh's debarment be permanent.

As a result of the foregoing finding, Paul S. Singh is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see sections 201(dd) (21 U.S.C. 321(dd)), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Paul S. Singh, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Singh provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications from Paul S. Singh during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Singh for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2016–N–1311 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket, and will be viewable at *http://www.regulations.gov* or at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 9, 2016.

Armando Zamora,

Deputy Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs.

[FR Doc. 2016–27418 Filed 11–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3710]

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of the Food and Drug Administration's Education at the Point of Sale Campaign

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the creation of a cohort of cigarette smoking adults between the ages of 25 and 54 for the evaluation of FDA's point of sale tobacco education campaign.

DATES: Submit either electronic or written comments on the collection of information by January 17, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–3710 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of the Food and Drug Administration's Education at the Point of Sale Campaign.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Evaluation of FDA's Point-of-Sale Public Education Campaign

OMB Control Number—0910–NEW

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amends

the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing a tobacco education intervention at the point of sale to reduce the public health burden of tobacco use. The campaign features advertisements intended to encourage future quit attempts among current smokers in stores that sell tobacco products.

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health, FDA requests OMB approval to collect information to evaluate the effectiveness of the point of sale tobacco education campaign. Data from this outcome evaluation study will be used to examine statistical associations between exposure to the campaign and specific outcomes of interest, which include awareness of the campaign and its messaging, campaign-related attitudes, beliefs and risk perceptions, motivation to quit smoking, self-efficacy for quitting, and increased intention to quit.

Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions. Comprehensive evaluation of FDA's public education campaigns will be used to document whether the intended audience is aware of and understands campaign messages, and whether campaign exposure influences campaign-related attitudes, beliefs and risk perceptions, motivation to quit smoking, self-efficacy for quitting, and increased intention to quit. All of the information collected is integral to that evaluation.

Evaluation of the Point of Sale Campaign. This outcome evaluation study will consist of three longitudinal data collection periods each lasting 3–4 months at 4 month intervals between data collection periods, with the first survey (Wave 1) occurring 3 months after campaign launch. Information will be collected from adult smokers, ages 25 to 54, about awareness of and exposure to campaign advertisements, tobacco use, and knowledge, attitudes, and beliefs related to tobacco use. Information will be collected on demographic variables including age, sex, race/ethnicity, and primary language. Participants will also be offered the option to download a smartphone application that will track their exposure to the campaign, and that will ask them to respond to a brief survey about every six months over the 18 month study period.

FDA's media contractor has identified 52 potential counties for the campaign. From this list, FDA's evaluation contractor will randomly select 36 counties to be included in the evaluation. Of these, 24 counties will receive the intervention, while 12 counties will not receive it (control counties).

Data will be collected from a longitudinal cohort that will consist of an entirely new sample of adult cigarette smokers. Addresses will be randomly selected from a predetermined list of U.S. counties and merged with household data on age and demographic characteristics commonly associated with smoking status in order to identify households that are likely to contain one or more adult smokers between the ages of 25 and 54. Pre-paid pre-addressed paper screening surveys will be mailed to approximately 71,875 (23,958 annualized) households that meet this criteria. For the purpose of calculating maximum burden, we assume that all 71,875 (23,958 annualized) households will be screened in one of two ways: (1) When an adult member of the household completes and returns the 10-minute screener they received by mail, or (2) during a 10 minute in-person screening interview conducted by trained field interviewers who visit all the addresses that do not return the screener. At 10 minutes per screening, the maximum potential burden hours for the mail screener is 12,219 (4,073 annualized).

Accounting for nonresponse, we estimate that the mail and in-person screenings will result in 5,750 (1,917 annualized) adults who meet criteria for participation and complete the full Wave 1 survey. The Wave 1 survey will be completed during an in-person visit to the home, either as a stand-alone visit (for households that returned the mail screener) or immediately after the in-person screening is completed (for households that did not return the mail screener). We estimate that the Wave 1 survey will take 40 minutes to complete, resulting in 3,853 (1,284 annualized) burden hours. Adjusting for loss to follow-up between waves, we anticipate that 4,600 (1,533 annualized) participants will complete the Wave 2 survey, which will take 40 minutes and result in 3,082 (1,027 annualized) burden hours, and that 3,772 (1,257 annualized) participants will complete the Wave 3 survey, which will take 40 minutes and result in 2,527 (842 annualized) burden hours. Both the Wave 2 and 3 surveys will also be administered in person by trained interviewers. The total burden hours for all three in-person surveys will be 9,462 (3,154 annualized).

We anticipate that approximately 2/3 of the participants (3,833 people [1,278 annualized]) who complete the Wave 1 survey will download a smartphone application that will deliver additional surveys to them starting one month after the end of the first data collection. These participants will complete 3 surveys lasting 5 minutes each (every 6 months over the course of 18 months), resulting in 307 (102 annualized) burden hours per app-based survey and 921 (307 annualized) burden hours total for all of the app-based surveys. The total burden hours for the screener, 3 in-person surveys, and 3 app-based surveys is 22,600 (7,533 annualized).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Households	Screener	23,958	1	23,958	0.17 (10 minutes)	4,073
Adults smokers ages 25 to 54	Wave 1 questionnaire (Current smokers).	1,917	1	1,917	0.67 (40 minutes)	1,284
	Wave 2 questionnaire	1,533	1	1,533	0.67 (40 minutes)	1,027
	Wave 3 questionnaire	1,257	1	1,257	0.67 (40 minutes)	842
Study participants (opt in)	App-based survey	1,278	3	3,834	0.08 (5 minutes)	307
Totals				32,499		7,533

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27330 Filed 11–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1162]

Louis Daniel Smith: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Louis Daniel Smith from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Smith was convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, or otherwise relating to the regulation of a drug product under the FD&C Act. Mr. Smith was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Smith failed to respond. Mr. Smith's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective November 15, 2016.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs (ELEM–4144), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Section 306(a)(2)(B) of the FD&C Act requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the FD&C Act.

On October 27, 2015, the U.S. District Court for the Eastern District of Washington entered judgment against Mr. Smith for one count of conspiracy, in violation of 18 U.S.C. 371, three counts of introducing misbranded drugs into interstate commerce with intent to defraud or mislead, in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(a)), which according to section 303(a)(2) of the FD&C Act (21 U.S.C. 333(a)(2)) constitutes a felony, and one count of smuggling in violation of 18 U.S.C. 545.

The factual basis for this conviction is as follows: Mr. Smith was a managing member of PGL International, LLC (PGL), and served as the director of PGL's operations. PGL is a Nevada corporation, which marketed and sold various health-related products, including Miracle Mineral Solution (MMS), a mixture of sodium chlorite and water. Sodium chlorite is an industrial chemical used as a pesticide and for hydraulic fracking and wastewater treatment. Sodium chlorite cannot be sold for human consumption and suppliers of the chemical include a warning sheet stating that it can cause potentially fatal side effects if swallowed. Mr. Smith obtained chemicals needed to manufacture the misbranded drug MMS without revealing to regulators and suppliers the true purpose of the chemicals; used those chemicals to manufacture the misbranded drug MMS in a facility that was not disclosed to regulators; offered the misbranded drug MMS for sale on Web sites Mr. Smith had established; and sold that drug in interstate commerce.

From on or about September 11, 2004, to at least on or about July 16, 2012, in the Eastern District of Washington and elsewhere, Mr. Smith introduced, delivered for introduction into interstate commerce, and caused the introduction and delivery for introduction into interstate commerce, with the intent to defraud or mislead, misbranded drugs. In addition, he knowingly defrauded the United States and also impeded the lawful government functions of FDA, specifically, FDA's duty to protect the health and safety of the public by, among other things, ensuring that drugs marketed in the United States are safe and effective for their intended uses and are manufactured in establishments that are registered with FDA, and that the labeling of such drugs bears true and accurate information.

As a result of this conviction, FDA sent Mr. Smith by certified mail on August 5, 2016, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2) of the FD&C Act, that Mr. Smith was convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, or conduct otherwise relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Smith an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Smith received the proposal on August 8, 2016. Mr. Smith did not request a hearing and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(a)(2) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Louis Daniel Smith has been convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, or conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Louis Daniel Smith is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see section 201(dd) (21 U.S.C. 321(dd)), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Louis Daniel Smith, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the

FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Smith provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications from Mr. Smith during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Smith for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2016–N–1162 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket, and will be viewable at *http://www.regulations.gov* or at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 9, 2016.

Armando Zamora,

Deputy Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs.

[FR Doc. 2016–27417 Filed 11–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2017 Through September 30, 2018

AGENCY: Office of the Secretary, DHHS.

ACTION: Notice.

SUMMARY: The Federal Medical Assistance Percentages (FMAP), Enhanced Federal Medical Assistance Percentages (eFMAP), and disaster-recovery FMAP adjustments for Fiscal Year 2018 have been calculated pursuant to the Social Security Act (the Act). These percentages will be effective from October 1, 2017 through September 30, 2018. This notice announces the calculated FMAP rates, in accordance with sections 1101(a)(8) and 1905(b) of the Act, that the U.S. Department of Health and Human Services (HHS) will use in determining the amount of federal matching for state medical assistance (Medicaid), Temporary Assistance for Needy Families (TANF) Contingency Funds, Child Support Enforcement collections, Child Care Mandatory and Matching Funds of the Child Care and Development Fund, Title IV–E Foster Care Maintenance payments, Adoption Assistance payments and Guardianship Assistance payments, and the eFMAP rates for the Children's Health Insurance Program (CHIP) expenditures. Table 1 gives figures for each of the 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. This notice reminds states of available disaster-recovery FMAP adjustments for qualifying states, and adjustments available for states meeting requirements for negative growth in total state personal income. At this time, no states qualify for such adjustments.

This notice also contains the increased eFMAPs for CHIP as authorized under the Patient Protection and Affordable Care Act (Affordable Care Act) for fiscal years 2016 through 2019 (October 1, 2015 through September 30, 2019).

Programs under title XIX of the Act exist in each jurisdiction. Programs under titles I, X, and XIV operate only in Guam and the Virgin Islands. The percentages in this notice apply to state expenditures for most medical assistance and child health assistance, and assistance payments for certain social services. The Act provides separately for federal matching of administrative costs.

Sections 1905(b) and 1101(a)(8)(B) of the Social Security Act (the Act) require the Secretary of HHS to publish the FMAP rates each year. The Secretary calculates the percentages, using formulas in sections 1905(b) and 1101(a)(8), and calculations by the Department of Commerce of average income per person in each state and for the Nation as a whole. The percentages must fall within the upper and lower limits specified in section 1905(b) of the Act. The percentages for the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands are specified in statute, and thus are not based on the statutory formula that determines the percentages for the 50 states.

Federal Medical Assistance Percentage (FMAP)

Section 1905(b) of the Act specifies the formula for calculating FMAPs as follows:

'' ''Federal medical assistance percentage'' for any state shall be 100 per centum less the state percentage; and the state percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such state bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the Federal medical assistance percentage shall in no case be less than 50 per centum or more than 83 per centum, (2) the Federal medical assistance percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 55 percent. . .''.

Section 4725(b) of the Balanced Budget Act of 1997 amended section 1905(b) to provide that the FMAP for the District of Columbia for purposes of titles XIX and XXI shall be 70 percent. For the District of Columbia, we note under Table 1 that other rates may apply in certain other programs. In addition, we note the rate that applies for Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands in certain other programs pursuant to section 1118 of the Act. The rates for the States, District of Columbia and the territories are displayed in Table 1, Column 1.

Section 1905(y) of the Act, as added by section 2001 of the Patient Protection and Affordable Care Act of 2010 (''Affordable Care Act''), provides for a significant increase in the FMAP for medical assistance expenditures for individuals determined eligible under the new adult group in the state and who will be considered to be ''newly eligible'' in 2014, as defined in section 1905(y)(2)(A) of the Act. This newly eligible FMAP is 100 percent for Calendar Years 2014, 2015, and 2016, gradually declining to 90 percent in 2020 where it remains indefinitely. In addition, section 1905(z) of the Act, as added by section 10201 of the Affordable Care Act, provides that states that had expanded substantial coverage to low-income parents and nonpregnant adults without children prior to the enactment of the Affordable Care Act, referred to as ''expansion states,'' shall receive an enhanced FMAP beginning in 2014 for medical assistance expenditures for nonpregnant childless adults who may be required to enroll in benchmark coverage. These provisions are discussed in more detail in the Medicaid Eligibility proposed rule published on August 17, 2011 (76 FR 51172) and the final rule published on March 23, 2012 (77 FR 17143). This notice is not intended to set forth the newly eligible or expansion state FMAP rates.

Other Adjustments to the FMAP

For purposes of Title XIX (Medicaid) of the Social Security Act, the Federal Medical Assistance Percentage (FMAP), defined in section 1905(b) of the Social Security Act, for each state beginning with fiscal year 2006 is subject to an adjustment pursuant to section 614 of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), Public Law 111–3. Section 614 of CHIPRA stipulates that a state's FMAP under Title XIX (Medicaid) must be adjusted in two situations.

In the first situation, if a state experiences positive growth in total personal income and an employer in that state has made a significantly disproportionate contribution to a pension or insurance fund, the state's FMAP must be adjusted. Employer pension and insurance fund contributions are significantly disproportionate if the increase in contributions exceeds 25 percent of the increase in total personal income in that state. A **Federal Register** Notice with comment period was issued on June 7, 2010 (75 FR 32182) announcing the methodology for calculating this adjustment; a final notice was issued on October 15, 2010 (75 FR 63480).

A second situation arises if a state experiences negative growth in total personal income. Beginning with Fiscal Year 2006, section 614(b)(3) of CHIPRA specifies that certain employer pension or insurance fund contributions shall be disregarded when computing the per capita income used to calculate the FMAP for states with negative growth in total personal income. In that instance, for the purposes of calculating the FMAP, for a calendar year in which a state's total personal income has declined, the portion of an employer pension and insurance fund contribution that exceeds 125 percent of the amount of the employer contribution in the previous calendar year shall be disregarded.

We request that states follow the same methodology to determine potential FMAP adjustments for negative growth in total personal income that HHS employs to make adjustments to the FMAP for states experiencing significantly disproportionate pension or insurance contributions. See also the information described in the January 21, 2014 **Federal Register** notice (79 FR 3385).

This notice does not contain an FY 2018 adjustment for a major statewide disaster for any state because no state's FMAP decreased by at least three percentage points from FY 2017 to FY 2018.

Enhanced Federal Medical Assistance Percentage (eFMAP) for CHIP

Section 2105(b) of the Act specifies the formula for calculating the eFMAP rates as follows:

> The ''enhanced FMAP'', for a state for a fiscal year, is equal to the Federal medical assistance percentage (as defined in the first sentence of section 1905(b)) for the state increased by a number of percentage points equal to 30 percent of the number of percentage points by which (1) such Federal medical assistance percentage for the state, is less than (2) 100 percent; but in no case shall the enhanced FMAP for a state exceed 85 percent.

In addition, Section 2105(b) of the Social Security Act, as amended by Section 2101 of the Affordable Care Act, increases the eFMAP for states by 23 percentage points:

> . . . during the period that begins on October 1, 2015, and ends on September 30, 2019, the enhanced FMAP determined for a state for a fiscal year (or for any portion of a fiscal year occurring during such period) shall be increased by 23 percentage points, but in no case shall exceed 100 percent.

The eFMAP rates are used in the Children's Health Insurance Program under Title XXI, and in the Medicaid program for certain children for expenditures for medical assistance described in sections 1905(u)(2) and 1905(u)(3) of the Act. There is no specific requirement to publish the eFMAP rates. We include them in this notice for the convenience of the states, and display both the normal eFMAP rates (Table 1, Column 2) and the Affordable Care Act's increased eFMAP rates (Table 1, Column 3) for comparison.

EFFECTIVE DATES: The percentages listed in Table 1 will be effective for each of the four quarter-year periods beginning October 1, 2017 and ending September 30, 2018.

FOR FURTHER INFORMATION CONTACT: Thomas Musco or Rose Chu, Office of Health Policy, Office of the Assistant Secretary for Planning and Evaluation, Room 447D–Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, (202) 690–6870.

(Catalog of Federal Domestic Assistance Program Nos. 93.558: TANF Contingency Funds; 93.563: Child Support Enforcement; 93.596: Child Care Mandatory and Matching Funds of the Child Care and Development Fund; 93.658: Foster Care Title IV–E; 93.659: Adoption Assistance; 93.090 Guardianship Assistance; 93.769: Ticket-to-Work and Work Incentives Improvement Act (TWWIIA) Demonstrations to Maintain Independence and Employment; 93.778: Medical Assistance Program; 93.767: Children's Health Insurance Program)

Dated: November 8, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

TABLE 1—FEDERAL MEDICAL ASSISTANCE PERCENTAGES AND ENHANCED FEDERAL MEDICAL ASSISTANCE PERCENTAGES, EFFECTIVE OCTOBER 1, 2017–SEPTEMBER 30, 2018

[Fiscal Year 2018]

State	Federal medical assistance percentages	Enhanced federal medical assistance percentages	Enhanced federal medical assistance percentages with ACA 23 Pt increase ***
Alabama	71.44	80.01	100.00
Alaska	50.00	65.00	88.00
American Samoa *	55.00	68.50	91.50
Arizona	69.89	78.92	100.00
Arkansas	70.87	79.61	100.00
California	50.00	65.00	88.00
Colorado	50.00	65.00	88.00
Connecticut	50.00	65.00	88.00
Delaware	56.43	69.50	92.50
District of Columbia **	70.00	79.00	100.00

TABLE 1—FEDERAL MEDICAL ASSISTANCE PERCENTAGES AND ENHANCED FEDERAL MEDICAL ASSISTANCE PERCENTAGES, EFFECTIVE OCTOBER 1, 2017–SEPTEMBER 30, 2018—Continued

[Fiscal Year 2018]

State	Federal medical assistance percentages	Enhanced federal medical assistance percentages	Enhanced federal medical assistance percentages with ACA 23 Pt increase ***
Florida	61.79	73.25	96.25
Georgia	68.50	77.95	100.00
Guam *	55.00	68.50	91.50
Hawaii	54.78	68.35	91.35
Idaho	71.17	79.82	100.00
Illinois	50.74	65.52	88.52
Indiana	65.59	75.91	98.91
Iowa	58.48	70.94	93.94
Kansas	54.74	68.32	91.32
Kentucky	71.17	79.82	100.00
Louisiana	63.69	74.58	97.58
Maine	64.34	75.04	98.04
Maryland	50.00	65.00	88.00
Massachusetts	50.00	65.00	88.00
Michigan	64.78	75.35	98.35
Minnesota	50.00	65.00	88.00
Mississippi	75.65	82.96	100.00
Missouri	64.61	75.23	98.23
Montana	65.38	75.77	98.77
Nebraska	52.55	66.79	89.79
Nevada	65.75	76.03	99.03
New Hampshire	50.00	65.00	88.00
New Jersey	50.00	65.00	88.00
New Mexico	72.16	80.51	100.00
New York	50.00	65.00	88.00
North Carolina	67.61	77.33	100.00
North Dakota	50.00	65.00	88.00
Northern Mariana Islands *	55.00	68.50	91.50
Ohio	62.78	73.95	96.95
Oklahoma	58.57	71.00	94.00
Oregon	63.62	74.53	97.53
Pennsylvania	51.82	66.27	89.27
Puerto Rico *	55.00	68.50	91.50
Rhode Island	51.45	66.02	89.02
South Carolina	71.58	80.11	100.00
South Dakota	55.34	68.74	91.74
Tennessee	65.82	76.07	99.07
Texas	56.88	69.82	92.82
Utah	70.26	78.18	100.00
Vermont	53.47	67.43	90.43
Virgin Islands *	55.00	68.50	91.50
Virginia	50.00	65.00	88.00
Washington	50.00	65.00	88.00
West Virginia	73.24	81.27	100.00
Wisconsin	58.77	71.14	94.14
Wyoming	50.00	65.00	88.00

* For purposes of section 1118 of the Social Security Act, the percentage used under titles I, X, XIV, and XVI will be 75 per centum.

** The values for the District of Columbia in the table were set for the state plan under titles XIX and XXI and for capitation payments and DSH allotments under those titles. For other purposes, the percentage for DC is 50.00, unless otherwise specified by law.

*** Section 2101(a) of the Affordable Care Act amended Section 2105(b) of the Social Security Act to increase the enhanced FMAP for states by 23 percentage points, but not to exceed 100 percent, for the period that begins on October 1, 2015 and ends on September 30, 2019 (fiscal years 2016 through 2019).

[FR Doc. 2016–27424 Filed 11–14–16; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (Parent R13/U13).

Date: December 5–8, 2016.

Time: 8:30 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Audrey O. Lau, MD, Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9823, Rockville, MD 20852, 240–669–2081.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Immunity in Neonates and Infants (U01).

Date: December 6–8, 2016.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Nancy Vazquez-Maldonado, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3F52B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892–9834, (240) 669–5044, *nvazquez@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 7, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–27340 Filed 11–14–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group; R21: Rapid Assessment of Zika Virus (ZIKV) Complications.

Date: December 1, 2016.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ana Olariu, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529, (301) 496–9223, *Ana.Olariu@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke, Initial Review Group, Review Proposals on Parkinsonism Biomarkers.

Date: December 5, 2016.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Joel Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529, (301) 496–9223, *joel.saydoff@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke, Initial Review Group, Udall CWOW Planning Grant.

Date: December 13, 2016.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Birgit Neuhuber, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529, *neuhuber@ninds.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: November 8, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–27342 Filed 11–14–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel RFA–TW–16–002: Fogarty Global Health Training Program.

Date: November 17, 2016.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301–435–1050, *freundr@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 8, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–27336 Filed 11–14–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions.

Date: November 30, 2016.

Time: 11:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301–451–2356, *gavinevanskm@mail.nih.gov.*

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892–9606, 301–443–7861, *dsommers@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel, NIMH Fellowship and Dissertation Research Review Teleconference.

Date: December 1, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Vinod Charles, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892–9606, 301–443–1606, *charlesvi@mail.nih.gov.*

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive BLVD, Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 8, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–27341 Filed 11–14–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the National Heart, Lung and Blood Institute, Office of Technology Transfer and Development, National Institutes of Health, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Immortalized Stria Vascularis Cell Line SV–k1

Description of Technology

Available for nonexclusive licensing for research uses is the cell line, SV–k1, derived from the Organ of Corti. The line was developed from the stria vascularis, an organ localized on the lateral wall of the cochlea, adjacent to the Organ of Corti, containing cell populations specialized in the production of an endolymph very rich in K^+ characteristic of the mammalian inner ear. SV–k1 cells express a set of biomarkers completely different of those expressed by OC–k3 cells (See notice for E–012–2017/0 published contemporaneously herewith), and are not sensitive to ototoxic drugs.

Potential Commercial Applications

- Research
- Hearing research

Development Stage

- Materials

Inventors

Gilda Mabel Canseco de Kalinec and Federico Kalinec (both of NIDCD).

Publications

1. Espreafico, EM et al., ''Localization of Myosin-V in the Centrosome'' (1998) *Proc Nat'l Acad Sci USA* 95(15):8636–8641, 1998.
2. Gratton MA et al., ''Strial marginal cells play a role in basement membrane homeostasis: In vitro and in vivo evidence.'' *Hear Res* 163:27–36, 2002.
3. Park, C., et al., ''HEl-OC1 Cells as a Model for Investigating Prestin Function.'' (2016) *Hear Res* 335:9–17.

Intellectual Property

HHS Reference No. E–013–2017/0—Research Material.

Licensing Contact

Michael Shmilovich, Esq, CLP; 301–435–5019; *shmilovm@mail.nih.gov.*

Dated: November 7, 2016.

Michael Shmilovich,

National Heart, Lung and Blood Institute, Office of Technology Transfer and Development, National Institutes of Health.

[FR Doc. 2016–27337 Filed 11–14–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Grant Review for NHLBI K Award Recipients.

Date: December 7, 2016.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Melissa E. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, 301–435–0297, *nagelinmh2@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 8, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–27339 Filed 11–14–16; 8:45 am]

BILLING CODE 4140–01–P

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Notice of Advisory Council on Historic Preservation Quarterly Business Meeting

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of Advisory Council on Historic Preservation quarterly business meeting.

SUMMARY: Notice is hereby given that the Advisory Council on Historic Preservation (ACHP) will hold its next quarterly meeting on Thursday, December 1, 2016. The meeting will be held in Room SR325 at the Russell Senate Office Building at Constitution and Delaware Avenues NE., Washington, DC, starting at 8:30 a.m. EST.

DATES: The quarterly meeting will take place on Thursday, December 1, 2016, starting at 8:30 a.m.

ADDRESSES: The meeting will be held in Room SR325 at the Russell Senate Office Building at Constitution and Delaware Avenues NE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Cindy Bienvenue, 202–517–0202, *cbienvenue@achp.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Council on Historic Preservation (ACHP) is an independent federal agency that promotes the preservation, enhancement, and sustainable use of our nation's diverse historic resources, and advises the President and the Congress on national historic preservation policy. The goal of the National Historic Preservation Act (NHPA), which established the ACHP in 1966, is to have federal agencies act as responsible stewards of our nation's resources when their actions affect historic properties. The ACHP is the only entity with the legal responsibility to encourage federal agencies to factor historic preservation into federal project requirements. For more information on the ACHP, please visit our Web site at *www.achp.gov.*

The agenda for the upcoming quarterly meeting of the ACHP is the following:

I. Chairman's Welcome
II. Swearing-In Ceremony
III. Transition
IV. Section 106 Issues
  A. Small Federal Handles and Tribal Consultation Issues
  B. Broadband on Federal Property
  C. Proposed Exemption for Railroad Rights-of-Way Under the Fixing America's Surface Transportation (FAST) Act
V. ACHP Native American Affairs Committee Activities
VI. Historic Preservation Policy and Programs
  A. Building a More Inclusive Preservation Program
  1. Youth Initiatives
  2. ACHP Policy Statement on Diversity and Inclusiveness
  B. Preservation50 and the ACHP Public Policy Initiative
  C. Policy Statement on Historic Preservation and Community Revitalization
  D. White House Council on Climate Preparedness and Resilience
  E. Historic Preservation Legislation in the 114th Congress
  1. Historic Preservation Fund Reauthorization and ACHP Amendments
  2. FY 2017 Interior Appropriations
  3. National Defense Authorization Act and Other Bills
VII. New Business
VIII. Adjourn

The meetings of the ACHP are open to the public. If you need special accommodations due to a disability, please contact Cindy Bienvenue, 202–517–0202 or *cbienvenue@achp.gov*, at least seven (7) days prior to the meeting.

Authority: 54 U.S.C. 304102.

Dated: November 9, 2016.

Javier E. Marques,

Associate General Counsel.

[FR Doc. 2016–27386 Filed 11–14–16; 8:45 am]

BILLING CODE 4310–K6–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0262]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0066

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval for reinstatement with change of the following collection of information: 1625–0066, Vessel and Facility Response Plans (Domestic and International), and Additional Response Requirements for Prince William Sound, Alaska. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before December 15, 2016.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2016–0262] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email: OIRA-submission@omb.eop.gov.*

(2) *Mail:* OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Fax:* 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection. The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2016–0262], and must be received by December 15, 2016.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0066.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (81 FR 28089, May 9, 2016) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collections.

Information Collection Request

Title: Vessel and Facility Response Plans (Domestic and International), and Additional Response Requirements for Prince William Sound.

OMB Control Number: 1625–0066

Summary: The Oil Pollution Act of 1990 (OPA 90) required the development of Vessel and Facility Response Plans to minimize the impact of oil spills. OPA 90 also required additional response requirements for Prince William Sound. Shipboard Oil Pollution Emergency Plans and Shipboard Marine Pollution Emergency Plans are required of other vessels to minimize impacts of oil spills.

Need: This information is needed to ensure that vessels and facilities are prepared to respond in event of a spill incident. The information will be reviewed by the Coast Guard to assess the effectiveness of the response plan.

Forms: CG–6083, Application for Approval/Revision of Vessel Pollution Response Plans and Vessel Response Plan (VRP) Express Search Tool.

Respondents: Owners and operators of vessels and facilities.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 136,460 hours to 75,395 hours a year. The decrease in burden is primarily due to a decrease in the estimated annual number of Facility Response Plan (FRP) respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: October 27, 2016.

Brian P. Burns,

U. S. Coast Guard, Deputy Chief Information Officer.

[FR Doc. 2016–27432 Filed 11–14–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R5–R–2016–N101; FXRS85510553RGO–XXX–FF05R04000]

Final Long Range Transportation Plan for U.S. Fish and Wildlife Service Lands in the Northeast Region

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; final long range transportation plan.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of the final long range transportation plan (LRTP). The Final LRTP outlines a strategy for improving and maintaining transportation assets that provide access to Service-managed lands in the Northeast Region (Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut, New York, Pennsylvania, New Jersey, Delaware, Maryland, Virginia, and West Virginia) over the next 20 years.

ADDRESSES: You may view or obtain copies of the final plan by any of the following methods. You may also request a hard copy or a CD–ROM.

Agency Web site: Download a copy of the document at *http://www.fws.gov/northeast/refuges/roads/pdf/northeast-region-long-range-transportation-plan.pdf.*

Email: Send requests to *carl_melberg@fws.gov,* and include ''Region 5 Final LRTP'' in the subject line of your email.

U.S. Mail: Carl Melberg, Acting Regional Transportation Coordinator, Northeast Region, U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, Massachusetts 01035.

Facsimile: Attention: Carl Melberg, 413–253–8468.

In-Person Viewing or Pickup: Call 413–253–8586 to make an appointment (necessary for view/pickup only) during regular business hours at Northeast Region, U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, Massachusetts 01035.

FOR FURTHER INFORMATION CONTACT: Carl Melberg, Acting Regional Transportation Coordinator, 413–253–8586 (phone); *carl_melberg@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we make the Final LRTP for the Northeast Region of the Service available for public review. Notice of availability and request for comments on the Draft LRTP was published in the **Federal Register** (FR00002485) on March 7, 2016. Comments received were evaluated and incorporated, as applicable, into this Final LRTP. The Final LRTP outlines a strategy for improving and maintaining transportation assets that provide access to Service-managed lands in the Northeast Region in Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut, New York, Pennsylvania, New Jersey, Delaware, Maryland, Virginia, and West Virginia.

Background

This final report also includes changes made in reference to the Federal multi-year transportation funding legislation. The Fixing America's Surface Transportation Act (FAST ACT) was signed in December 2015, and replaces the 2012 Moving Ahead for Progress in the 21st Century Act (MAP–21). Both require all Federal land management agencies to conduct long range transportation planning in a manner that is consistent with metropolitan planning organization and State departments of transportation planning. This LRTP was initiated within the Service to achieve the following:

- Establish a structure for sound transportation planning and decision-making.
- Establish a vision, mission, goals, and objectives for transportation planning in the Service's Northeast Region.
- Implement coordinated and cooperative transportation partnerships in an effort to improve the Service's transportation infrastructure.
- Integrate transportation planning and funding for wildlife refuges and fish hatcheries into existing and future Service management plans and strategies *e.g.,* comprehensive conservation plans and comprehensive hatchery management plans.
- Increase awareness of Alternative Transportation Systems and associated benefits.
- Develop best management practices for transportation improvements on Service lands.
- Serve as a pilot project for the implementation of a Regional-level transportation planning process within the Service.

LRTP Mission, Goals, and Objectives

Through a collaborative effort, the National Wildlife Refuge System (Refuge System) and the Fish and Aquatic Conservation programs, in cooperation with the Planning Group and the Division of Refuge Field Support within the Service's Northeast Region, have contributed to defining the mission, goals, and objectives presented in this document. The resulting mission, goals, and objectives are intended to provide a systematic approach to guide the process for evaluating and selecting transportation improvements for the Service lands in the Northeast Region. These guiding principles have shaped the development, conclusions, and recommendations of this LRTP.

Mission

To support the Service's mission by connecting people to fish, wildlife, and their habitats through strategic implementation of transportation programs.

Goals and Objectives

This long range transportation plan has six categories of goals: Coordinated Opportunities; Asset Management; Safety; Environmental; Access, Mobility, and Connectivity; and Visitor Experience. Under each goal, we present distinct objectives that move us to the goal.

1. Coordinated Opportunities: The program will seek joint transportation opportunities that support the Service mission, maximize the utility of Service resources, and provide mutual benefits to the Service and external partners.

Objectives:

- Identify and increase key internal and external partnerships at the national, regional, and unit levels.
- Maximize leveraged opportunities by identifying and pursuing funding for projects of mutual interest and benefit.
- Develop best practices for external engagement that illustrates success in forming and nurturing coalitions and partnerships that support the Service's mission.
- Coordinate within Service programs, including the Refuge System, Ecological Services, Migratory Birds, and Fish and Aquatic Conservation during the development of Regional long-range and project-level plans.

2. Asset Management: The program will operate and maintain a functional, financially sustainable and resilient transportation network to satisfy current and future land management needs in the face of a changing climate.

Objectives:

- Use asset management principles to maintain important infrastructure at an appropriate condition level.
- Prioritize work programs through the project selection process detailed in this plan or an adaptation thereof.
- Evaluate life cycle costs when considering new assets to determine long-term financial sustainability.
- Consider the impacts of climate change in the planning and management of transportation assets.

3. Safety: The program's network will provide a superior level of safety for all users and all modes of transportation to and within Service lands.

Objectives:

- Identify safety issue 'hot-spots' within the Service's transportation system with the Safety Analysis Toolkit.
- Implement appropriate safety countermeasures to resolve safety issues and reduce the frequency and severity of crashes (also with the Safety Analysis Toolkit).
- Address wildlife-vehicle collisions with design solutions (Environmental Enhancements).
- Use cooperation and communication among the ''4E's'' of safety, including: Engineering, education, enforcement, and emergency medical services.

4. Environmental: Transportation infrastructure will be landscape appropriate and play a key role in the improvement of environmental conditions in and around Service lands.

Objectives:

- Follow the Roadway Design Guidelines for best practices in design, planning, management, maintenance, and construction of transportation assets.
- Reduce greenhouse gas emissions and air pollutants by increasing transportation options and use of alternative fuels.
- Protect wildlife corridors, reduce habitat fragmentation, and enhance terrestrial and aquatic organism passage

on and adjacent to Service lands to conserve fish, wildlife, and plant populations.

5. Access, Mobility, and Connectivity: The program will ensure that units open to public visitation have adequate transportation options for all users including underserved, underrepresented, and mobility-limited populations.

Objectives:

- Offer a wide range of transportation modes and linkages for onsite and offsite access.
- Provide a clear way for finding information both on and off Service lands.
- Through the Urban Wildlife Conservation Program, integrate Service transportation facilities with local community transportation systems in a way that encourages local visitation and provides economic benefits to partner and gateway communities.
- Through coordinated planning, provide context-appropriate transportation facilities that address the specific needs of local visitor groups and respect the natural setting of the refuge or hatchery.
- Address congestion issues to and within Service units.

6. Visitor Experience: The program will enhance the visitation experience through improvement and investment in the transportation network.

Objectives:

- Integrate interpretation, education, and resource stewardship principles into the transportation experience.
- Evaluate the feasibility of alternative transportation systems at all stations and implement where appropriate.
- Encourage connections with existing and planned public and private transportation services.
- Design infrastructures in such a way that highlights the landscape and not the transportation facility.

Comments

We solicited comments on the Draft LRTP from March 7 to April 7, 2016 (FR00002485). During the comment period, we received two written responses. Comments received were evaluated and incorporated, as applicable, into this Final LRTP.

Changes to the Final LRTP

After considering the comments we received on the Draft LRTP, we have updated the report to highlight partnership opportunities at the Potomac River National Wildlife Refuge Complex. This final report also includes changes made in referencing the Federal multi-year transportation funding legislation. The FAST Act was signed in December 2015, and replaces the MAP–21.

Next Steps

We will document the Final LRTP, which will be published in the **Federal Register**.

Dated: August 9, 2016.

Deborah Rocque,

Acting Regional Director, Northeast Region.

[FR Doc. 2016–27442 Filed 11–14–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWY–957000–17–L13100000–PP0000]

Filing of Plats of Survey, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) is scheduled to file plats of survey thirty (30) calendar days from the date of this publication in the BLM Wyoming State Office, Cheyenne, Wyoming. The surveys were executed at the request of the Bureau of Land Management, the U.S. Forest Service and the National Park Service and are necessary for the management of these lands. The lands surveyed are:

The plat and field notes representing the dependent resurvey of a portion of the west boundary, Tracts 37, 38 and 40, portions of Tract 41, and portions of the subdivisional lines, and the survey of the subdivision of section 27, Township 13 North, Range 101 West, Sixth Principal Meridian, Wyoming, Group No. 937, was accepted November 8, 2016.

The plat and field notes representing the dependent resurvey of portions of the west and north boundaries, and portions of the subdivisional lines, and the survey of the subdivision of section 6, Township 26 North, Range 71 West, Sixth Principal Meridian, Wyoming, Group No. 941, was accepted November 8, 2016.

The plat and field notes representing the dependent resurvey of portions of Tracts 37 and 38, and portions of the subdivisional lines, and the survey of the subdivision of sections 12, 26 and 27, Township 26 North, Range 72 West, Sixth Principal Meridian, Wyoming, Group No. 942, was accepted November 8, 2016.

The plat and field notes representing the dependent resurvey of portions of the west boundary and subdivisional lines, the survey of the subdivision of section 18, and the survey of the meanders of portions of the left bank of Belle Fourche River, Township 53 North, Range 65 West, Sixth Principal Meridian, Wyoming, Group No. 945, was accepted November 8, 2016.

The plat and field notes representing the dependent resurvey of portions of the subdivisional lines and the survey of the subdivision of sections 12 and 13, Township 53 North, Range 66 West, Sixth Principal Meridian, Wyoming, Group No. 945, was accepted November 8, 2016.

FOR FURTHER INFORMATION CONTACT: WY957, Bureau of Land Management, 5353 Yellowstone Road, P.O. Box 1828, Cheyenne, Wyoming 82003.

SUPPLEMENTARY INFORMATION: A person or party who wishes to protest against any of the above surveys must file a written notice within thirty (30) calendar days from the date of this publication with the Wyoming State Director, Bureau of Land Management, at the above address, stating that they wish to protest. A statement of reasons for the protest may be filed with the notice of protest and must be filed with the Wyoming State Director within thirty (30) calendar days after the protest is filed. If a protest against the survey is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. A plat will not be officially filed until the day after all protests have been dismissed or otherwise resolved. Before including your address, phone number, email address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Copies of the preceding described plats and field notes are available to the public at a cost of $4.20 per plat and $.13 per page of field notes.

Dated: November 8, 2016.

John P. Lee,

Chief Cadastral Surveyor, Division of Support Services.

[FR Doc. 2016–27445 Filed 11–14–16; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—ASTM International Standards

Notice is hereby given that, on September 12, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), ASTM International (''ASTM'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ASTM has provided an updated list of current, ongoing ASTM standards activities originating between May 2016 and September 2016 designated as Work Items. A complete list of ASTM Work Items, along with a description of each, is available at *http://www.astm.org.*

On September 15, 2004, ASTM filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 10, 2004 (69 FR 65226).

The last notification with the Attorney General was filed on May 18, 2016. A notice was filed in the **Federal Register** on June 21, 2016 (81 FR 40352).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–27405 Filed 11–14–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on Energy Storage System Evaluation and Safety II

Notice is hereby given that, on September 21, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on Energy Storage System Evaluation and Safety II (''EssES–II'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties to the venture are: Allison Transmission, Inc., Indianapolis, IN; BAE Systems, Johnson City, NY; Deere & Company, Moline, IL; Tata Motors European Technical Centre (TMETC), London, United Kingdom; and Underwriters Laboratories, Inc., Northbrook, IL. The general area of EssES–II's planned activity is to develop detailed cell level data on current or near market technology across a diverse number of manufacturers to allow a relative comparison between available technologies. The program will provide performance, life, abuse and consistency of manufacturing test data for member-selected systems in a private, independent third party laboratory format (non-governmental). This will provide members with the data required to assess the pertinent performance characteristics of various battery topologies, chemistries and manufacturers to assist in the selection of cells for a vehicular or stationary energy storage system. Additionally, the level of data and the detail in which it is provided will be sufficient to aid in the development of models, pack integration work and thermal management strategy development.

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–27406 Filed 11–14–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Vendor Security Alliance

Notice is hereby given that, on October 19, 2016, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Vendor Security Alliance (''VSA'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties to the venture are: Airbnb, Inc., San Francisco, CA; Atlassian Pty Ltd., Sydney, NSW, Australia; Docker, Inc.; San Francisco, CA; Dropbox, Inc., San Francisco, CA; GoDaddy.com, LLC, Scottsdale, AZ; Palantir Technologies, Inc., Palo Alto, CA; Square, Inc., San Francisco, CA; Twitter, Inc., San Francisco, CA; and Uber Technologies, Inc., San Francisco, CA.

The general area of VSA's planned activity is: Improving Internet security and streamlining vendor security compliance by developing a standardized way for companies to assess cybersecurity practices.

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2016–27402 Filed 11–14–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (NIJ) Docket No. 1729]

Baseline Specifications for Law Enforcement Service Pistols With Security Technology

AGENCY: National Institute of Justice, Justice.

ACTION: Notice.

SUMMARY: The National Institute of Justice (NIJ) announces the publication of *Baseline Specifications for Law Enforcement Service Pistols with Security Technology*, which defines baseline specifications for law enforcement service pistols with additional technology to enhance the security of the firearms, found here: *http://nij.gov/topics/technology/firearms/pages/welcome.aspx.*

FOR FURTHER INFORMATION CONTACT: Mark Greene, Office of Science and Technology, National Institute of Justice, 810 7th Street NW., Washington, DC 20531; telephone number: (202) 598–9412; email address: *mark.greene2@usdoj.gov.*

SUPPLEMENTARY INFORMATION: On April 29, 2016, the U.S. Departments of Justice (DOJ), Homeland Security (DHS), and Defense (DoD) submitted a joint report to the President outlining a strategy to expedite deployment of gun safety technology, found here: *https://*

www.whitehouse.gov/sites/default/files/docs/final_report-smart_gun_report.pdf.

The report was published in response to Presidential Memorandum, *Promoting Smart Gun Technology*, found here: *https://www.whitehouse.gov/the-press-office/2016/01/05/memorandum-promoting-smart-gun-technology.* The report described the potential benefits of advanced gun safety technology, but noted that additional work was required before this technology is ready for widespread adoption by law enforcement agencies. In particular, the report stressed the importance of integrating this technology into a firearm's design without compromising the reliability, durability, and accuracy that officers expect from their service weapons.

To address these issues, the report called on law enforcement agencies to develop ''baseline specifications,'' which would outline the agencies' operational requirements for any firearms equipped with gun safety technology. By developing baseline specifications, federal, state, and municipal law enforcement agencies can make clear to private manufacturers what they expect from this technology.

DOJ and DHS recently assembled a working group of experts in firearms technology to identify operational needs and prepare a draft document that defines generic baseline specifications for law enforcement service pistols with additional technology to enhance the security of firearms. The additional security specifications that may be addressed by smart gun technology are distinguished from more familiar firearm safety mechanisms. The distinction between safety and security can be nuanced, and the additional security specifications may also function as safety features under certain circumstances. However, this distinction forms the basis of the use of the different terminology. The working group was led by NIJ and was comprised of subject matter experts from various federal law enforcement agencies. The pistols defined by this document are semi-automatic, recoil-operated, magazine-fed, striker-fired, and fire 9 mm Luger or .40 S&W ammunition. The information detailed in this document is informed in part by specifications enumerated in recent handgun solicitations by the Federal Bureau of Investigation (FBI) and Immigration and Customs Enforcement (ICE), which are publicly available on FedBizOpps (*http://www.fbo.gov*) under solicitation numbers RFP–OSCU–DSU1503 and HSCEMS–16–R–00003, respectively.

NIJ published a **Federal Register** notice (*https://www.federalregister.gov/d/2016-16759*) on July 15, 2016, seeking feedback from the public on the draft document that defined generic baseline specifications for law enforcement service pistols with additional technology to enhance the security of the firearms. The 60-day public comment period closed on September 13, 2016. The working group made revisions to the draft document, and the final version of the document, *Baseline Specifications for Law Enforcement Service Pistols with Security Technology*, is published here: *http://nij.gov/topics/technology/firearms/pages/welcome.aspx.*

Nancy Rodriguez,

Director, National Institute of Justice.

[FR Doc. 2016–27387 Filed 11–14–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0003]

Proposed Extension of Information Collection; Radiation Sampling and Exposure Records (Pertains to Underground Metal and Nonmetal Mines)

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

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 collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection for Radiation Sampling and Exposure Records (pertains to underground metal and nonmetal mines).

DATES: All comments must be received on or before January 17, 2017.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below.

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments for docket number MSHA–2016–0038.
- *Regular Mail: Send comments to USDOL–MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452.*
- *Hand Delivery: USDOL-Mine Safety and Health Administration, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.*

FOR FURTHER INFORMATION CONTACT: Sheila McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at *MSHA.information.collections@dol.gov* (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Under the authority of Section 103 of the Federal Mine Safety and Health Act of 1977, MSHA is required to issue regulations requiring operators to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under any applicable mandatory health or safety standard promulgated under this Act.

Airborne radon and radon daughters exist in every uranium mine and in several other underground mining commodities. Radon is radioactive gas. It diffuses into the underground mine atmosphere through the rock and the ground water. Radon decays in a series of steps into other radioactive elements, which are solids, called radon daughters. Radon and radon daughters are invisible and odorless. Decay of radon and its daughters results in emissions of alpha energy.

Medical doctors and scientists have associated high radon daughter exposures with lung cancer. The health hazard arises from breathing air contaminated with radon daughters which are in turn deposited in the lungs. The lung tissues are sensitive to alpha radioactivity.

The amounts of airborne radon daughters to which most miners can be exposed with no adverse effects have been established and are expressed as working levels (WL). The current MSHA standard is a maximum personal exposure of 4 working level months (WLM) per year.

Excess lung cancer in uranium miners, just as coal workers'

pneumoconiosis, silicosis, and other debilitating occupational diseases, has been recognized for many years. Thus, an adequate base of accurate exposure level data is essential to control miners' exposures and permit an evaluation of the effectiveness of existing regulations.

The standard at 30 CFR 57.5037 established the procedures to be used by the mine operator in sampling mine air for the presence and concentrations of radon daughters. Operators are required to conduct weekly sampling where concentrations of radon daughters exceed 0.3 WL. Sampling is required bi-weekly where uranium mines have readings of 0.1 WL to 0.3 WL and every 3 months in non-uranium underground mines where the readings are 0.1 WL to 0.3 WL. Mine operators are required to keep records of all mandatory samplings. Records must include the sample date, location, and results, and must be retained at the mine site or nearest mine office for at least 2 years.

The standard at 30 CFR 57.5040 requires mine operators to calculate and record individual exposures to radon daughters on MSHA Form 4000–9 ''Record of Individual Exposure to Radon Daughters.'' The calculations are based on the results of the weekly sampling required by 30 CFR 57.5037. Records must be maintained by the operator and submitted to MSHA annually.

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to Radiation Sampling and Exposure Records (pertains to underground metal and nonmetal mines).

- MSHA is particularly interested in comments that:
- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

The information collection request will be available on *http://www.regulations.gov.* MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on *www.regulations.gov* and *www.reginfo.gov.*

The public may also examine publicly available documents at USDOL-Mine Safety and Health Administration, 201 *12*th South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION** section of this notice.

III. Current Actions

This request for collection of information contains provisions for Radiation Sampling and Exposure Records (pertains to underground metal and nonmetal mines). MSHA has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0003.

Affected Public: Business or other for-profit.

Number of Respondents: 5.

Frequency: Weekly.

Number of Responses: 505.

Annual Burden Hours: 502 hours.

Annual Respondent or Recordkeeper Cost: $17,433.

MSHA Forms: MSHA Form 4000–9, Record of Individual Exposure to Radon Daughters.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Sheila McConnell,

Certifying Officer.

[FR Doc. 2016–27343 Filed 11–14–16; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2006–0028]

MET Laboratories, Inc.: Application for Expansion of Recognition and Proposed Modification to the NRTL Program's List of Appropriate Test Standards

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the application of MET Laboratories, Inc. for expansion of its recognition as a Nationally Recognized Testing Laboratory (NRTL) and presents the Agency's preliminary finding to grant the application. Additionally, OSHA proposed to add a new test standing to the NRTL Program's List of Appropriate Test Standards.

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before November 30, 2016.

ADDRESSES: Submit comments by any of the following methods:

1. *Electronically:* Submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions.

2. *Facsimile:* If submissions, including attachments, are not longer than 10 pages, commenters may fax them to the OSHA Docket Office at (202) 693–1648.

3. *Regular or express mail, hand delivery, or messenger (courier) service:* Submit comments, requests, and any attachments to the OSHA Docket Office, Docket No. OSHA–2006–0028, Technical Data Center, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3653, Washington, DC 20210; telephone: (202) 693–2350 (TTY number: (877) 889–5627). Note that security procedures may result in significant delays in receiving comments and other written materials by regular mail. Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express mail, hand delivery, or messenger service. The hours of operation for the OSHA Docket Office are 8:15 a.m.–4:45 p.m., e.t.

4. *Instructions:* All submissions must include the Agency name and the OSHA docket number (OSHA–2006–0028). OSHA places comments and other

materials, including any personal information, in the public docket without revision, and these materials will be available online at *http://www.regulations.gov.* Therefore, the Agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

5. *Docket:* To read or download submissions or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

6. *Extension of comment period:* Submit requests for an extension of the comment period on or before November 30, 2016 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210, or by fax to (202) 693–1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3647, Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210; phone: (202) 693–2110 or email: *robinson.kevin@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Notice of the Application for Expansion

The Occupational Safety and Health Administration is providing notice that MET Laboratories, Inc. (MET), is applying for expansion of its current recognition as an NRTL. MET requests the addition of five test standards to its NRTL scope of recognition.

OSHA recognition of an NRTL signifies that the organization meets the requirements specified in 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition. Each NRTL's scope of recognition includes (1) the type of products the NRTL may test, with each type specified by its applicable test standard; and (2) the recognized site(s) that has/have the technical capability to perform the product-testing and product-certification activities for test standards within the NRTL's scope. Recognition is not a delegation or grant of government authority; however, recognition enables employers to use products approved by the NRTL to meet OSHA standards that require product testing and certification.

The Agency processes applications by an NRTL for initial recognition and for an expansion or renewal of this recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding. In the second notice, the Agency provides its final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational Web page for each NRTL, including MET, which details the NRTL's scope of recognition. These pages are available from the OSHA Web site at *http://www.osha.gov/dts/otpca/nrtl/index.html.*

MET currently has one facility (site) recognized by OSHA for product testing and certification, with its headquarters located at: MET Laboratories, Inc., 914 West Patapsco Avenue, Baltimore, Maryland 21230. A complete list of MET's scope of recognition is available at *https://www.osha.gov/dts/otpca/nrtl/met.html.*

II. General Background on the Application

MET submitted five applications, four dated July 7, 2015 (OSHA–2006–0028–0026), (OSHA–2006–0028–0027), (OSHA–2006–0028–0028), (OSHA–2006–0028–0029) and one dated August 4, 2015 (OSHA–2006–0028–0025), to expand its recognition to include five additional test standards. OSHA staff performed a detailed analysis of the application packet and reviewed other pertinent information. OSHA did not perform any on-site reviews in relation to this application.

Table 1 below lists the appropriate test standards found in MET's application for expansion for testing and certification of products under the NRTL Program.

TABLE 1—PROPOSED LIST OF APPROPRIATE TEST STANDARDS FOR INCLUSION IN MET'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 62368–1	Audio/Video, Information and Communication Technology Equipment—Part 1: Safety Requirements.
UL 60079–0	Explosive Atmospheres—Part 0: Equipment—General Requirements.
UL 60079–2*	Explosive Atmospheres—Part 2: Equipment Protection by Pressurized Enclosure "p".
UL 60079–11	Explosive Atmospheres—Part 11: Equipment Protection by Intrinsic Safety "i".
UL 60079–15	Explosive Atmospheres—Part 15: Equipment Protection by Type of Protection "n".

* Represents the standard that OSHA proposes to add to the NRTL Program's List of Appropriate Test Standards.

III. Proposal To Add New Test Standard to the NRTL Program's List of Appropriate Test Standards

Periodically, OSHA will propose to add new test standards to the NRTL list of appropriate test standards following an evaluation of the test standard document. To qualify as an appropriate test standard, the Agency evaluates the document to (1) verify it represents a product category for which OSHA requires certification by an NRTL, (2) verify the document represents an end product and not a component, and (3) verify the document defines safety test specifications (not installation or operational performance specifications). OSHA becomes aware of new test standards through various avenues. For example, OSHA may become aware of

new test standards by: (1) Monitoring notifications issued by certain SDOs; (2) reviewing applications by NRTLs or applicants seeking recognition to include a new test standard in their scopes of recognition; and (3) obtaining notification from manufacturers, manufacturing organizations, government agencies, or other parties. OSHA may determine to include a new test standard in the list, for example, if the test standard is for a particular type of product that another test standard also covers or it covers a type of product that no standard previously covered.

In this notice, OSHA proposes to add a new test standard to the NRTL Program's List of Appropriate Test Standards. Table 1, below, lists the test standard that is new to the NRTL Program. OSHA preliminarily determined that this test standard is an appropriate test standard and proposes to include it in the NRTL Program's List of Appropriate Test Standards. OSHA seeks public comment on this preliminary determination.

TABLE 1—TEST STANDARDS OSHA IS PROPOSING TO ADD TO THE NRTL PROGRAM'S LIST OF APPROPRIATE TEST STANDARDS

Test standard	Test standard title
UL 60079–2	Explosive Atmospheres—Part 2: Equipment Protection by Pressurized Enclosure "p".

IV. Preliminary Findings on the Application

MET submitted an acceptable application for expansion of its scope of recognition. OSHA's review of the application file, and pertinent documentation, indicate that MET can meet the requirements prescribed by 29 CFR 1910.7 for expanding its recognition to include the addition of these five test standards for NRTL testing and certification listed above. This preliminary finding does not constitute an interim or temporary approval of MET's application.

OSHA welcomes public comment as to whether MET meets the requirements of 29 CFR 1910.7 for expansion of its recognition as an NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. Commenters must submit the written request for an extension by the due date for comments. OSHA will limit any extension to 10 days unless the requester justifies a longer period. OSHA may deny a request for an extension if the request is not adequately justified. To obtain or review copies of the exhibits identified in this notice, as well as comments submitted to the docket, contact the Docket Office, Room N–2625, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address. These materials also are available online at *http://www.regulations.gov* under Docket No. OSHA–2006–0028.

OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will recommend to the Assistant Secretary for Occupational Safety and Health whether to grant MET's application for expansion of its scope of recognition. The Assistant Secretary will make the final decision on granting the application. In making this decision, the Assistant Secretary may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of its final decision in the **Federal Register**.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on November 7, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2016–27356 Filed 11–14–16; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act: Notice of Agency Meeting

TIME AND DATE: 10:00 a.m., Thursday, November 17, 2016.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street (All visitors must use Diagonal Road Entrance), Alexandria, VA 22314–3428.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Share Insurance Fund Quarterly Report.
2. NCUA's Rules and Regulations, Community Development Revolving Loan Fund.
3. 2017/2018 Operating Budget.
4. Board Briefing, 2017 Overhead Transfer Rate.
5. Board Briefing, Share Insurance Fund Equity Ratio Projections and 2017 Premium Range.

FOR FURTHER INFORMATION CONTACT: Gerard Poliquin, Secretary of the Board, Telephone: 703–518–6304.

Gerard Poliquin,

Secretary of the Board.

[FR Doc. 2016–27543 Filed 11–10–16; 4:15 pm]

BILLING CODE 7535–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meetings of Humanities Panel

AGENCY: National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: The National Endowment for the Humanities will hold fourteen meetings of the Humanities Panel, a federal advisory committee, during December, 2016. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965.

DATES: See **SUPPLEMENTARY INFORMATION** section for meeting dates. The meetings will open at 8:30 a.m. and will adjourn by 5:00 p.m. on the dates specified below.

ADDRESSES: The meetings will be held at the National Endowment for the Humanities at Constitution Center at 400 7th Street SW., Washington, DC 20506, unless otherwise indicated.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW., Room 4060, Washington, DC 20506; (202)606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given of the following meetings:

1. *Date:* December 1, 2016.

This meeting will discuss applications on the subject of World Studies II: Modern Era, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

2. *Date:* December 1, 2016.

This meeting will discuss applications for the Humanities Connections grant program, submitted to the Division of Education Programs.

3. *Date:* December 1, 2016.

Address: The Library of Congress, Jefferson Building, 10 First Street SE., Washington, DC 20540.

This meeting will discuss applications for Kluge Fellowships, submitted to the Division of Research Programs.

4. *Date:* December 2, 2016.

This meeting will discuss applications for the Humanities Connections grant program, submitted to the Division of Education Programs.

5. *Date:* December 2, 2016.

Address: The Library of Congress, Jefferson Building, 10 First Street SE., Washington, DC 20540.

This meeting will discuss applications for Kluge Fellowships, submitted to the Division of Research Programs.

6. *Date:* December 2, 2016

This meeting will discuss applications on the subject of Linguistics, for the Humanities Collections and Reference Resources grant program, submitted to the Division of Preservation and Access.

7. *Date:* December 5, 2016.

This meeting will discuss applications for the Humanities Connections grant program, submitted to the Division of Education Programs.

8. *Date:* December 6, 2016.

This meeting will discuss applications for the Humanities Connections grant program, submitted to the Division of Education Programs.

9. *Date:* December 6, 2016.

This meeting will discuss applications for Fellowship Programs at Independent Research Institutions, submitted to the Division of Research Programs.

10. *Date:* December 7, 2016.

This meeting will discuss applications for the Humanities Connections grant program, submitted to the Division of Education Programs.

11. *Date:* December 12, 2016.

This meeting will discuss applications to the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.

12. *Date:* December 13, 2016.

This meeting will discuss applications to the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.

13. *Date:* December 14, 2016.

This meeting will discuss applications to the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.

14. *Date:* December 15, 2016.

This meeting will discuss applications to the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C., as amended. The Committee Management Officer, Elizabeth Voyatzis, has made this determination pursuant to the authority granted her by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: November 8, 2016.

Elizabeth Voyatzis,

Committee Management Officer.

[FR Doc. 2016–27420 Filed 11–14–16; 8:45 am]

BILLING CODE 7536–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting

Investigation Presentation

TIME AND DATE: 9:30 a.m., Tuesday, November 15, 2016.

PLACE: NTSB Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594.

STATUS: The one item is open to the public.

STAFF PRESENTATION: *Briefs on Two Midair Collisions*—July 7, 2015, accident involving a Cessna 150M and a Lockheed Martin F–16CM near Moncks Corner, South Carolina (ERA15MA259A/B); and August 16, 2015, accident involving a Cessna 172M and a North American Rockwell NA265–60SC Sabreliner near San Diego, California (WPR15MA243A/B); Safety Recommendation Report; and Safety Alert—Preventing Midair Collisions: Don't Depend on Vision Alone.

TIME AND DATE: 1:30 p.m., Tuesday, November 15, 2016.

PLACE: NTSB Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594.

STATUS: The one item is open to the public.

MATTER TO BE CONSIDERED: 8737A *Highway Accident Report: Amphibious Passenger Vehicle* DUCK 6 *Lane Crossover Collision With Motorcoach on State Route 99, Aurora Bridge, Seattle, Washington, September 24, 2015* (HWY15MH011)

NEWS MEDIA CONTACT: Telephone: (202) 314–6100.

The press and public may enter the NTSB Conference Center one hour prior to the meeting for set up and seating.

Individuals requesting specific accommodations should contact Rochelle Hall at (202) 314–6305 or by email at *Rochelle.Hall@ntsb.gov* by Wednesday, November 10, 2016.

The public may view the meeting via a live or archived webcast by accessing a link under ''News & Events'' on the NTSB home page at *www.ntsb.gov.*

Schedule updates, including weather-related cancellations, are also available at *www.ntsb.gov.*

FOR MORE INFORMATION CONTACT: Candi Bing at (202) 314–6403 or by email at *bingc@ntsb.gov.*

FOR MEDIA INFORMATION CONTACT: Terry Williams at (202) 314–6100 or by email at *terry.williams@ntsb.gov,* or Peter Knudson at (202) 314–6100 or by email at *peter.knudson@ntsb.gov* for the aviation item.

Terry Williams at (202) 314–6100 or by email at *terry.williams@ntsb.gov,* or Keith Holloway at (202) 314–6100 or by email at *keith.holloway@ntsb.gov* for the highway item.

Wednesday, November 9, 2016.

Candi R. Bing,

Federal Register Liaison Officer.

[FR Doc. 2016–27477 Filed 11–10–16; 11:15 am]

BILLING CODE 7533–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79269; File No. SR–BatsBYX–2016–29]

Self-Regulatory Organizations; Bats BYX Exchange, Inc.; Notice of Filing of a Proposed Rule Change in Connection With the Proposed Corporate Transaction Involving Bats Global Markets, Inc. and CBOE Holdings, Inc.

November 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 2, 2016, Bats BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal in connection with the proposed corporate transaction (the ''Transaction''), as described in more detail below, involving its ultimate parent company, Bats Global Markets, Inc. (''BGM''), CBOE Holdings, Inc. (''CBOE Holdings''), and two wholly owned subsidiaries of CBOE Holdings, CBOE Corporation and CBOE V, LLC (''CBOE V''). CBOE Holdings is the parent company of Chicago Board Options Exchange, Incorporated (''CBOE'') and C2 Options Exchange, Incorporated (''C2''), each a national securities exchange registered with the Commission pursuant to Section 6(a) of the Act,[3] and CBOE Futures Exchange, LLC (''CBOE Futures,'' and together with CBOE and C2, the ''CBOE Exchanges''), a national securities exchange that lists or trades security-futures products notice-registered with the Commission pursuant to Section 6(g) of the Act.[4]

Upon completion of the mergers described below that effectuate the Transaction (the ''Closing''), the business of BGM will be carried on by CBOE V. CBOE V, rather than BGM, will be the direct parent company of Bats Global Markets Holdings, Inc. (''BGM Holdings''), which is the direct parent company of the Exchange. As a result, CBOE Holdings will become the ultimate parent company of BGM Holdings and of the Exchange.

To effectuate the Transaction, the Exchange seeks to obtain the Commission's approval of: (i) the resolutions of BGM's board of directors (the ''BGM Board'') waiving certain provisions of the Amended and Restated Certificate of Incorporation of BGM (the ''BGM Charter'') and making certain related determinations regarding CBOE Holdings and the impact of the Transaction on the Exchange (the ''Resolutions''); (ii) the CBOE Holdings Second Amended and Restated Certificate of Incorporation (the ''CBOE Holdings Charter'') and the CBOE Holdings Third Amended and Restated Bylaws (the ''CBOE Holdings Bylaws''); (iii) the Certificate of Formation of CBOE V (the ''CBOE V Certificate'') and the Limited Liability Company Operating Agreement of CBOE V (the ''CBOE V Operating Agreement''); (iv) the proposed amendments to the Amended and Restated Certificate of Incorporation of BGM Holdings (the ''BGM Holdings Charter''); (v) the proposed amendments to the Fourth Amended and Restated Bylaws of the Exchange (the ''Exchange Bylaws''); and (vi) the proposed amendments to BYX Rules 2.3 and 2.10 (the ''Exchange Rules'').

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange submits this Proposed Rule Change to seek the Commission's approval of the organizational and governance documents of the Exchange and its current and proposed future parent companies, and related actions that are necessary in connection with the Closing of the Transaction, as described below.

Other than as described herein and set forth in Exhibits 5A through 5H, the Exchange will continue to conduct its regulated activities (including operating and regulating its market and members) in the manner currently conducted, and will not make any changes to its regulated activities in connection with the Transaction. Except as set forth in this Proposed Rule Change, the Exchange is not proposing any amendments to its trading and regulatory rules at this time. If the Exchange determines to make any such changes, it will seek the approval of the Commission to the extent required by the Act, and the Commission's rules thereunder, and the Rules of the Exchange.

1. Current Corporate Structures

The Exchange, Bats BZX Exchange, Inc. (''BZX''), Bats EDGX Exchange, Inc. (''EDGX'') and Bats EDGA Exchange, Inc. (''EDGA,'' and together with the Exchange, BZX and EDGX, the ''Bats Exchanges'') are each Delaware corporations that are national securities exchanges registered with the Commission pursuant to Section 6(a) of the Act.[5]

The Exchange and BZX are each direct, wholly owned subsidiaries of BGM Holdings, a Delaware corporation that is a direct, wholly owned subsidiary of BGM. In addition to certain other subsidiaries not registered with the Commission in any capacity, BGM Holdings also owns 100 percent of the equity interest in Bats Trading, Inc. (''Bats Trading''), a Delaware corporation that is a broker-dealer registered with the Commission that provides routing services outbound from, and in certain instances inbound to, each Bats Exchange. EDGX and EDGA are direct, wholly owned subsidiaries of Direct Edge LLC, a Delaware limited liability company that is a direct, wholly owned subsidiary of BGM. BGM, a Delaware corporation, is a publicly traded company listed on BZX.

CBOE Holdings, a Delaware corporation, is a publicly traded company listed on The NASDAQ Stock Market. CBOE Holdings owns 100 percent of the equity interest in the CBOE Exchanges.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f(a).

[4] 15 U.S.C. 78f(g).

[5] 15 U.S.C. 78f(a).

In contemplation of the Transaction, CBOE Holdings formed two additional entities, CBOE Corporation, a Delaware corporation, and CBOE V, a Delaware limited liability company, each of which are direct, wholly owned subsidiaries of CBOE Holdings. Each of CBOE Corporation and CBOE V currently have no material assets or conduct any operations.

2. The Transaction

On September 25, 2016, BGM, CBOE Holdings, CBOE Corporation and CBOE V entered into an Agreement and Plan of Merger (the ''Merger Agreement''). Pursuant to and subject to the terms of the Merger Agreement, at the Closing, among other things:

(i) CBOE Corporation will be merged with and into BGM, whereupon the separate existence of CBOE Corporation will cease and BGM will be the surviving company (the ''Merger'');

(ii) by virtue of the Merger and without any action required on the part of BGM, CBOE Corporation or any holder of BGM or CBOE Corporation stock, each share of BGM common stock (whether voting or non-voting) issued and outstanding (with the exception of shares owned by CBOE Holdings, BGM or any of their respective subsidiaries and certain shares held by persons that are entitled to and properly demand appraisal rights) will be converted into the right to receive a particular number of shares of CBOE Holdings and/or cash, at the election of the holder of such share of BGM common stock (the ''Merger Consideration''), and each share of CBOE Corporation issued and outstanding will be converted into one share of BGM, such that BGM will become a wholly owned subsidiary of CBOE Holdings; and

(iii) immediately following the Merger, BGM will be merged with and into CBOE V, whereupon the separate existence of BGM will cease and CBOE V will be the surviving company (the ''Subsequent Merger'').

Upon the Closing, the BGM Holdings Charter, the Exchange Bylaws and the Exchange Rules will be amended to take into account the post-Closing corporate structure, described below.

3. Post-Closing Corporate Structure

As a result of the Transaction, BGM will cease to exist and the business of BGM will be carried on by CBOE V, which is a wholly owned subsidiary of CBOE Holdings.[6] CBOE V will own 100 percent of the equity interest in BGM Holdings and Direct Edge LLC. BGM Holdings will continue to own 100 percent of the equity interest in the Exchange, BZX, Bats Trading, and certain other subsidiaries not registered with the Commission in any capacity.[7] Direct Edge LLC will continue to own 100 percent of the equity interest in EDGX and EDGA.

4. Ownership and Voting Limitations of BGM; Resolutions

The BGM Charter provides that (i) no Person,[8] either alone or together with its Related Persons,[9] may own, directly or indirectly, of record or beneficially, shares constituting more than 40 percent of any class of its capital stock, and no Exchange Member, either alone or together with its Related Persons, may own, directly or indirectly, of record or beneficially, shares constituting more than 20 percent of any class of its capital stock (collectively, the ''BGM Ownership Limitation''); and (ii) subject to certain exceptions, no Person, either alone or together with its Related Persons, at any time, may, directly, indirectly or pursuant to any of various arrangements, vote or cause the voting of shares or give any consent or proxy with respect to shares representing more than 20 percent of the voting power of its then issued and outstanding capital stock (the ''BGM Voting Limitation'').[10] Purported transfers that would result in a violation of the BGM Ownership Limitation are not recognized by BGM to the extent of any ownership in excess of the BGM Ownership Limitation, and purported voting or voting arrangements in violation of the BGM Voting Limitation are not honored by BGM to the extent of any voting in excess of the limitation.[11]

However, the BGM Charter provides that each of the BGM Ownership Limitation and the BGM Voting Limitation may be waived (except with respect to Exchange Members and their Related Persons) pursuant to a resolution duly adopted by the BGM Board if, in connection with taking such action, the BGM Board states in such resolution that it is the determination of the BGM Board that the waiver:

- will not impair the ability of each Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder;
- is otherwise in the best interests of BGM, its stockholders, and each Bats Exchange;
- will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder; and
- shall not be effective until it is filed with and approved by the Commission.[12]

In granting such a waiver, the BGM Board has the discretion to impose on

[6] In connection with the Transaction, CBOE Holdings agreed in the Merger Agreement to take all requisite actions so, as of the Closing, the CBOE Holdings Board will include three individuals designated by BGM who (1) are serving as BGM directors immediately prior to the Closing and (2) comply with the policies (including clarifications of the policies provided to BGM) of the Nominating and Governance Committee of the CBOE Holdings Board as in effect on the date of the Merger Agreement and previously provided to BGM (each of whom will be appointed to the CBOE Holdings Board as of the Closing). The CBOE Holdings Board currently consists of 14 directors. The Exchange expects three current CBOE Holdings directors to resign effective prior to the Closing and the remaining CBOE Holdings directors to fill those vacancies with the three BGM directors designated by BGM.

[7] As described above, the Transaction will result in a change of ownership of Bats Trading, which is a member of the Financial Industry Regulatory Authority, Inc. (''FINRA''). The Exchange understands that, pursuant to NASD Rule 1017, Bats Trading is seeking approval for this change of ownership from FINRA.

[8] The BGM Charter generally defines a ''Person'' as a natural person, partnership, corporation, limited liability company, entity, government, or political subdivision, agency or instrumentality of a government. *See* BGM Charter, Art. FIFTH, para. (a)(i).

[9] The BGM Charter generally defines a ''Related Person'' as, with respect to any Person, (i) any ''affiliate'' of such Person (as defined in Rule 12b–2 under the Act); (ii) any other Person with which such first Person has any agreement, arrangement or understanding (whether or not in writing) to act together for the purpose of acquiring, voting, holding or disposing of shares of the capital stock of BGM; (iii) in the case of a Person that is a company, corporation or similar entity, any executive officer (as defined under Rule 3b–7 under the Act) or director of such Person and, in the case of a Person that is a partnership or limited liability company, any general partner, managing member or manager of such Person, as applicable; (iv) in the case of any Person that is a registered broker or dealer that has been admitted to membership in any of the Bats Exchanges (for purposes of this definition of ''Related Person,'' each such national securities exchange shall be referred to generally as an ''Exchange'' and any member of such Exchange, an ''Exchange Member''), any Person that is associated with the Exchange Member (as determined using the definition of ''person associated with a member'' as defined under Section 3(a)(21) of the Act); (v) in the case of a Person that is a natural person and Exchange Member, any broker or dealer that is also an Exchange Member with which such Person is associated; (vi) in the case of a Person that is a natural person, any relative or spouse of such Person, or any relative of such spouse who has the same home as such Person or who is a director or officer of BGM or any of its parents or subsidiaries; (vii) in the case of a Person that is an executive officer (as defined under Rule 3b–7 under the Act) or a director of a company, corporation or similar entity, such company, corporation or entity, as applicable; and (viii) in the case of a Person that is a general partner, managing member or manager of a partnership or limited liability company, such partnership or limited liability company, as applicable. *See* BGM Charter, Art. FIFTH, para. (a)(ii).

[10] *See* BGM Charter, Art. FIFTH, para. (b).

[11] *See* BGM Charter, Art. FIFTH, para. (d).

[12] *See* BGM Charter, Art. FIFTH, para. (b)(ii)(B).

the Person and its Related Persons, such conditions and restrictions that it deems necessary, appropriate or desirable in furtherance of the objectives of the Act and the rules and regulations promulgated thereunder, and the governance of each Bats Exchange.[13]

In addition, notwithstanding the above, the BGM Charter provides[14] that in any case where a Person, either alone or with its Related Persons, would own or vote more than the BGM Ownership Limitation or BGM Voting Limitation, respectively, upon consummation of any proposed sale, assignment or transfer of BGM's capital stock, such a transaction will not become effective until the BGM Board determines, by resolution, that such Person and its Related Persons are not subject to any ''statutory disqualification,'' as defined in Section 3(a)(39) of the Act.[15]

As described above, as a result of the Merger (and prior to its separate existence ceasing as a result of the Subsequent Merger), BGM will become a wholly owned subsidiary of CBOE Holdings, such that CBOE Holdings will possess ownership and voting rights in BGM in excess of the Ownership Limitation and the Voting Limitation. In addition, as a result of the Subsequent Merger, BGM will merge with and into CBOE V, terminating the BGM Charter and becoming an entity whose ownership and voting is held entirely by CBOE Holdings, in excess of the BGM Ownership Limitation and the BGM Voting Limitation that would otherwise apply.

The BGM Board therefore determined that in order to effect the Transaction, a waiver of the BGM Ownership Limitation and the BGM Voting Limitation with respect to CBOE Holdings would be required. To do so, the BGM Board adopted the Resolutions, attached as Exhibit 5A, making certain determinations with respect to CBOE Holdings and the Transaction that are necessary to waive the BGM Ownership Limitation and BGM Voting Limitation. Specifically, the BGM Board determined that:

- the acquisition of the proposed ownership by CBOE Holdings in BGM will not impair the ability of each Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder, is otherwise in the best interests of BGM, its stockholders and the Bats Exchanges, and will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder;
- the acquisition or exercise of the proposed voting rights by CBOE Holdings in BGM will not impair the ability of each Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder, is otherwise in the best interests of BGM, its stockholders and the Bats Exchanges, and will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder;
- neither CBOE Holdings nor any of its Related Persons is subject to ''statutory disqualification'' within the meaning of Section 3(a)(39) of the Act;[16] and
- neither CBOE Holdings nor any of its Related Persons is an Exchange Member.[17]

The Exchange has reviewed such Resolutions and requests that the Commission approve such Resolutions. The Exchange believes that the Commission should approve the Resolutions, as the Transaction will not impair the ability of any Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder, or the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder. The Bats Exchanges will continue to operate and regulate their markets and members as they have done prior to the Transaction. Thus, each Bats Exchange will continue to enforce the Act, the Commission's rules thereunder, and each Exchange's own rules, in the manner it does today. Further, the Commission will continue to have plenary regulatory authority over the Bats Exchanges, as is currently the case with these entities.

The Exchange also notes that the Resolutions reflect the determination by the BGM Board that the Transaction and CBOE Holdings' resulting ownership and voting rights in BGM following the Merger, and CBOE V's ownership and voting rights following the Subsequent Merger, are otherwise in the best interests of BGM, its stockholders and the Bats Exchanges. The Bats Exchanges will be ultimately held by an entity, CBOE Holdings, that already owns other national securities exchanges and is subject to governance documents that similarly restrict concentration of ownership and voting rights.

As described in more detail below, the Exchange is also requesting approval of the adoption of the CBOE Holdings Charter and the CBOE Holdings Bylaws. The CBOE Holdings Charter includes a number of provisions relating to the Commission's regulatory oversight that have a similar effect as those in the BGM Charter, including the BGM Ownership Limitation and the BGM Voting Limitation. Therefore, notwithstanding the Resolutions and the Transaction, provisions similar (and, in some cases, more stringent) to the BGM Ownership Limitation and the BGM Voting Limitation will remain in place with respect to potential future transactions involving the ultimate parent company of the Bats Exchanges. This means that the Exchange ownership structure will continue to provide the Commission with appropriate oversight tools to ensure that the Commission will have the ability to enforce the Act with respect to the Exchange, its direct and indirect parent companies, and its directors, officers, employees and agents to the extent they are involved in the activities of the Exchange, and protect the independence of the Exchange's self-regulatory activities.

The Exchange therefore requests that the Commission approve the Resolutions, attached as Exhibit 5A.

5. CBOE Holdings Charter and CBOE Holdings Bylaws

CBOE Holdings currently holds a direct ownership interest in the CBOE Exchanges. The Commission has previously approved the CBOE Holdings Charter and the CBOE Holdings Bylaws (collectively, the ''CBOE Holdings Organizational Documents''), attached as Exhibits 5B and 5C, respectively. [18]

[13] *Id.*

[14] *See* BGM Charter, Art. FIFTH, para. (b)(iii).

[15] 15 U.S.C. 78c(a)(39).

[16] *Id.*

[17] In addition, the Resolutions contain a determination that the execution and delivery of the Merger Agreement by CBOE Holdings constituted notice of CBOE Holdings' intention to acquire ownership and voting rights in excess of the BGM Ownership Limitation and BGM Voting Limitation, respectively, in writing and not less than 45 days before the Closing. *See* BGM Charter, Art. FIFTH, para. (b)(iv). The Exchange notes that Art. FIFTH, para. (c)(i) of the BGM Charter further requires that any Person that, either alone or together with its Related Persons, owns, directly or indirectly (whether by acquisition or by a change in the number of shares outstanding), of record or beneficially, five percent or more of the then outstanding shares of capital stock of BGM must immediately upon acquiring knowledge of its ownership of five percent or more give written notice of such ownership to the BGM Board. The Merger Agreement provides that the Merger Agreement constitutes such notice with respect to certain voting agreements entered into concurrently with the Merger Agreement. *See* Merger Agreement, Section 5.21.

[18] *See* Securities Exchange Act Release No. 62158 (May 24, 2010), 75 FR 30082 (May 28, 2010) (SR–CBOE–2008–88). The CBOE Organizational Documents have been subsequently amended from time to time pursuant to proposed rule changes that were filed with the Commission for immediate

Continued

In connection with the Transaction, upon the Closing, CBOE Holdings will become the indirect owner (through CBOE V and BGM Holdings) of the Exchange, BZX and Bats Trading (and certain other subsidiaries not registered with the Commission in any capacity), and the indirect owner (through CBOE V and Direct Edge LLC) of EDGA and EDGX.

The CBOE Holdings Organizational Documents include various provisions relating to any ''Regulated Securities Exchange Subsidiary,'' which is defined as any national securities exchange controlled, directly or indirectly, by CBOE Holdings. Upon the Closing, the Exchange will be covered by the definition of Regulated Securities Exchange Subsidiary for purposes of the CBOE Holdings Organizational Documents. As a result, no amendments to the CBOE Holdings Organizational Documents will be necessary to reflect CBOE Holdings' indirect ownership of the Exchange.

The Exchange believes that the CBOE Holdings Organizational Documents will protect and maintain the integrity of the self-regulatory functions of the Exchange and facilitate the ability of the Exchange and the Commission to carry out their regulatory and oversight obligations under the Act, as the CBOE Organizational Documents do with respect to the CBOE Exchanges.

In addition, the CBOE Organizational Documents contain provisions, including those with respect to the following, that are similar to those contained in the BGM Charter and BGM's Amended and Restated Bylaws (the ''BGM Bylaws''), which the Commission has previously found to be consistent with the Act: [19]

• *Ownership and Voting Limitations.* Similar to the BGM Voting Limitation and the BGM Ownership Limitation contained in the BGM Charter, the CBOE Holdings Charter limits the extent of ownership and voting rights which certain persons may possess or exercise.[20] Like the BGM Charter, the CBOE Holdings Charter similarly prohibits any Person, [21] together with its Related Persons,[22] from exercising voting rights with respect to more than 20 percent of the then outstanding votes entitled to be cast on such matter.[23] However, with respect to ownership limitations, the CBOE Holdings Charter contains a more stringent threshold than contained in the BGM Charter. Under the CBOE Holdings Charter, no Person, together with its Related Persons, is permitted at any time to beneficially own directly or indirectly shares of stock of CBOE Holdings representing in the aggregate more than 20 percent of the then outstanding shares of stock of CBOE Holdings.[24] In contrast, the BGM Ownership Limitation only applies a 20 percent threshold to any Exchange Member together with its Related Persons, while applying a 40 percent threshold to any other Person together with its Related Persons. As a result, the CBOE Holdings Charter should be at least as effective as the BGM Charter at preventing any stockholder from exercising undue control over the operation of the Exchange.

• *Independence and Non-Interference.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that for so long as CBOE Holdings controls, directly or indirectly, a Regulated Securities Exchange Subsidiary, each officer, director and employee of CBOE Holdings must give due regard to the preservation of the independence of the self-regulatory function of the Regulated Securities Exchange Subsidiaries and may not take any actions that he or she knows or reasonably should have known would interfere with the effectuation of any decisions by the board of directors of any Regulated Securities Exchange Subsidiary relating to such Regulated Securities Exchange Subsidiary's regulatory functions (including disciplinary matters) or that would adversely affect the ability of the Regulated Securities Exchange Subsidiary to carry out such Regulated Securities Exchange Subsidiary's responsibilities under the Act.[25]

• *Confidentiality.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that, to the fullest extent permitted by applicable law, all confidential information pertaining to the self-regulatory function of Regulated Securities Exchange Subsidiaries contained in the books and records of any Regulated Securities Exchange Subsidiary that shall come into the possession of the CBOE Holdings must be retained in confidence by CBOE Holdings and its officers, directors, employees and agents and must not be used for any commercial purposes.[26]

• *Books and Records.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that, for so long as CBOE Holdings directly or indirectly controls any Regulated Securities Exchange Subsidiary, the books, records, premises, officers, directors and employees of CBOE Holdings shall be deemed to be the books, records, premises, officers, directors and employees of the Regulated Securities Exchange Subsidiary for purposes of and subject to oversight pursuant to the Act, but only to the extent that such books, records, premises, officers, directors and employees of the Corporation relate to the business of such Regulated Securities Exchange Subsidiary.[27]

• *Compliance with Securities Laws; Cooperation with the Commission.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that CBOE Holdings shall comply with the federal securities laws and the rules and regulations thereunder and shall cooperate with the Commission, and each Regulated Securities Exchange Subsidiary pursuant to and to the extent of its regulatory authority, and shall take reasonable steps necessary to cause its agents to cooperate with the Commission and, where applicable, the Regulated Securities Exchange Subsidiaries pursuant to their regulatory authority, with respect to such agents' activities related to the Regulated Securities Exchange Subsidiaries.[28]

• *Consent to Jurisdiction.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that CBOE Holdings, its directors, officers, agents and employees, irrevocably submit to the jurisdiction of the U.S. federal courts, the Commission, and the Regulated Securities Exchange Subsidiaries, for the purposes of any suit, action or proceeding pursuant to U.S. federal

effectiveness. *See, e.g.,* Securities Exchange Act Release No. 76282 (October 27, 2015), 80 FR 67464 (November 2, 2015) (SR–CBOE–2015–092).

[19] *See* Securities Exchange Act Release No. 77464 (March 29, 2016), 81 FR 19252 (April 4, 2016) (File Nos. SR–BATS–2016–10, SR–BYX–2016–02, SR–EDGX–2016–04, and SR–EDGA–2016–01).

[20] *Compare* CBOE Holdings Charter, Art. SIXTH *with* BGM Charter, Art. FIFTH.

[21] ''Person'' mean an individual, partnership (general or limited), joint stock company, corporation, limited liability company, trust or unincorporated organization, or any governmental entity or agency or political subdivision thereof. *See* CBOE Holdings Charter, Art. FIFTH, para. (a)(iv).

[22] ''Related Person'' is defined in the CBOE Holdings Charter in a manner substantially the same as it is defined in the BGM Charter. *See supra* note 9; CBOE Holdings Charter, Art. FIFTH, para. (a)(vi).

[23] *See* CBOE Holdings Charter, Art. SIXTH, para. (a).

[24] *See* CBOE Holdings Charter, Art. SIXTH, para. (b).

[25] *Compare* CBOE Holdings Charter, Art. SIXTEENTH, para. (c) *with* BGM Bylaws, Section 12.01.

[26] *Compare* CBOE Holdings Charter, Art. FIFTEENTH *with* BGM Bylaws, Section 12.02.

[27] *Compare* CBOE Holdings Charter, Art. FIFTEENTH *with* BGM Bylaws, Section 12.03.

[28] *Compare* CBOE Holdings Charter, Art. SIXTEENTH, para. (a) *with* BGM Bylaws, Section 12.04.

securities laws or the rules or regulations thereunder, commenced or initiated by the Commission arising out of, or relating to, the Regulated Securities Exchange Subsidiaries' activities.[29]

• *Amendments.* Similar to provisions contained in the BGM Charter and BGM Bylaws, the CBOE Organizational Documents provide that for so long as CBOE Holdings controls, directly or indirectly, Regulated Securities Exchange, before any amendment to or repeal of the CBOE Holdings Charter or CBOE Holdings Bylaws may be effective, such amendment or repeal must be submitted to the board of directors of each such exchange, and if the amendment or repeal is required to be filed with, or filed with and approved by the Commission, then such change shall not be effective until filed with, or filed with and approved by, the Commission, as the case may be.[30]

As stated above, the Exchange believes that the foregoing provisions will assist the Exchange in fulfilling its self-regulatory obligations and in administering and complying with the requirements of the Act.

6. CBOE V Certificate and CBOE V Operating Agreement

Effective as of the Closing of the Transaction, CBOE V will hold direct ownership of (i) BGM Holdings, which will continue to hold direct ownership of the Exchange, BZX and Bats Trading (and certain other subsidiaries not registered with the Commission in any capacity) and (ii) Direct Edge LLC, which will continue to hold direct ownership of EDGX and EDGA. However, unlike BGM currently, CBOE V will not be the ultimate holding company under the post-Closing corporate structure, but rather will be an intermediate holding company owned by CBOE Holdings. The Exchange believes that the CBOE V Operating Agreement contains provisions relating to its indirect ownership of one or more national securities exchanges, including such exchanges' regulatory functions and Commission oversight, that are appropriate for an intermediate holding company in the ownership chain of a national securities exchange. Many of the provisions of the CBOE V Operating Agreement relating to these matters are similar to the organizational documents of BGM Holdings, which currently is, and following the Subsequent Merger will be, similarly situated as an intermediate holding company of the Exchange. The Commission has previously found the BGM Holdings certificate of incorporation and bylaws to be consistent with the Act.[31]

Although CBOE V will not carry out any regulatory functions, the Exchange notes that its activities with respect to the operation of the Bats Exchanges must be consistent with, and must not interfere with, the self-regulatory obligations of each Bats Exchange. The CBOE V Operating Agreement therefore includes certain provisions that are designed to maintain the independence of the Bats Exchanges' self-regulatory functions, enable the Bats Exchanges to operate in a manner that complies with the federal securities laws, including the objectives of Sections 6(b)[32] and 19(g)[33] of the Act, and facilitate the ability of each Bats Exchange and the Commission to fulfill their respective regulatory and oversight obligations under the Act.

a. CBOE V Certificate of Formation

The CBOE V Certificate, attached as Exhibit 5D, includes the following provisions required under Delaware law: (i) the full name of CBOE V as ''CBOE V, LLC'', and (ii) the name and address of CBOE V's registered office in the State of Delaware and the name of CBOE V's registered agent at such address.[34] In addition, the CBOE V Certificate contains a provision providing that CBOE V shall indemnify members of its board of directors and certain other persons, subject to certain conditions.

As the Exchange believes is customary for limited liability companies formed in the State of Delaware, other substantive provisions governing the ownership, operation and management of CBOE V are set forth in the CBOE V Operating Agreement, discussed below.

b. CBOE V Operating Agreement

With respect to ownership and control of CBOE V, the CBOE V Operating Agreement, attached as Exhibit 5E, specifically provides that CBOE V's sole member is CBOE Holdings, until the CBOE V Operating Agreement is amended (subject to Commission approval, as described below).[35] Further, for so long as CBOE V controls, directly or indirectly, a subsidiary that is registered with the Commission as a national securities exchange (an ''Exchange Subsidiary''), CBOE Holdings may not sell, assign, transfer, convey, gift, exchange or otherwise dispose of any or all of its member interest in CBOE V, except pursuant to an amendment to the CBOE V Operating Agreement that is filed with and approved by the Commission.[36] These restrictions are designed to ensure that any change to the ownership or control of any Exchange Subsidiary, including without limitation the Bats Exchanges, may only occur through a change in the ownership or control of CBOE Holdings. As such, any purported change of such ownership or control (unless pursuant to a Commission-approved change of ownership of CBOE V) would need to comply with the CBOE Holdings Charter and CBOE Holdings Bylaws, including the ownership and voting limitations discussed above (or a Commission-approved waiver therefrom).

The CBOE V Operating Agreement also contains several provisions designed to protect the independence of the self-regulatory functions of the Bats Exchanges. The CBOE V Operating Agreement requires that, for so long as CBOE V, directly or indirectly, controls any Exchange Subsidiary, CBOE Holdings, as the sole member of CBOE V, and officers, employees and agents of CBOE V must give due regard to the preservation of independence of the self-regulatory functions of such Exchange Subsidiary, as well as to its obligations to investors and the general public, and not interfere with the effectuation of any decisions by the board of directors of an Exchange Subsidiary relating to its regulatory functions (including disciplinary matters) or which would interfere with the ability of such Exchange Subsidiary to carry out its responsibilities under the Act.[37]

The CBOE V Operating Agreement also would require that CBOE V comply with the U.S. federal securities laws and rules and regulations thereunder and cooperate with the Commission and each Exchange Subsidiary, as applicable, pursuant to and to the extent of their respective regulatory authority.[38] Further, CBOE V's officers, directors, employees and agents shall be deemed to agree to (i) comply with the U.S. federal securities laws and the

[29] *Compare* CBOE Holdings Charter, Art. FOURTEENTH *with* BGM Bylaws, Section 12.05.

[30] *Compare* CBOE Holdings Charter, Arts. ELEVENTH, TWELFTH and CBOE Holdings Bylaws, Section 10.2 *with* BGM Charter, Art. FOURTEENTH and BGM Bylaws, Article XI.

[31] *See* Securities Exchange Act Release No. 71375 (January 23, 2014), 79 FR 4771 (January 29, 2014) (SR–BATS–2013–059; SR–BYX–2013–039).

[32] 15 U.S.C. 78f(b).

[33] 15 U.S.C. 78s(g).

[34] Delaware Limited Liability Company Act, Section 18–201.

[35] *See* CBOE V Operating Agreement, Section 1.1.

[36] *See* CBOE V Operating Agreement, Section 5.1.

[37] *See* CBOE V Operating Agreement, Section 10.1(a).

[38] *See* CBOE V Operating Agreement, Section 10.2(a).

rules and regulations thereunder; and (ii) cooperate with the Commission and each Exchange Subsidiary in respect of the Commission's oversight responsibilities regarding such Exchange Subsidiary and the self-regulatory functions and responsibilities of the Exchange Subsidiaries, and CBOE V will take reasonable steps to cause its officers, employees and agents to so cooperate.[39]

Furthermore, to the fullest extent permitted by law, CBOE V and its officers, directors, employees and agents will be deemed to irrevocably submit to the jurisdiction of the U.S. federal courts, the Commission, and each Exchange Subsidiary, as applicable, for purposes of any suit, action, or proceeding pursuant to the U.S. federal securities laws or the rules or regulations thereunder arising out of, or relating to, the activities of such Exchange Subsidiary.[40]

The proposed CBOE V Operating Agreement also contains a number of provisions designed to ensure that the Exchange will have sufficient access to the books and records of CBOE V as they relate to any Exchange Subsidiary. Pursuant to the CBOE V Operating Agreement, to the extent they are related to the operation or administration of an Exchange Subsidiary, the books, records, premises, officers, agents, and employees of CBOE V are deemed to be the books, records, premises, officers, agents and employees of such Exchange Subsidiary for the purposes of, and subject to oversight pursuant to, the Act.[41] In addition, for as long as CBOE V controls, directly or indirectly, an Exchange Subsidiary, CBOE V's books and records shall be subject at all times to inspection and copying by the Commission and the applicable Exchange Subsidiary, provided that such books and records are related to the operation or administration of an Exchange Subsidiary.[42]

The proposed CBOE V Operating Agreement also provides that, to the fullest extent permitted by law, all books and records of any Exchange Subsidiary reflecting confidential information pertaining to the self-regulatory function of such Exchange Subsidiary (including disciplinary matters, trading data, trading practices and audit information) that comes into the possession of CBOE V, shall be retained in confidence by CBOE V, CBOE V's officers, employees and agents and CBOE Holdings, and not used for any non-regulatory purposes.[43] The proposed CBOE V Operating Agreement provides, however, that the foregoing shall not limit or impede the rights of the Commission or an Exchange Subsidiary to access and examine such confidential information pursuant to the U.S. federal securities laws and the rules and regulations thereunder, or limit or impede the ability of CBOE Holdings or any of CBOE V's officers, employees or agents to disclose such confidential information to the Commission or an Exchange Subsidiary.[44]

In addition, the CBOE V Operating Agreement provides that for so long as CBOE V controls, directly or indirectly, any Exchange Subsidiary, before any amendment to or repeal of any provision of the CBOE V Operating Agreement will be effective, those changes must be submitted to the board of directors of each Exchange Subsidiary, and if the same must be filed with, or filed with and approved by, the Commission before the changes may be effective under Section 19 of the Act [45] and the rules promulgated thereunder, then the proposed changes shall not be effective until filed with, or filed with and approved by, the Commission, as the case may be.[46]

7. BGM Holdings Charter

The BGM Holdings Charter currently provides that the sole stockholder of BGM Holdings is BGM. However, as a result of the Transaction, CBOE V will become the sole stockholder of BGM Holdings. The Exchange proposes to amend the BGM Holdings Charter to reflect this change, as set forth in Exhibit 5F.

8. Bylaws of the Exchange

In connection with the Transaction, the Exchange proposes to amend and restate its Fourth Amended and Restated Bylaws and adopt the amended Exchange Bylaws as its Fifth Amended and Restated Bylaws, attached as Exhibit 5G. Specifically, the Exchange proposes to (i) expand the prohibition contained in Section 2 of Article XI of the Exchange Bylaws; and (ii) add a definition of ''Trading Permit Holder'' to Article I.

Currently, Section 2 of Article XI of the Exchange Bylaws prohibits directors of BGM or BGM Holdings who are not also directors, officers, staff, counsel or advisors of the Exchange from participating in any meetings of the Exchange's board of directors (or any committee thereof) pertaining to the self-regulatory function of the Exchange (including disciplinary matters). This provision refers to BGM and BGM Holdings because they are currently the only direct and indirect owners of the Exchange. However, following the Transaction, the Exchange will be owned indirectly by CBOE V and CBOE Holdings (in addition to its direct ownership by BGM Holdings). Therefore, the Exchange is proposing to remove the reference to BGM and insert references to CBOE V and CBOE Holdings, so that CBOE V and CBOE Holdings will both be covered by this prohibition. The Exchange believes that this amendment will protect the independence of the Exchange's self-regulatory activities.

In addition, as noted above, the CBOE Holdings Charter currently prohibits certain persons from owning or exercising voting rights over certain percentages of ownership of CBOE Holdings. The CBOE Holdings Charter permits the board of directors of CBOE Holdings to waive the limitation on the exercise of voting rights in excess of 20 percent of the then outstanding votes entitled to be cast on such matter only if, among other things, ''for so long as [CBOE Holdings] directly or indirectly controls any Regulated Securities Exchange Subsidiary, neither such Person nor any of its Related Persons is a 'Trading Permit Holder' (as defined in the Bylaws of any Regulated Securities Exchange Subsidiary as they may be amended from time to time).'' [47]

The Exchange does not issue ''trading permits,'' but admits members. The Exchange believes the provisions of the CBOE Holdings Charter that refer to Trading Permit Holders of its Regulated Securities Exchange Subsidiaries should apply equally to members of the Exchange once it becomes a Regulated Securities Exchange Subsidiary of CBOE Holdings. As a result, the Exchange proposes to add clause (ff) to Article I of the Exchange Bylaws, providing that '' 'Trading Permit Holder' shall have the same meaning as Exchange Member.'' This will ensure that the Exchange's members will be considered Trading Permit Holders of a Regulated Securities Exchange Subsidiary for purposes of the CBOE Holdings Charter.

[39] *Id.*

[40] *See* CBOE V Operating Agreement, Section 10.3(a).

[41] *See* CBOE V Operating Agreement, Section 8.4(b).

[42] *Id.*

[43] *See* CBOE V Operating Agreement, Section 8.4(a).

[44] *Id.*

[45] 15 U.S.C. 78s.

[46] *See* CBOE V Operating Agreement, Section 11.2.

[47] *See* CBOE Holdings Charter, Art. SIXTH, para. (a)(ii)(C).

9. Exchange Rules

a. Exchange Rule 2.3—Member Eligibility

Pursuant to Exchange Rule 2.3, in order to be eligible for membership in the Exchange, a registered broker or dealer is currently required to be a member of at least one other national securities association or national securities exchange. However, membership in the Exchange's affiliated national securities exchanges, BZX, EDGA or EDGX, is not sufficient for purposes of eligibility for Exchange membership. The Exchange adopted this because the Bats Exchanges have historically not functioned as the designated examining authority for any of its members, and the Exchange wanted to be sure that any member would be appropriately supervised by another national securities association or national securities exchange that has the capacity to function as the member's designated examining authority.

As a result of the Transaction, the Exchange will additionally become affiliated with the CBOE Exchanges. As with the Bats Exchanges, C2 does not currently serve as the designated examination authority for any of its members. CBOE, however, does act as the designated examining authority for certain of its members. Therefore, the Exchange proposes to amend Exchange Rule 2.3 to specify that a registered broker or dealer will be eligible for membership only if it is a member of a national securities association or national securities exchange other than or in addition to the following affiliates of the Exchange: BZX, EDGA, EDGX and C2.

In addition, to ensure there is no confusion with respect to the possibility that a broker or dealer could qualify for membership in the Exchange based solely on membership in CBOE Futures or any other national securities exchange notice-registered with the Commission pursuant to Section 6(g) of the Act [48] that lists or trades security-futures products, the Exchange proposes to also specify that eligibility for membership requires membership in a national securities association registered pursuant to Section 15A of the Act or a national securities exchange registered with the Commission pursuant to Section 6(a) of the Act, so as to exclude a national securities exchange registered solely under Section 6(g) of the Act. The proposed amendments to Exchange Rule 2.3 are set forth in Exhibit 5H.

b. Exchange Rule 2.10—No Affiliation Between Exchange and any Member

Exchange Rule 2.10 provides that, without prior approval of the Commission, neither the Exchange, nor any of its affiliates, shall directly or indirectly acquire or maintain an ownership interest in a member of the Exchange. This restriction is intended to address potential conflicts of interest that could result from affiliation between the Exchange and a member. Notwithstanding this general restriction, Exchange Rule 2.10 provides that it does not prohibit a member or its affiliate from acquiring or holding an equity interest in BGM that is permitted by the ownership and voting limitations contained in the BGM Charter and the BGM Bylaws. In addition, Exchange Rule 2.10 states that it does not prohibit a member from being or becoming an affiliate of the Exchange, or an affiliate of any affiliate of the Exchange, solely by reason of such member or any officer, director, manager, managing member, partner or affiliate of such member being or becoming either (a) a Director of the Exchange pursuant to the Bylaws of the Exchange, or (b) a Director of the Exchange serving on the Board of Directors of BGM. The Exchange proposes to replace the references to BGM in Rule 2.10 with references to CBOE Holdings to reflect the fact that following the Transaction, CBOE Holdings will replace BGM as the ultimate parent holding company of the Exchange. In addition to these changes, the Exchange proposes to replace all references in Rule 2.10 to ''By-Laws'' with ''Bylaws'' in order to maintain consistency with the actual documents referred to and EDGA and EDGX Rules 2.10. The proposed amendments to Exchange Rule 2.10 are set forth in Exhibit 5H.

2. Statutory Basis

The Exchange believes that the Proposed Rule Change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[49] In particular, the proposal is consistent with Section 6(b)(1) of the Act [50] in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the Rules of the Exchange.

The Proposed Rule Change is designed to enable the Exchange to continue to have the authority and ability to effectively fulfill its self-regulatory duties pursuant to the Act and the rules promulgated thereunder. In particular, the Proposed Rule Change includes in the CBOE Holdings Charter and CBOE Holdings Bylaws, like the BGM Charter and BGM Bylaws, various provisions intended to protect and maintain the integrity of the self-regulatory functions of the Exchange upon Closing. For example, the CBOE Holdings Charter, as described above, is drafted to preserve the independence of the Exchange's self-regulatory function and carry out its regulatory responsibilities under the Act. In addition, the CBOE Holdings Charter imposes limitations similar to the BGM Ownership Limitation and BGM Voting Limitation to preclude undue influence over or interference with the Exchange's self-regulatory functions and fulfillment of its regulatory duties under the Act.

Moreover, notwithstanding the Proposed Rule Change, including the change to the indirect ownership of the Exchange, the Commission will continue to have regulatory authority over the Exchange, as is currently the case, as well as jurisdiction over the Exchange's direct and indirect parent companies with respect to activities related to the Exchange.[51] As a result, the Proposed Rule Change will facilitate an ownership structure that will provide the Commission with appropriate oversight tools to ensure that the Commission will have the ability to enforce the Act with respect to the Exchange, its direct and indirect parent companies and their directors, officers, employees and agents to the extent they are involved in the activities of the Exchange.

The Exchange also believes that the Proposed Rule Change furthers the objectives of Section 6(b)(5) of the Act [52] because the Proposed Rule Change would be consistent with and facilitate a governance and regulatory structure that is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the

[48] 15 U.S.C. 78f(g).

[49] 15 U.S.C. 78f(b).

[50] 15 U.S.C. 78f(b)(1).

[51] *See, e.g.,* CBOE Holdings Charter, Art. FOURTEENTH; CBOE V Operating Agreement, Section 10.3; BGM Holdings Bylaws, Section 7.3.

[52] 15 U.S.C. 78f(b)(5).

mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

In addition, as discussed further in the Exchange's Statement on Burden on Competition below, the Exchange expects that the Transaction will foster further innovation while facilitating efficient, transparent and well-regulated markets for issuers and investors, removing impediments to, and perfecting the mechanism of a free and open market and a national market system. The Transaction will benefit investors and the securities market as a whole by, among other things, enhancing competition among securities venues and reducing costs.

Furthermore, the Exchange is not proposing any significant changes to its existing operational and trading structure in connection with the change in ownership; the Exchange will operate in essentially the same manner upon Closing as it operates today. Therefore, the Exchange believes that it will continue to satisfy the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange. The changes that the Exchange is proposing to the Exchange Rules are designed to reflect the prospective affiliation with CBOE Holdings and the CBOE Exchanges. The Exchange believes that the proposed change to its Rules is consistent with the requirements of the Act and the rules and regulations thereunder.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the Proposed Rule Change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Indeed, the Exchange believes that the Proposed Rule Change will enhance competition among trading venues, as the Exchange believes that the Transaction will result in various synergies and efficiencies. For example, the Transaction will allow the Bats Exchanges and the CBOE Exchanges to utilize a single technology platform, which the Exchange expects will reduce Bats Exchanges' and the CBOE Exchanges' combined costs, creating the opportunity to further reduce costs to their respective members and other constituents. The potential use of a single technology platform may also reduce investors' costs of connecting to and using the Bats Exchanges and the CBOE Exchanges, including through the combination of data centers and market data services. Combining the expertise of the CBOE Exchanges' personnel with the expertise of the Bats Exchanges' personnel will also facilitate ongoing innovation, including through new product creation and platform improvements.

The Exchange notes that the Bats Exchanges and the CBOE Exchanges generally operate with different business models, target different customer bases and primarily focus on different asset classes, limiting any concern that the Transaction could burden competition. Therefore, the Exchange expects that the Transaction will benefit investors, issuers, shareholders and the market as a whole. The Exchange will continue to conduct regulated activities (including operating and regulating its market and members) of the type it currently conducts, but will be able to do so in a more efficient manner to the benefit of its members. These efficiencies will pass through to the benefit of investors and issuers, promoting further efficiencies, competition and capital formation, placing no burden on competition not necessary or appropriate in furtherance of the Act.

Furthermore, the Exchange's conclusion that the Proposed Rule Change would not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act is consistent with the Commission's prior conclusions about similar combinations involving multiple exchanges in a single corporate family.[53]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited or received written comments on the Proposed Rule Change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BatsBYX–2016–29 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsBYX–2016–29. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsBYX–2016–29, and should be submitted on or before December 6, 2016.

[53] *See, e.g.,* Securities Exchange Act Release Nos. 71375 (January 23, 2014), 79 FR 4771 (January 29, 2014) (SR–BATS–2013–059; SR–BYX–2013–039); 66071 (December 29, 2011), 77 FR 521 (January 5, 2012) (SR–CBOE–2011–107 and SR–NSX–2011–14); 58324 (August 7, 2008), 73 FR 46936 (August 12, 2008) (SR–BSE–2008–02; SR–BSE–2008–23; SR–BSE–2008–25; SR–BSECC–2008–01); 53382 (February 27, 2006), 71 FR 11251 (March 6, 2006) (SR–NYSE–2005–77).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[54]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27374 Filed 11–14–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79266; File No. SR–BatsBZX–2016–68]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change in Connection With the Proposed Corporate Transaction Involving Bats Global Markets, Inc. and CBOE Holdings, Inc.

November 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 2, 2016, Bats BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposed rule change (the ''Proposed Rule Change'') in connection with the proposed corporate transaction (the ''Transaction''), as described in more detail below, involving its ultimate parent company, Bats Global Markets, Inc. (''BGM''), CBOE Holdings, Inc. (''CBOE Holdings''), and two wholly owned subsidiaries of CBOE Holdings, CBOE Corporation and CBOE V, LLC (''CBOE V''). CBOE Holdings is the parent company of Chicago Board Options Exchange, Incorporated (''CBOE'') and C2 Options Exchange, Incorporated (''C2''), each a national securities exchange registered with the Commission pursuant to Section 6(a) of the Act,[3] and CBOE Futures Exchange, LLC (''CBOE Futures,'' and together with CBOE and C2, the ''CBOE Exchanges''), a national securities exchange that lists or trades security-futures products notice-registered with the Commission pursuant to Section 6(g) of the Act.[4]

Upon completion of the mergers described below that effectuate the Transaction (the ''Closing''), the business of BGM will be carried on by CBOE V. CBOE V, rather than BGM, will be the direct parent company of Bats Global Markets Holdings, Inc. (''BGM Holdings''), which is the direct parent company of the Exchange. As a result, CBOE Holdings will become the ultimate parent company of BGM Holdings and of the Exchange.

To effectuate the Transaction, the Exchange seeks to obtain the Commission's approval of: (i) The resolutions of BGM's board of directors (the ''BGM Board'') waiving certain provisions of the Amended and Restated Certificate of Incorporation of BGM (the ''BGM Charter'') and making certain related determinations regarding CBOE Holdings and the impact of the Transaction on the Exchange (the ''Resolutions''); (ii) the CBOE Holdings Second Amended and Restated Certificate of Incorporation (the ''CBOE Holdings Charter'') and the CBOE Holdings Third Amended and Restated Bylaws (the ''CBOE Holdings Bylaws''); (iii) the Certificate of Formation of CBOE V (the ''CBOE V Certificate'') and the Limited Liability Company Operating Agreement of CBOE V (the ''CBOE V Operating Agreement''); (iv) the proposed amendments to the Amended and Restated Certificate of Incorporation of BGM Holdings (the ''BGM Holdings Charter''); (v) the proposed amendments to the Fourth Amended and Restated Bylaws of the Exchange (the ''Exchange Bylaws''); and (vi) the proposed amendments to BZX Rules 2.3 and 2.10 (the ''Exchange Rules'').

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange submits this Proposed Rule Change to seek the Commission's approval of the organizational and governance documents of the Exchange and its current and proposed future parent companies, and related actions that are necessary in connection with the Closing of the Transaction, as described below.

Other than as described herein and set forth in Exhibits 5A through 5H, the Exchange will continue to conduct its regulated activities (including operating and regulating its market and members) in the manner currently conducted, and will not make any changes to its regulated activities in connection with the Transaction. Except as set forth in this Proposed Rule Change, the Exchange is not proposing any amendments to its trading and regulatory rules at this time. If the Exchange determines to make any such changes, it will seek the approval of the Commission to the extent required by the Act, and the Commission's rules thereunder, and the Rules of the Exchange.

1. Current Corporate Structures

The Exchange, Bats BYX Exchange, Inc. (''BYX''), Bats EDGX Exchange, Inc. (''EDGX'') and Bats EDGA Exchange, Inc. (''EDGA,'' and together with the Exchange, BYX and EDGX, the ''Bats Exchanges'') are each Delaware corporations that are national securities exchanges registered with the Commission pursuant to Section 6(a) of the Act.[5]

The Exchange and BYX are each direct, wholly owned subsidiaries of BGM Holdings, a Delaware corporation that is a direct, wholly owned subsidiary of BGM. In addition to certain other subsidiaries not registered with the Commission in any capacity, BGM Holdings also owns 100 percent of the equity interest in Bats Trading, Inc. (''Bats Trading''), a Delaware corporation that is a broker-dealer registered with the Commission that provides routing services outbound from, and in certain instances inbound to, each Bats Exchange. EDGX and EDGA are direct, wholly owned subsidiaries of Direct Edge LLC, a

[54] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f(a).

[4] 15 U.S.C. 78f(g).

[5] 15 U.S.C. 78f(a).

Delaware limited liability company that is a direct, wholly owned subsidiary of BGM. BGM, a Delaware corporation, is a publicly traded company listed on the Exchange.

CBOE Holdings, a Delaware corporation, is a publicly traded company listed on The NASDAQ Stock Market. CBOE Holdings owns 100 percent of the equity interest in the CBOE Exchanges.

In contemplation of the Transaction, CBOE Holdings formed two additional entities, CBOE Corporation, a Delaware corporation, and CBOE V, a Delaware limited liability company, each of which are direct, wholly owned subsidiaries of CBOE Holdings. Each of CBOE Corporation and CBOE V currently have no material assets or conduct any operations.

2. The Transaction

On September 25, 2016, BGM, CBOE Holdings, CBOE Corporation and CBOE V entered into an Agreement and Plan of Merger (the ''Merger Agreement''). Pursuant to and subject to the terms of the Merger Agreement, at the Closing, among other things:

(i) CBOE Corporation will be merged with and into BGM, whereupon the separate existence of CBOE Corporation will cease and BGM will be the surviving company (the ''Merger'');

(ii) by virtue of the Merger and without any action required on the part of BGM, CBOE Corporation or any holder of BGM or CBOE Corporation stock, each share of BGM common stock (whether voting or non-voting) issued and outstanding (with the exception of shares owned by CBOE Holdings, BGM or any of their respective subsidiaries and certain shares held by persons that are entitled to and properly demand appraisal rights) will be converted into the right to receive a particular number of shares of CBOE Holdings and/or cash, at the election of the holder of such share of BGM common stock (the ''Merger Consideration''), and each share of CBOE Corporation issued and outstanding will be converted into one share of BGM, such that BGM will become a wholly owned subsidiary of CBOE Holdings; and

(iii) immediately following the Merger, BGM will be merged with and into CBOE V, whereupon the separate existence of BGM will cease and CBOE V will be the surviving company (the ''Subsequent Merger'').

Upon the Closing, the BGM Holdings Charter, the Exchange Bylaws and the Exchange Rules will be amended to take into account the post-Closing corporate structure, described below.

3. Post-Closing Corporate Structure

As a result of the Transaction, BGM will cease to exist and the business of BGM will be carried on by CBOE V, which is a wholly owned subsidiary of CBOE Holdings.[6] CBOE V will own 100 percent of the equity interest in BGM Holdings and Direct Edge LLC. BGM Holdings will continue to own 100 percent of the equity interest in the Exchange, BYX, Bats Trading, and certain other subsidiaries not registered with the Commission in any capacity.[7] Direct Edge LLC will continue to own 100 percent of the equity interest in EDGX and EDGA.

4. Ownership and Voting Limitations of BGM; Resolutions

The BGM Charter provides that (i) no Person,[8] either alone or together with its Related Persons,[9] may own, directly or indirectly, of record or beneficially, shares constituting more than 40 percent of any class of its capital stock, and no Exchange Member, either alone or together with its Related Persons, may own, directly or indirectly, of record or beneficially, shares constituting more than 20 percent of any class of its capital stock (collectively, the ''BGM Ownership Limitation''); and (ii) subject to certain exceptions, no Person, either alone or together with its Related Persons, at any time, may, directly, indirectly or pursuant to any of various arrangements, vote or cause the voting of shares or give any consent or proxy with respect to shares representing more than 20 percent of the voting power of its then issued and outstanding capital stock (the ''BGM Voting Limitation'').[10] Purported transfers that would result in a violation of the BGM Ownership Limitation are not recognized by BGM to the extent of any ownership in excess of the BGM Ownership Limitation, and purported voting or voting arrangements in violation of the BGM Voting Limitation are not honored by BGM to the extent of any voting in excess of the limitation.[11]

However, the BGM Charter provides that each of the BGM Ownership Limitation and the BGM Voting Limitation may be waived (except with respect to Exchange Members and their Related Persons) pursuant to a resolution duly adopted by the BGM Board if, in connection with taking such action, the BGM Board states in such resolution that it is the determination of the BGM Board that the waiver:

- Will not impair the ability of each Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder;
- is otherwise in the best interests of BGM, its stockholders, and each Bats Exchange;

[6] In connection with the Transaction, CBOE Holdings agreed in the Merger Agreement to take all requisite actions so, as of the Closing, the CBOE Holdings Board will include three individuals designated by BGM who (1) are serving as BGM directors immediately prior to the Closing and (2) comply with the policies (including clarifications of the policies provided to BGM) of the Nominating and Governance Committee of the CBOE Holdings Board as in effect on the date of the Merger Agreement and previously provided to BGM (each of whom will be appointed to the CBOE Holdings Board as of the Closing). The CBOE Holdings Board currently consists of 14 directors. The Exchange expects three current CBOE Holdings directors to resign effective prior to the Closing and the remaining CBOE Holdings directors to fill those vacancies with the three BGM directors designated by BGM.

[7] As described above, the Transaction will result in a change of ownership of Bats Trading, which is a member of the Financial Industry Regulatory Authority, Inc. (''FINRA''). The Exchange understands that, pursuant to NASD Rule 1017, Bats Trading is seeking approval for this change of ownership from FINRA.

[8] The BGM Charter generally defines a ''Person'' as a natural person, partnership, corporation, limited liability company, entity, government, or political subdivision, agency or instrumentality of a government. *See* BGM Charter, Art. FIFTH, para. (a)(i).

[9] The BGM Charter generally defines a ''Related Person'' as, with respect to any Person, (i) any ''affiliate'' of such Person (as defined in Rule 12b–2 under the Act); (ii) any other Person with which such first Person has any agreement, arrangement or understanding (whether or not in writing) to act together for the purpose of acquiring, voting, holding or disposing of shares of the capital stock of BGM; (iii) in the case of a Person that is a company, corporation or similar entity, any executive officer (as defined under Rule 3b–7 under the Act) or director of such Person and, in the case of a Person that is a partnership or limited liability company, any general partner, managing member or manager of such Person, as applicable; (iv) in the case of any Person that is a registered broker or dealer that has been admitted to membership in any of the Bats Exchanges (for purposes of this definition of ''Related Person,'' each such national securities exchange shall be referred to generally as an ''Exchange'' and any member of such Exchange, an ''Exchange Member''), any Person that is associated with the Exchange Member (as determined using the definition of ''person associated with a member'' as defined under Section 3(a)(21) of the Act); (v) in the case of a Person that is a natural person and Exchange Member, any broker or dealer that is also an Exchange Member with which such Person is associated; (vi) in the case of a Person that is a natural person, any relative or spouse of such Person, or any relative of such spouse who has the same home as such Person or who is a director or officer of BGM or any of its parents or subsidiaries; (vii) in the case of a Person that is an executive officer (as defined under Rule 3b–7 under the Act) or a director of a company, corporation or similar entity, such company, corporation or entity, as applicable; and (viii) in the case of a Person that is a general partner, managing member or manager of a partnership or limited liability company, such partnership or limited liability company, as applicable. *See* BGM Charter, Art. FIFTH, para. (a)(ii).

[10] *See* BGM Charter, Art. FIFTH, para. (b).

[11] *See* BGM Charter, Art. FIFTH, para. (d).

• will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder; and

• shall not be effective until it is filed with and approved by the Commission.[12]

In granting such a waiver, the BGM Board has the discretion to impose on the Person and its Related Persons, such conditions and restrictions that it deems necessary, appropriate or desirable in furtherance of the objectives of the Act and the rules and regulations promulgated thereunder, and the governance of each Bats Exchange.[13]

In addition, notwithstanding the above, the BGM Charter provides [14] that in any case where a Person, either alone or with its Related Persons, would own or vote more than the BGM Ownership Limitation or BGM Voting Limitation, respectively, upon consummation of any proposed sale, assignment or transfer of BGM's capital stock, such a transaction will not become effective until the BGM Board determines, by resolution, that such Person and its Related Persons are not subject to any ''statutory disqualification,'' as defined in Section 3(a)(39) of the Act.[15]

As described above, as a result of the Merger (and prior to its separate existence ceasing as a result of the Subsequent Merger), BGM will become a wholly owned subsidiary of CBOE Holdings, such that CBOE Holdings will possess ownership and voting rights in BGM in excess of the Ownership Limitation and the Voting Limitation. In addition, as a result of the Subsequent Merger, BGM will merge with and into CBOE V, terminating the BGM Charter and becoming an entity whose ownership and voting is held entirely by CBOE Holdings, in excess of the BGM Ownership Limitation and the BGM Voting Limitation that would otherwise apply.

The BGM Board therefore determined that in order to effect the Transaction, a waiver of the BGM Ownership Limitation and the BGM Voting Limitation with respect to CBOE Holdings would be required. To do so, the BGM Board adopted the Resolutions, attached as Exhibit 5A, making certain determinations with respect to CBOE Holdings and the Transaction that are necessary to waive the BGM Ownership Limitation and BGM Voting Limitation. Specifically, the BGM Board determined that:

• The acquisition of the proposed ownership by CBOE Holdings in BGM will not impair the ability of each Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder, is otherwise in the best interests of BGM, its stockholders and the Bats Exchanges, and will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder;

• the acquisition or exercise of the proposed voting rights by CBOE Holdings in BGM will not impair the ability of each Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder, is otherwise in the best interests of BGM, its stockholders and the Bats Exchanges, and will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder;

• neither CBOE Holdings nor any of its Related Persons is subject to ''statutory disqualification'' within the meaning of Section 3(a)(39) of the Act; [16] and

• neither CBOE Holdings nor any of its Related Persons is an Exchange Member.[17]

The Exchange has reviewed such Resolutions and requests that the Commission approve such Resolutions. The Exchange believes that the Commission should approve the Resolutions, as the Transaction will not impair the ability of any Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder, or the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder. The Bats Exchanges will continue to operate and regulate their markets and members as they have done prior to the Transaction. Thus, each Bats Exchange will continue to enforce the Act, the Commission's rules thereunder, and each Exchange's own rules, in the manner it does today. Further, the Commission will continue to have plenary regulatory authority over the Bats Exchanges, as is currently the case with these entities.

The Exchange also notes that the Resolutions reflect the determination by the BGM Board that the Transaction and CBOE Holdings' resulting ownership and voting rights in BGM following the Merger, and CBOE V's ownership and voting rights following the Subsequent Merger, are otherwise in the best interests of BGM, its stockholders and the Bats Exchanges. The Bats Exchanges will be ultimately held by an entity, CBOE Holdings, that already owns other national securities exchanges and is subject to governance documents that similarly restrict concentration of ownership and voting rights.

As described in more detail below, the Exchange is also requesting approval of the adoption of the CBOE Holdings Charter and the CBOE Holdings Bylaws. The CBOE Holdings Charter includes a number of provisions relating to the Commission's regulatory oversight that have a similar effect as those in the BGM Charter, including the BGM Ownership Limitation and the BGM Voting Limitation. Therefore, notwithstanding the Resolutions and the Transaction, provisions similar (and, in some cases, more stringent) to the BGM Ownership Limitation and the BGM Voting Limitation will remain in place with respect to potential future transactions involving the ultimate parent company of the Bats Exchanges. This means that the Exchange ownership structure will continue to provide the Commission with appropriate oversight tools to ensure that the Commission will have the ability to enforce the Act with respect to the Exchange, its direct and indirect parent companies, and its directors, officers, employees and agents to the extent they are involved in the activities of the Exchange, and protect the independence of the Exchange's self-regulatory activities.

The Exchange therefore requests that the Commission approve the Resolutions, attached as Exhibit 5A.

5. CBOE Holdings Charter and CBOE Holdings Bylaws

CBOE Holdings currently holds a direct ownership interest in the CBOE Exchanges. The Commission has

[12] *See* BGM Charter, Art. FIFTH, para. (b)(ii)(B).

[13] *Id.*

[14] *See* BGM Charter, Art. FIFTH, para. (b)(iii).

[15] 15 U.S.C. 78c(a)(39).

[16] *Id.*

[17] In addition, the Resolutions contain a determination that the execution and delivery of the Merger Agreement by CBOE Holdings constituted notice of CBOE Holdings' intention to acquire ownership and voting rights in excess of the BGM Ownership Limitation and BGM Voting Limitation, respectively, in writing and not less than 45 days before the Closing. *See* BGM Charter, Art. FIFTH, para. (b)(iv). The Exchange notes that Art. FIFTH, para. (c)(i) of the BGM Charter further requires that any Person that, either alone or together with its Related Persons, owns, directly or indirectly (whether by acquisition or by a change in the number of shares outstanding), of record or beneficially, five percent or more of the then outstanding shares of capital stock of BGM must immediately upon acquiring knowledge of its ownership of five percent or more give written notice of such ownership to the BGM Board. The Merger Agreement provides that the Merger Agreement constitutes such notice with respect to certain voting agreements entered into concurrently with the Merger Agreement. *See* Merger Agreement, Section 5.21.

previously approved the CBOE Holdings Charter and the CBOE Holdings Bylaws (collectively, the ''CBOE Holdings Organizational Documents''), attached as Exhibits 5B and 5C, respectively.[18]

In connection with the Transaction, upon the Closing, CBOE Holdings will become the indirect owner (through CBOE V and BGM Holdings) of the Exchange, BYX and Bats Trading (and certain other subsidiaries not registered with the Commission in any capacity), and the indirect owner (through CBOE V and Direct Edge LLC) of EDGA and EDGX.

The CBOE Holdings Organizational Documents include various provisions relating to any ''Regulated Securities Exchange Subsidiary,'' which is defined as any national securities exchange controlled, directly or indirectly, by CBOE Holdings. Upon the Closing, the Exchange will be covered by the definition of Regulated Securities Exchange Subsidiary for purposes of the CBOE Holdings Organizational Documents. As a result, no amendments to the CBOE Holdings Organizational Documents will be necessary to reflect CBOE Holdings' indirect ownership of the Exchange.

The Exchange believes that the CBOE Holdings Organizational Documents will protect and maintain the integrity of the self-regulatory functions of the Exchange and facilitate the ability of the Exchange and the Commission to carry out their regulatory and oversight obligations under the Act, as the CBOE Organizational Documents do with respect to the CBOE Exchanges.

In addition, the CBOE Organizational Documents contain provisions, including those with respect to the following, that are similar to those contained in the BGM Charter and BGM's Amended and Restated Bylaws (the ''BGM Bylaws''), which the Commission has previously found to be consistent with the Act: [19]

• *Ownership and Voting Limitations.* Similar to the BGM Voting Limitation and the BGM Ownership Limitation contained in the BGM Charter, the CBOE Holdings Charter limits the extent of ownership and voting rights which certain persons may possess or exercise.[20] Like the BGM Charter, the CBOE Holdings Charter similarly prohibits any Person,[21] together with its Related Persons,[22] from exercising voting rights with respect to more than 20 percent of the then outstanding votes entitled to be cast on such matter.[23] However, with respect to ownership limitations, the CBOE Holdings Charter contains a more stringent threshold than contained in the BGM Charter. Under the CBOE Holdings Charter, no Person, together with its Related Persons, is permitted at any time to beneficially own directly or indirectly shares of stock of CBOE Holdings representing in the aggregate more than 20 percent of the then outstanding shares of stock of CBOE Holdings.[24] In contrast, the BGM Ownership Limitation only applies a 20 percent threshold to any Exchange Member together with its Related Persons, while applying a 40 percent threshold to any other Person together with its Related Persons. As a result, the CBOE Holdings Charter should be at least as effective as the BGM Charter at preventing any stockholder from exercising undue control over the operation of the Exchange.

• *Independence and Non-Interference.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that for so long as CBOE Holdings controls, directly or indirectly, a Regulated Securities Exchange Subsidiary, each officer, director and employee of CBOE Holdings must give due regard to the preservation of the independence of the self-regulatory function of the Regulated Securities Exchange Subsidiaries and may not take any actions that he or she knows or reasonably should have known would interfere with the effectuation of any decisions by the board of directors of any Regulated Securities Exchange Subsidiary relating to such Regulated Securities Exchange Subsidiary's regulatory functions (including disciplinary matters) or that would adversely affect the ability of the Regulated Securities Exchange Subsidiary to carry out such Regulated Securities Exchange Subsidiary's responsibilities under the Act.[25]

• *Confidentiality.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that, to the fullest extent permitted by applicable law, all confidential information pertaining to the self-regulatory function of Regulated Securities Exchange Subsidiaries contained in the books and records of any Regulated Securities Exchange Subsidiary that shall come into the possession of the CBOE Holdings must be retained in confidence by CBOE Holdings and its officers, directors, employees and agents and must not be used for any commercial purposes.[26]

• *Books and Records.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that, for so long as CBOE Holdings directly or indirectly controls any Regulated Securities Exchange Subsidiary, the books, records, premises, officers, directors and employees of CBOE Holdings shall be deemed to be the books, records, premises, officers, directors and employees of the Regulated Securities Exchange Subsidiary for purposes of and subject to oversight pursuant to the Act, but only to the extent that such books, records, premises, officers, directors and employees of the Corporation relate to the business of such Regulated Securities Exchange Subsidiary.[27]

• *Compliance With Securities Laws; Cooperation With the Commission.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that CBOE Holdings shall comply with the federal securities laws and the rules and regulations thereunder and shall cooperate with the Commission, and each Regulated Securities Exchange Subsidiary pursuant to and to the extent of its regulatory authority, and shall take reasonable steps necessary to cause its agents to cooperate with the Commission and, where applicable, the Regulated Securities Exchange Subsidiaries pursuant to their regulatory authority, with respect to such agents' activities related to the Regulated Securities Exchange Subsidiaries.[28]

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[18] *See* Securities Exchange Act Release No. 62158 (May 24, 2010), 75 FR 30082 (May 28, 2010) (SR–CBOE–2008–88). The CBOE Organizational Documents have been subsequently amended from time to time pursuant to proposed rule changes that were filed with the Commission for immediate effectiveness. *See, e.g.,* Securities Exchange Act Release No. 76282 (October 27, 2015), 80 FR 67464 (November 2, 2015) (SR–CBOE–2015–092).

[19] *See* Securities Exchange Act Release No. 77464 (March 29, 2016), 81 FR 19252 (April 4, 2016) (File Nos. SR–BATS–2016–10, SR–BYX–2016–02, SR–EDGX–2016–04, and SR–EDGA–2016–01).

[20] *Compare* CBOE Holdings Charter, Art. SIXTH *with* BGM Charter, Art. FIFTH.

[21] ''Person'' mean an individual, partnership (general or limited), joint stock company, corporation, limited liability company, trust or unincorporated organization, or any governmental entity or agency or political subdivision thereof. *See* CBOE Holdings Charter, Art. FIFTH, para. (a)(iv).

[22] ''Related Person'' is defined in the CBOE Holdings Charter in a manner substantially the same as it is defined in the BGM Charter. *See supra* note 9; CBOE Holdings Charter, Art. FIFTH, para. (a)(vi).

[23] *See* CBOE Holdings Charter, Art. SIXTH, para. (a).

[24] *See* CBOE Holdings Charter, Art. SIXTH, para. (b).

[25] *Compare* CBOE Holdings Charter, Art. SIXTEENTH, para. (c) *with* BGM Bylaws, Section 12.01.

[26] *Compare* CBOE Holdings Charter, Art. FIFTEENTH *with* BGM Bylaws, Section 12.02.

[27] *Compare* CBOE Holdings Charter, Art. FIFTEENTH *with* BGM Bylaws, Section 12.03.

[28] *Compare* CBOE Holdings Charter, Art. SIXTEENTH, para. (a) *with* BGM Bylaws, Section 12.04.

• *Consent to Jurisdiction.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that CBOE Holdings, its directors, officers, agents and employees, irrevocably submit to the jurisdiction of the U.S. federal courts, the Commission, and the Regulated Securities Exchange Subsidiaries, for the purposes of any suit, action or proceeding pursuant to U.S. federal securities laws or the rules or regulations thereunder, commenced or initiated by the Commission arising out of, or relating to, the Regulated Securities Exchange Subsidiaries' activities.[29]

• *Amendments.* Similar to provisions contained in the BGM Charter and BGM Bylaws, the CBOE Organizational Documents provide that for so long as CBOE Holdings controls, directly or indirectly, Regulated Securities Exchange, before any amendment to or repeal of the CBOE Holdings Charter or CBOE Holdings Bylaws may be effective, such amendment or repeal must be submitted to the board of directors of each such exchange, and if the amendment or repeal is required to be filed with, or filed with and approved by the Commission, then such change shall not be effective until filed with, or filed with and approved by, the Commission, as the case may be.[30]

As stated above, the Exchange believes that the foregoing provisions will assist the Exchange in fulfilling its self-regulatory obligations and in administering and complying with the requirements of the Act.

6. CBOE V Certificate and CBOE V Operating Agreement

Effective as of the Closing of the Transaction, CBOE V will hold direct ownership of (i) BGM Holdings, which will continue to hold direct ownership of the Exchange, BYX and Bats Trading (and certain other subsidiaries not registered with the Commission in any capacity) and (ii) Direct Edge LLC, which will continue to hold direct ownership of EDGX and EDGA. However, unlike BGM currently, CBOE V will not be the ultimate holding company under the post-Closing corporate structure, but rather will be an intermediate holding company owned by CBOE Holdings. The Exchange believes that the CBOE V Operating Agreement contains provisions relating to its indirect ownership of one or more national securities exchanges, including such exchanges' regulatory functions and Commission oversight, that are appropriate for an intermediate holding company in the ownership chain of a national securities exchange. Many of the provisions of the CBOE V Operating Agreement relating to these matters are similar to the organizational documents of BGM Holdings, which currently is, and following the Subsequent Merger will be, similarly situated as an intermediate holding company of the Exchange. The Commission has previously found the BGM Holdings certificate of incorporation and bylaws to be consistent with the Act.[31]

Although CBOE V will not carry out any regulatory functions, the Exchange notes that its activities with respect to the operation of the Bats Exchanges must be consistent with, and must not interfere with, the self-regulatory obligations of each Bats Exchange. The CBOE V Operating Agreement therefore includes certain provisions that are designed to maintain the independence of the Bats Exchanges' self-regulatory functions, enable the Bats Exchanges to operate in a manner that complies with the federal securities laws, including the objectives of Sections 6(b)[32] and 19(g)[33] of the Act, and facilitate the ability of each Bats Exchange and the Commission to fulfill their respective regulatory and oversight obligations under the Act.

a. CBOE V Certificate of Formation

The CBOE V Certificate, attached as Exhibit 5D, includes the following provisions required under Delaware law: (i) The full name of CBOE V as ''CBOE V, LLC'', and (ii) the name and address of CBOE V's registered office in the State of Delaware and the name of CBOE V's registered agent at such address.[34] In addition, the CBOE V Certificate contains a provision providing that CBOE V shall indemnify members of its board of directors and certain other persons, subject to certain conditions.

As the Exchange believes is customary for limited liability companies formed in the State of Delaware, other substantive provisions governing the ownership, operation and management of CBOE V are set forth in the CBOE V Operating Agreement, discussed below.

b. CBOE V Operating Agreement

With respect to ownership and control of CBOE V, the CBOE V Operating Agreement, attached as Exhibit 5E, specifically provides that CBOE V's sole member is CBOE Holdings, until the CBOE V Operating Agreement is amended (subject to Commission approval, as described below).[35] Further, for so long as CBOE V controls, directly or indirectly, a subsidiary that is registered with the Commission as a national securities exchange (an ''Exchange Subsidiary''), CBOE Holdings may not sell, assign, transfer, convey, gift, exchange or otherwise dispose of any or all of its member interest in CBOE V, except pursuant to an amendment to the CBOE V Operating Agreement that is filed with and approved by the Commission.[36] These restrictions are designed to ensure that any change to the ownership or control of any Exchange Subsidiary, including without limitation the Bats Exchanges, may only occur through a change in the ownership or control of CBOE Holdings. As such, any purported change of such ownership or control (unless pursuant to a Commission-approved change of ownership of CBOE V) would need to comply with the CBOE Holdings Charter and CBOE Holdings Bylaws, including the ownership and voting limitations discussed above (or a Commission-approved waiver therefrom).

The CBOE V Operating Agreement also contains several provisions designed to protect the independence of the self-regulatory functions of the Bats Exchanges. The CBOE V Operating Agreement requires that, for so long as CBOE V, directly or indirectly, controls any Exchange Subsidiary, CBOE Holdings, as the sole member of CBOE V, and officers, employees and agents of CBOE V must give due regard to the preservation of independence of the self-regulatory functions of such Exchange Subsidiary, as well as to its obligations to investors and the general public, and not interfere with the effectuation of any decisions by the board of directors of an Exchange Subsidiary relating to its regulatory functions (including disciplinary matters) or which would interfere with the ability of such Exchange Subsidiary to carry out its responsibilities under the Act.[37]

The CBOE V Operating Agreement also would require that CBOE V comply with the U.S. federal securities laws and

[29] *Compare* CBOE Holdings Charter, Art. FOURTEENTH *with* BGM Bylaws, Section 12.05.

[30] *Compare* CBOE Holdings Charter, Arts. ELEVENTH, TWELFTH and CBOE Holdings Bylaws, Section 10.2 *with* BGM Charter, Art. FOURTEENTH and BGM Bylaws, Article XI.

[31] *See* Securities Exchange Act Release No. 71375 (January 23, 2014), 79 FR 4771 (January 29, 2014) (SR–BATS–2013–059; SR–BYX–2013–039).

[32] 15 U.S.C. 78f(b).

[33] 15 U.S.C. 78s(g).

[34] Delaware Limited Liability Company Act, Section 18–201.

[35] *See* CBOE V Operating Agreement, Section 1.1.

[36] *See* CBOE V Operating Agreement, Section 5.1.

[37] *See* CBOE V Operating Agreement, Section 10.1(a).

rules and regulations thereunder and cooperate with the Commission and each Exchange Subsidiary, as applicable, pursuant to and to the extent of their respective regulatory authority.[38] Further, CBOE V's officers, directors, employees and agents shall be deemed to agree to (i) comply with the U.S. federal securities laws and the rules and regulations thereunder; and (ii) cooperate with the Commission and each Exchange Subsidiary in respect of the Commission's oversight responsibilities regarding such Exchange Subsidiary and the self-regulatory functions and responsibilities of the Exchange Subsidiaries, and CBOE V will take reasonable steps to cause its officers, employees and agents to so cooperate.[39]

Furthermore, to the fullest extent permitted by law, CBOE V and its officers, directors, employees and agents will be deemed to irrevocably submit to the jurisdiction of the U.S. federal courts, the Commission, and each Exchange Subsidiary, as applicable, for purposes of any suit, action, or proceeding pursuant to the U.S. federal securities laws or the rules or regulations thereunder arising out of, or relating to, the activities of such Exchange Subsidiary.[40]

The proposed CBOE V Operating Agreement also contains a number of provisions designed to ensure that the Exchange will have sufficient access to the books and records of CBOE V as they relate to any Exchange Subsidiary. Pursuant to the CBOE V Operating Agreement, to the extent they are related to the operation or administration of an Exchange Subsidiary, the books, records, premises, officers, agents, and employees of CBOE V are deemed to be the books, records, premises, officers, agents and employees of such Exchange Subsidiary for the purposes of, and subject to oversight pursuant to, the Act.[41] In addition, for as long as CBOE V controls, directly or indirectly, an Exchange Subsidiary, CBOE V's books and records shall be subject at all times to inspection and copying by the Commission and the applicable Exchange Subsidiary, provided that such books and records are related to the operation or administration of an Exchange Subsidiary.[42]

The proposed CBOE V Operating Agreement also provides that, to the fullest extent permitted by law, all books and records of any Exchange Subsidiary reflecting confidential information pertaining to the self-regulatory function of such Exchange Subsidiary (including disciplinary matters, trading data, trading practices and audit information) that comes into the possession of CBOE V, shall be retained in confidence by CBOE V, CBOE V's officers, employees and agents and CBOE Holdings, and not used for any non-regulatory purposes.[43] The proposed CBOE V Operating Agreement provides, however, that the foregoing shall not limit or impede the rights of the Commission or an Exchange Subsidiary to access and examine such confidential information pursuant to the U.S. federal securities laws and the rules and regulations thereunder, or limit or impede the ability of CBOE Holdings or any of CBOE V's officers, employees or agents to disclose such confidential information to the Commission or an Exchange Subsidiary.[44]

In addition, the CBOE V Operating Agreement provides that for so long as CBOE V controls, directly or indirectly, any Exchange Subsidiary, before any amendment to or repeal of any provision of the CBOE V Operating Agreement will be effective, those changes must be submitted to the board of directors of each Exchange Subsidiary, and if the same must be filed with, or filed with and approved by, the Commission before the changes may be effective under Section 19 of the Act[45] and the rules promulgated thereunder, then the proposed changes shall not be effective until filed with, or filed with and approved by, the Commission, as the case may be.[46]

7. BGM Holdings Charter

The BGM Holdings Charter currently provides that the sole stockholder of BGM Holdings is BGM. However, as a result of the Transaction, CBOE V will become the sole stockholder of BGM Holdings. The Exchange proposes to amend the BGM Holdings Charter to reflect this change, as set forth in Exhibit 5F.

8. Bylaws of the Exchange

In connection with the Transaction, the Exchange proposes to amend and restate its Fourth Amended and Restated Bylaws and adopt the amended Exchange Bylaws as its Fifth Amended and Restated Bylaws, attached as Exhibit 5G. Specifically, the Exchange proposes to (i) expand the prohibition contained in Section 2 of Article XI of the Exchange Bylaws; and (ii) add a definition of ''Trading Permit Holder'' to Article I.

Currently, Section 2 of Article XI of the Exchange Bylaws prohibits directors of BGM or BGM Holdings who are not also directors, officers, staff, counsel or advisors of the Exchange from participating in any meetings of the Exchange's board of directors (or any committee thereof) pertaining to the self-regulatory function of the Exchange (including disciplinary matters). This provision refers to BGM and BGM Holdings because they are currently the only direct and indirect owners of the Exchange. However, following the Transaction, the Exchange will be owned indirectly by CBOE V and CBOE Holdings (in addition to its direct ownership by BGM Holdings). Therefore, the Exchange is proposing to remove the reference to BGM and insert references to CBOE V and CBOE Holdings, so that CBOE V and CBOE Holdings will both be covered by this prohibition. The Exchange believes that this amendment will protect the independence of the Exchange's self-regulatory activities.

In addition, as noted above, the CBOE Holdings Charter currently prohibits certain persons from owning or exercising voting rights over certain percentages of ownership of CBOE Holdings. The CBOE Holdings Charter permits the board of directors of CBOE Holdings to waive the limitation on the exercise of voting rights in excess of 20 percent of the then outstanding votes entitled to be cast on such matter only if, among other things, ''for so long as [CBOE Holdings] directly or indirectly controls any Regulated Securities Exchange Subsidiary, neither such Person nor any of its Related Persons is a 'Trading Permit Holder' (as defined in the Bylaws of any Regulated Securities Exchange Subsidiary as they may be amended from time to time).''[47]

The Exchange does not issue ''trading permits,'' but admits members. The Exchange believes the provisions of the CBOE Holdings Charter that refer to Trading Permit Holders of its Regulated Securities Exchange Subsidiaries should apply equally to members of the Exchange once it becomes a Regulated Securities Exchange Subsidiary of CBOE Holdings. As a result, the Exchange proposes to add clause (ff) to Article I of the Exchange Bylaws, providing that

[38] *See* CBOE V Operating Agreement, Section 10.2(a).

[39] *Id.*

[40] *See* CBOE V Operating Agreement, Section 10.3(a).

[41] *See* CBOE V Operating Agreement, Section 8.4(b).

[42] *Id.*

[43] *See* CBOE V Operating Agreement, Section 8.4(a).

[44] *Id.*

[45] 15 U.S.C. 78s.

[46] *See* CBOE V Operating Agreement, Section 11.2.

[47] *See* CBOE Holdings Charter, Art. SIXTH, para. (a)(ii)(C).

'' 'Trading Permit Holder' shall have the same meaning as Exchange Member.'' This will ensure that the Exchange's members will be considered Trading Permit Holders of a Regulated Securities Exchange Subsidiary for purposes of the CBOE Holdings Charter.

9. Exchange Rules

a. Exchange Rule 2.3—Member Eligibility

Pursuant to Exchange Rule 2.3, in order to be eligible for membership in the Exchange, a registered broker or dealer is currently required to be a member of at least one other national securities association or national securities exchange. However, membership in the Exchange's affiliated national securities exchanges, BYX, EDGA or EDGX, is not sufficient for purposes of eligibility for Exchange membership. The Exchange adopted this because the Bats Exchanges have historically not functioned as the designated examining authority for any of its members, and the Exchange wanted to be sure that any member would be appropriately supervised by another national securities association or national securities exchange that has the capacity to function as the member's designated examining authority.

As a result of the Transaction, the Exchange will additionally become affiliated with the CBOE Exchanges. As with the Bats Exchanges, C2 does not currently serve as the designated examination authority for any of its members. CBOE, however, does act as the designated examining authority for certain of its members. Therefore, the Exchange proposes to amend Exchange Rule 2.3 to specify that a registered broker or dealer will be eligible for membership only if it is a member of a national securities association or national securities exchange other than or in addition to the following affiliates of the Exchange: BYX, EDGA, EDGX and C2.

In addition, to ensure there is no confusion with respect to the possibility that a broker or dealer could qualify for membership in the Exchange based solely on membership in CBOE Futures or any other national securities exchange notice-registered with the Commission pursuant to Section 6(g) of the Act [48] that lists or trades security-futures products, the Exchange proposes to also specify that eligibility for membership requires membership in a national securities association registered pursuant to Section 15A of the Act or a national securities exchange registered with the Commission pursuant to Section 6(a) of the Act, so as to exclude a national securities exchange registered solely under Section 6(g) of the Act. The proposed amendments to Exchange Rule 2.3 are set forth in Exhibit 5H.

b. Exchange Rule 2.10—No Affiliation Between Exchange and any Member

Exchange Rule 2.10 provides that, without prior approval of the Commission, neither the Exchange, nor any of its affiliates, shall directly or indirectly acquire or maintain an ownership interest in a member of the Exchange. This restriction is intended to address potential conflicts of interest that could result from affiliation between the Exchange and a member. Notwithstanding this general restriction, Exchange Rule 2.10 provides that it does not prohibit a member or its affiliate from acquiring or holding an equity interest in BGM that is permitted by the ownership and voting limitations contained in the BGM Charter and the BGM Bylaws. In addition, Exchange Rule 2.10 states that it does not prohibit a member from being or becoming an affiliate of the Exchange, or an affiliate of any affiliate of the Exchange, solely by reason of such member or any officer, director, manager, managing member, partner or affiliate of such member being or becoming either (a) a Director of the Exchange pursuant to the Bylaws of the Exchange, or (b) a Director of the Exchange serving on the Board of Directors of BGM. The Exchange proposes to replace the references to BGM in Rule 2.10 with references to CBOE Holdings to reflect the fact that following the Transaction, CBOE Holdings will replace BGM as the ultimate parent holding company of the Exchange. In addition to these changes, the Exchange proposes to replace all references in Rule 2.10 to ''By-Laws'' with ''Bylaws'' in order to maintain consistency with the actual documents referred to and EDGA and EDGX Rules 2.10. The proposed amendments to Exchange Rule 2.10 are set forth in Exhibit 5H.

2. Statutory Basis

The Exchange believes that the Proposed Rule Change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[49] In particular, the proposal is consistent with Section 6(b)(1) of the Act [50] in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the Rules of the Exchange.

The Proposed Rule Change is designed to enable the Exchange to continue to have the authority and ability to effectively fulfill its self-regulatory duties pursuant to the Act and the rules promulgated thereunder. In particular, the Proposed Rule Change includes in the CBOE Holdings Charter and CBOE Holdings Bylaws, like the BGM Charter and BGM Bylaws, various provisions intended to protect and maintain the integrity of the self-regulatory functions of the Exchange upon Closing. For example, the CBOE Holdings Charter, as described above, is drafted to preserve the independence of the Exchange's self-regulatory function and carry out its regulatory responsibilities under the Act. In addition, the CBOE Holdings Charter imposes limitations similar to the BGM Ownership Limitation and BGM Voting Limitation to preclude undue influence over or interference with the Exchange's self-regulatory functions and fulfillment of its regulatory duties under the Act.

Moreover, notwithstanding the Proposed Rule Change, including the change to the indirect ownership of the Exchange, the Commission will continue to have regulatory authority over the Exchange, as is currently the case, as well as jurisdiction over the Exchange's direct and indirect parent companies with respect to activities related to the Exchange.[51] As a result, the Proposed Rule Change will facilitate an ownership structure that will provide the Commission with appropriate oversight tools to ensure that the Commission will have the ability to enforce the Act with respect to the Exchange, its direct and indirect parent companies and their directors, officers, employees and agents to the extent they are involved in the activities of the Exchange.

The Exchange also believes that the Proposed Rule Change furthers the objectives of Section 6(b)(5) of the Act [52] because the Proposed Rule Change would be consistent with and facilitate a governance and regulatory structure that is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of

[48] 15 U.S.C. 78f(g).

[49] 15 U.S.C. 78f(b).

[50] 15 U.S.C. 78f(b)(1).

[51] *See, e.g.,* CBOE Holdings Charter, Art. FOURTEENTH; CBOE V Operating Agreement, Section 10.3; BGM Holdings Bylaws, Section 7.3.

[52] 15 U.S.C. 78f(b)(5).

trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

In addition, as discussed further in the Exchange's Statement on Burden on Competition below, the Exchange expects that the Transaction will foster further innovation while facilitating efficient, transparent and well-regulated markets for issuers and investors, removing impediments to, and perfecting the mechanism of a free and open market and a national market system. The Transaction will benefit investors and the securities market as a whole by, among other things, enhancing competition among securities venues and reducing costs.

Furthermore, the Exchange is not proposing any significant changes to its existing operational and trading structure in connection with the change in ownership; the Exchange will operate in essentially the same manner upon Closing as it operates today. Therefore, the Exchange believes that it will continue to satisfy the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange. The changes that the Exchange is proposing to the Exchange Rules are designed to reflect the prospective affiliation with CBOE Holdings and the CBOE Exchanges. The Exchange believes that the proposed change to its Rules is consistent with the requirements of the Act and the rules and regulations thereunder.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the Proposed Rule Change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Indeed, the Exchange believes that the Proposed Rule Change will enhance competition among trading venues, as the Exchange believes that the Transaction will result in various synergies and efficiencies. For example, the Transaction will allow the Bats Exchanges and the CBOE Exchanges to utilize a single technology platform, which the Exchange expects will reduce Bats Exchanges' and the CBOE Exchanges' combined costs, creating the opportunity to further reduce costs to their respective members and other constituents. The potential use of a single technology platform may also reduce investors' costs of connecting to and using the Bats Exchanges and the CBOE Exchanges, including through the combination of data centers and market data services. Combining the expertise of the CBOE Exchanges' personnel with the expertise of the Bats Exchanges' personnel will also facilitate ongoing innovation, including through new product creation and platform improvements.

The Exchange notes that the Bats Exchanges and the CBOE Exchanges generally operate with different business models, target different customer bases and primarily focus on different asset classes, limiting any concern that the Transaction could burden competition. Therefore, the Exchange expects that the Transaction will benefit investors, issuers, shareholders and the market as a whole. The Exchange will continue to conduct regulated activities (including operating and regulating its market and members) of the type it currently conducts, but will be able to do so in a more efficient manner to the benefit of its members. These efficiencies will pass through to the benefit of investors and issuers, promoting further efficiencies, competition and capital formation, placing no burden on competition not necessary or appropriate in furtherance of the Act.

Furthermore, the Exchange's conclusion that the Proposed Rule Change would not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act is consistent with the Commission's prior conclusions about similar combinations involving multiple exchanges in a single corporate family.[53]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited or received written comments on the Proposed Rule Change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BatsBZX–2016–68 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR-BatsBZX–2016–68. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make

[53] *See, e.g.,* Securities Exchange Act Release Nos. 71375 (January 23, 2014), 79 FR 4771 (January 29, 2014) (SR–BATS–2013–059; SR–BYX–2013–039); 66071 (December 29, 2011), 77 FR 521 (January 5, 2012) (SR–CBOE–2011–107 and SR–NSX–2011–14); 58324 (August 7, 2008), 73 FR 46936 (August 12, 2008) (SR–BSE–2008–02; SR–BSE–2008–23; SR–BSE–2008–25; SR–BSECC–2008–01); 53382 (February 27, 2006), 71 FR 11251 (March 6, 2006) (SR–NYSE–2005–77).

available publicly. All submissions should refer to File Number SR-BatsBZX–2016–68, and should be submitted on or before December 6, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[54]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27371 Filed 11–14–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79260; File No. SR–BX–2016–055]

Self-Regulatory Organizations; NASDAQ BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Cease and Desist Authority Rules

November 8, 2016

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 28, 2016, NASDAQ BX, Inc. (''BX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt Rules 9556 and 9800, which were previously adopted as a pilot the term of which has since expired, and to make related changes to the 9100, 9200, 9300, 9550, and 9800 Rule Series.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxbx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to adopt new Rules 9556 and 9800, which were previously adopted as a pilot the term of which has since expired, and to make related changes to the 9100, 9200, 9300, 9550, and 9800 Rule Series. In May 2003, the Commission approved, on a pilot basis, a rule change to adopt NASD Rules 9556 and 9800 that gave NASD, now known as FINRA, authority to issue temporary cease and desist orders and made explicit NASD's ability to impose permanent cease and desist orders as a remedy in disciplinary cases.[3] Because NASD was, and now FINRA is, the Exchange's regulatory services provider and administers the Exchange's disciplinary program under contract, the Exchange seeks to maintain comparability between its disciplinary procedure rules and those of NASD and now FINRA. As a consequence, the Exchange adopted Rules 9556 and 9800 to mirror the then-FINRA rules to operate as a pilot in conjunction with the related FINRA pilot.[4]

On June 23, 2009, the Exchange's Rule 9556 and 9800 pilot programs expired, at which time those rules and certain references thereto became obsolete, notwithstanding that they remained in the rulebook. The FINRA pilot program, however, continued and was approved on July 14, 2009 on a permanent basis.[5]

Neither the Exchange nor FINRA, acting on behalf of the Exchange pursuant to agreement, have [sic] used the cease and desist authority under Rules 9556 and 9800 during the time that the rules were effective. Nonetheless, the Exchange believes that, in addition to maintaining similar disciplinary rules, adoption of Rules 9556 and 9800 is important to the Exchange's disciplinary program. The authority under these rules will provide the Exchange and FINRA, operating on behalf of the Exchange, with a mechanism to take appropriate remedial action against a member or an associated person that has engaged (or is engaging) in violative conduct that could cause continuing harm to the investing public if not addressed expeditiously, such as dissipation or conversion of assets. It must be emphasized, however, that the cease and desist provisions contain numerous procedural protections for respondents to ensure that the proceedings are fair. Consequently, the Exchange believes that adoption of these rules is important to its regulatory program, notwithstanding that it anticipates exercising the authority provided by the rules sparingly.

The Exchange is proposing to delete Rules 9556 and 9800 (and related references in other rules[6]) because the pilot period for these rules has expired rendering them void, and adopt new Rules 9556 and 9800 (and related references in other rules)[7] based on FINRA's analogous cease and desist rules, which include amendments to the former BX cease and desist rules to reflect changes that FINRA has made to its cease and desist rules in 2011 and 2015 after they were made permanent.[8] The Exchange is also proposing to amend other Rules under the 9000 Series to incorporate changes that FINRA made to its analogous rules in

[54] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 47925 (May 23, 2003) (File No. SR–NASD–98–80), 68 FR 33548 (June 4, 2003). *See also* Securities Exchange Act Release No. 51860 (June 16, 2005), 70 FR 36427 (June 23, 2005) (SR–NASD–2005–061) (extending the pilot to June 23, 2007 and making non-substantive changes); and Securities Exchange Act Release No. 55819 (May 25, 2007), 72 FR 30895 (June 4, 2007) (SR–NASD–2007–033) (extending the pilot to June 23, 2009 and making non-substantive changes).

[4] *See* Securities Exchange Act Release No. 59154 (December 23, 2008), 73 FR 80468 (December 31, 2008) (SR–BSE–2008–48).

[5] Securities Exchange Act Release No. 60306 (July 14, 2009), 74 FR 36292 (July 22, 2009) (SR–FINRA–2009–035). The Exchange notes that FINRA, in its rule change proposal to make its pilot program permanent, noted that it had used the authority under Rules 9556 and 9800 sparingly. *Id.* at 36293.

[6] The Exchange is deleting text from related provisions of Rules 8310, IM–8310–3(c)(1), 9120(r), 9241(c), 9290, 9311(b), 9312(b), and 9360 that also expired on June 23, 2009 and is inserting new text identical to what was deleted.

[7] As a consequence of the expiration of the pilot rendering the existing related rule text void, in certain cases the Exchange is deleting the void text and reinserting identical rule text thereafter so the text may have effect once again. For example, the Exchange is deleting Rule 8310(a)(6), concerning imposition of a temporary or permanent cease and desist order, and adopting a new Rule 8310(a)(6) identical to what was deleted.

[8] In 2013, FINRA consolidated the publication standards for expedited proceeding decisions, including under FINRA Rule 9556, in FINRA Rule 8313(a)(3) and consequently amended FINRA Rule 9556 to remove paragraph (h) ''Notice to Membership'' from the rule. *See* Securities Exchange Act Release No. 69825 (June 21, 2013), 78 FR 38771 (June 27, 2013) (SR–FINRA–2013–018). The Exchange did not have such a provision in its Rule 9556. The Exchange's disclosure obligations are provided under IM–8310–3, including the Exchange's disclosure obligations related to expedited proceedings. *See* IM–8310–3(c).

2015, as discussed below. These proposed changes include significant amendments made by FINRA to not only its Rules 9556 and 9800, but also to its 9100, 9200, 9300, 9550, and 9800 Rule Series in 2015. Unless otherwise noted, BX is adopting the FINRA Rules with only minor changes to reflect the Exchange's committee structure and rules,[9] as described below.

2011 FINRA Rule Changes

In 2011, FINRA amended Rules 9552(b), 9553(b), 9554(b), 9555(b), and 9556(b), all of which concern service of notice.[10] Each of these rules concern [sic] the process followed when a person or entity subject to FINRA's jurisdiction fail [sic] to comply with various requirements under its rules. FINRA amended the rule provisions noted above to allow notice of failure to comply with a temporary or permanent cease and desist order to be served on counsel representing the member or person, or other person authorized to represent others under FINRA Rule 9141,[11] when counsel or other person authorized to represent others under FINRA Rule 9141 agrees to accept service for the member or person.

2015 FINRA Rule Changes

In 2015, FINRA made significant changes to its temporary and permanent cease and desist rules.[12] FINRA lowered the evidentiary standard to obtain a temporary cease and desist order, adopted a new expedited proceedings [sic] to address situations involving repeated violations of temporary or permanent cease and desist orders, and made a series of rule amendments to the temporary cease and desist order rules under FINRA Rule Series 9800, the expedited proceedings rules under FINRA Rule Series 9550,[13] and FINRA's Code of Procedure (FINRA Rule Series 9000) that harmonize service provisions in temporary cease and desist proceedings and expedited proceedings, ease administrative burdens in temporary cease and desist proceedings, and clarify the process by which permanent cease and desist orders may be imposed.

(i) Evidentiary Standard for Imposing a Temporary Cease and Desist Order

FINRA amended FINRA Rule 9840(a)(1) to change the evidentiary standard applied by Hearing Panels in issuing a temporary cease and desist order. Specifically, FINRA changed the standard for issuing a temporary cease and desist order from ''by a preponderance of the evidence that the alleged violation specified in the notice has occurred'' to a ''showing of a likelihood of success on the merits.'' FINRA noted that it believed that the ''preponderance of the evidence'' standard set too high an evidentiary threshold for this critical investor-protection tool, and noted that it is the identical standard for proving a violation in the underlying disciplinary proceeding that must be pursued at the same time.[14] Thus, to obtain a temporary cease and desist order—and thereby prevent the likely and significant dissipation or conversion of assets or other significant harm to investors—FINRA's prosecuting department had to make an evidentiary presentation in the temporary cease and desist proceeding that is similar in extent to its evidentiary presentation in the subsequent underlying disciplinary proceeding, but in an expedited manner.

FINRA also made a corresponding amendment to FINRA Rule 9840(a)(2). Prior to the amendment, FINRA Rule 9840(a)(2) provided that a temporary cease and desist order shall be imposed if the Hearing Panel finds that the violative conduct or continuation thereof is likely to result in significant dissipation or conversion of assets or other significant harm to investors prior to the completion of the underlying proceeding. The 2015 rule change modified this requirement to apply to the ''alleged'' violative conduct or continuation thereof, to be consistent with the proposed change to the evidentiary standard.

(ii) Failures To Comply With Temporary Cease and Desist Orders and Permanent Cease and Desist Orders (FINRA Rule 9556)

FINRA also made amendments to FINRA Rule 9556, which sets forth expedited procedures for enforcing violations of FINRA-issued temporary and permanent cease and desist orders. FINRA was concerned that their [sic] existing expedited procedures may permit cease and desist orders to be circumvented without any real threat of a sanction.[15] Thus, FINRA amended FINRA Rule 9556 to adopt a new paragraph (h) to permit its staff (with prior authorization from FINRA's Chief Executive Officer or other designated senior officer) to institute a new kind of expedited proceeding if the subject of a temporary or permanent cease and desist order fails to comply with that order and has previously been served with a notice under Rule 9556(a) for failure to comply with any provision of the same temporary or permanent cease and desist order. FINRA adopted the change to prevent a respondent from abusing the existing process by repeatedly violating a cease and desist order and curing that violation before the effective date of any FINRA Rule 9556 notice,[16] without being subject to the immediate sanctions or review by the Office of Hearing Officers for a prolonged period. FINRA noted in its filing that the new FINRA Rule 9556(h) proceeding differs from other FINRA Rule 9556 expedited proceedings in other respects that reflect the response that FINRA believes is warranted for situations involving repeated violations of temporary or permanent cease and desist orders.[17] These differences include the following:

[9] The Exchange is replacing references to FINRA and FINRA staff with references to the Exchange and Exchange staff, which are the appropriate analogous parties at BX. The Exchange is also replacing FINRA text that states ''Chief Executive Officer or such other senior officer as the Chief Executive Officer may designate'' with ''Chief Regulatory Officer,'' which is the Exchange officer vested with the authority described under the rules. For example, old Rules 9556(a) and 9860 vested authority with the Chief Regulatory Officer to authorize notice and initiation of proceedings, respectively, whereas the analogous FINRA rules authorize its Chief Executive Officer or such other senior officer as the Chief Executive Officer may designate instead. Last, the Exchange is adding clarifying language to Rule 9810 to make it clear that initiation of a proceeding must not only be authorized by FINRA's Chief Executive Officer or such other senior officer as the Chief Executive Officer may designate, but also BX's Chief Regulatory Officer. As a practical matter, the Chief Regulatory Officer must agree that such a proceeding should be brought pursuant to BX rules.

[10] Securities Exchange Act Release No. 60306 (January 4, 2012), 77 FR 1524 (January 10, 2012) (SR–FINRA–2011–044). FINRA also amended other rules in the FINRA Rule 9000 Series not addressed in this filing. *Id.*

[11] FINRA Rule 9141, entitled ''Appearance and Practice; Notice of Appearance,'' provides, among other things, what is permissible in terms of representation before an Adjudicator. Exchange Rule 9141 is consistent with FINRA Rule 9141.

[12] Securities Exchange Act Release No. 75629 (August 6, 2015), 80 FR 48379 (August 12, 2015) (SR–FINRA–2015–019).

[13] FINRA amended its Rule 9551 ''Failure to Comply with Public Communications Standards.'' BX does not have such a rule (BX Rule 9551 is held in reserve) and is thus not incorporating those changes. In a related change, the Exchange is also amending its Rule 9559 to delete the references to Rule 9551, which were erroneously included in the rule.

[14] *See* Securities Exchange Act Release No. 75333 (June 30, 2015), 80 FR 38783 (July 7, 2015) (Notice of Filing File No. SR–FINRA–2015–019) at 38784.

[15] *Id.* at 38785.

[16] Under the then-current FINRA Rule 9556, if a member or person failed to comply with a temporary or permanent cease and desist order, FINRA staff (with prior authorization from FINRA's Chief Executive Officer or other designated senior officer) may have issued a notice stating that the failure to comply within seven days will result in a suspension or cancellation of membership or a suspension or bar from associating with any member and also would have stated what the respondent must do to avoid such action.

[17] *See supra* note 14 at 38785.

• A FINRA Rule 9556(h) proceeding could be initiated only if the respondent has previously been served, under FINRA Rule 9556(a), with a notice for failing to comply with any provision of the same temporary or permanent cease and desist order;
• FINRA's prosecuting department would initiate a FINRA Rule 9556(h) proceeding by filing a petition with FINRA's Office of Hearing Officers (and serving the respondent) that seeks the imposition of sanctions for the violation (rather than issuing a notice to the respondent);
• FINRA's prosecuting department would seek the imposition of any fitting sanction at the outset of the FINRA Rule 9556(h) proceeding (in contrast to other FINRA Rule 9556 expedited proceedings, where the recipient of a notice is not subject to the imposition of any fitting sanction unless such recipient opts for a hearing);
• a hearing is required in a FINRA Rule 9556(h) proceeding;
• the hearing for a FINRA Rule 9556(h) proceeding must be held in a condensed time frame (ten business days after a respondent is served the petition, versus other Rule 9556 proceedings which require a respondent to request a hearing within seven business days after service of a notice instituting a proceeding and require hearings to be held within 14 days after a request for a hearing is filed); [18]
• a FINRA Rule 9556(h) proceeding is presided over by a Hearing Officer,[19] rather than a Hearing Panel; [20] and
• the Hearing Officer may issue default decisions in FINRA Rule 9556(h) proceedings.[21]

Under amended FINRA Rule 9556(h)(4), the FINRA department that filed the petition can withdraw it without prejudice and shall be permitted to refile a petition based on allegations concerning the same facts and circumstances that are set forth in the withdrawn petition. FINRA noted that this provision provides it the flexibility to withdraw the petition where, for instance, the respondent evidences a good faith intent to comply with the temporary or permanent cease and desist order without the need to adjudicate the petition, while preserving FINRA's right to refile the petition if the respondent fails to do so.[22]

(iii) Service Provisions in Temporary Cease and Desist Proceedings and Expedited Proceedings

FINRA also made the rules that govern service of documents in temporary cease and desist proceedings and the eight different types of expedited proceedings under the Rule 9550 Series more consistent.[23] Prior to the changes, some provisions of these rules explicitly addressed service by facsimile and on counsel, while some did not. FINRA's amendments explicitly allow service by facsimile and on counsel across all temporary cease and desist and expedited proceedings, noting that doing so removed unnecessary burdens and inefficiencies. FINRA also amended its rules to permit service by email for all temporary cease and desist proceedings and expedited proceedings. FINRA noted that email service would allow parties to receive information quickly, which is particularly important in these types of proceedings, considering the short time frames involved.[24] As part of the changes allowing service by email, FINRA also now requires duplicate service through some other means such as overnight courier or personal delivery and made changes to its Rule 9550 Series to reflect this requirement.

(iv) Clarifying FINRA's Authority To Impose Permanent Cease and Desist Orders

FINRA clarified its rules concerning the process for imposing permanent cease and desist orders in disciplinary proceedings. FINRA noted that when it obtained the authority to impose temporary cease and desist orders, it also obtained the authority to impose permanent cease and desist orders.[25] Thus, the clarifying changes were procedural in nature and did not reflect any change to FINRA's prior representations concerning the context in which it would seek permanent cease and desist orders.

(v) Administrative Changes to Temporary Cease and Desist Proceedings

FINRA also expanded the pool of persons eligible to serve on hearing panels to include those who may serve on hearing panels for disciplinary matters, as provided under FINRA Rules 9231(b) and 9559(d)(2).[26] Specifically, FINRA amended its Rule 9820 to provide that the potential panelists for the Hearing Panels that preside over temporary cease and desist proceedings to [sic] include persons who currently serve or previously served on a District Committee; [27] previously served on the National Adjudicatory Council; [28] previously served on a disciplinary subcommittee of the National Adjudicatory Council or the National Business Conduct Committee;[29] previously served as a member of the Board of Directors of FINRA Regulation or of the Board of Governors of FINRA; or currently serve or previously served on a committee appointed or approved by the Board of Governors of FINRA, but do not serve currently on the National Adjudicatory Council or as a member of the Board of Directors of FINRA Regulation or of the Board of Governors of FINRA. The amendment to FINRA Rule 9820 also required that each panelist be associated with a member of FINRA or retired therefrom. FINRA noted that, while its Office of Hearing Officers has presided over only a limited number of temporary cease and desist proceedings, those experiences have revealed that the narrowly circumscribed set of potential panelists can impede the recruitment of Hearing Panel members, especially considering that the expedited nature of temporary cease and desist proceedings will

[18] *See* FINRA Rule 9559(f)(2) and (3); FINRA Rule 9556(e).

[19] As defined by FINRA Rule 9120(r).

[20] As defined by FINRA Rule 9120(s). *See* FINRA Rule 9559(d)(1) and (2) for a description of the appointment and authority [sic] of a Hearing Officer and/or Hearing Panel in expedited proceedings.

[21] *See* FINRA Rule 9559(m)(2).

[22] *See supra* note 14 at 38785.

[23] The Exchange notes that in SR–FINRA–2015–019 FINRA replaced references to ''contact questionnaires'' with reference to the ''FINRA Contact System,'' FINRA's proprietary system that facilitates member firm reporting of key contacts to FINRA. Exchange members are required to use the FINRA Contact System to report to the Exchange all contact information required by the Exchange and update its required contact information promptly. *See* Rule 1160. Under the FINRA Rule 9550 Series, the rules cite Article 4, Section III of the FINRA By-Laws as the authority pursuant to which its members have an obligation to report required contact information to it via the FINRA Contact System, whereas the Exchange's authority is pursuant to Rule 1160, as noted above. Thus, the Exchange is instead referencing Rule 1160 in the Rule 9550 Series as the authority pursuant to which members have the reporting obligation.

[24] *See supra* note 14 at 38785–6.

[25] *See supra* note 14 at 38786.

[26] FINRA harmonized the categories of individuals eligible for appointment as a Hearing Panelist under FINRA Rule 9820 with FINRA Rule 9231(b) (providing that each panelist shall be associated with a member of FINRA or retired therefrom and that the pool of panelists for disciplinary proceedings includes current or previous members of District Committees, former members of the National Adjudicatory Council, past members of disciplinary subcommittees of the National Adjudicatory Council or the National Business Conduct Committee, past members of the Board of Directors of FINRA Regulation or past members of the Board of Governors of FINRA, and current or previous members of committees appointed or approved by the Board of Governors of FINRA); FINRA Rule 9559(d)(2) (providing for the same pool for FINRA Rule 9556 expedited proceedings).

[27] As defined by FINRA Rule 9120(g).

[28] *See* By-Laws of FINRA Regulation, Inc., Article V, National Adjudicatory Council.

[29] The predecessor to the FINRA National Adjudicatory Council.

already preclude many from being able to serve.[30] FINRA also noted that it had concerns that the small pool of potential panelists will often make it difficult to recruit hearing panelists who can serve on both the temporary cease and desist proceeding and the subsequent underlying disciplinary proceeding, as well as any related expedited proceeding under FINRA Rule 9556.[31]

The Exchange is proposing to, likewise, expand the categories of individuals eligible to participate as Hearing Panelists. Like FINRA, the Exchange is harmonizing the categories of eligible individuals with the criteria under Rules 9231(b) and 9559(d)(2).[32] Thus, the Exchange is allowing the Chief Hearing Officer to select as a Panelist pursuant to proposed Rule 9820(a) a person who: previously served on the Exchange Review Council; [33] previously served on a disciplinary subcommittee of the Exchange Review Council, including a Subcommittee, an Extended Proceeding Committee,[34] or their predecessor subcommittees; previously served as a Director, or as a Governor of the Exchange prior to its acquisition by The NASDAQ OMX Group, Inc., but does not serve currently in that position; or is a FINRA Panelist approved by the Exchange Board at least annually, including a member of FINRA's Market Regulation Committee or a person who previously served on the Market Regulation Committee not earlier than four years before the date the complaint was served upon the Respondent who was the first served Respondent in the disciplinary proceeding for which the Hearing Panel or the Extended Hearing Panel is being appointed, or from other sources the Board deems appropriate given the responsibilities of Panelists.

FINRA's proposed changes also eased other administrative burdens created by the shortened time frame of a temporary cease and desist proceeding. Those proposed changes were aimed at improving Hearing Panels' and parties' ability to prepare for hearings and giving Hearing Officers some needed flexibility. For example, under FINRA Rule 9830(a) prior to the 2015 amendments a Hearing Officer was not able to extend a hearing date in a temporary cease and desist proceeding unless all parties consented to the extension. The requirement to obtain the parties' consent was problematic in instances whereby the Office of Hearing Officers, rather than one of the parties, had a need for an extension, such as when it encounters difficulty in quickly appointing a Hearing Panel. To address this problem, FINRA amended its Rule 9830(a) to allow hearing deadlines to be extended by the Chief Hearing Officer or Deputy Chief Hearing Officer for good cause shown.

FINRA also made similar amendments to the process by which extensions are obtained to the deadlines for issuing decisions in temporary cease and desist proceedings and responding to requests to modify, set aside, limit, or suspend a temporary cease and desist order. Before the amendments to FINRA Rule 9840(a), the Hearing Panel's deadline for issuing its written decision could not be extended, even where there was good cause, without the consent of the parties. Likewise, prior to amending FINRA Rule 9850, a Hearing Panel's deadline for responding to an application to have a temporary cease and desist order modified, set aside, limited, or suspended could not be extended, even where there was a good cause, without the consent of the Parties. To allow a Hearing Panel some flexibility where there is a need for additional time to prepare its decision or respond to a FINRA Rule 9850 request (*e.g.,* when a member of the Hearing Panel becomes ill, where the temporary cease and desist proceeding is highly complex), FINRA amended FINRA Rules 9840(a) and 9850 to permit the deadlines for issuing decisions and responding to FINRA Rule 9850 applications to be extended by the Chief Hearing Officer or Deputy Chief Hearing Officer for good cause shown.

To further address the burdens created by the short time frame of temporary cease and desist proceedings, FINRA amended its rules to: (i) Require FINRA's prosecuting department to file a memorandum of points and authorities with the notice initiating a temporary cease and desist proceeding; and (ii) permit the Hearing Officer to order a party to furnish to all other parties and the Hearing Panel such information as deemed appropriate, including any or all of the pre-hearing submissions described in FINRA Rule 9242(a). FINRA noted that requiring its prosecuting department to file a memorandum of points and authorities at the initiation of the proceeding provides more context to the allegations and set [sic] forth legal authorities on which the notice seeking a temporary cease and desist order is premised.[35] FINRA believed that the change would, in turn, facilitate a more efficient process and improve the quality of the hearing through more thorough preparation, which are the same goals of the pre-hearing processes in FINRA disciplinary proceedings. FINRA also noted that requiring the filing of a memorandum of points and authorities at the initiation of a temporary cease and desist proceeding also enhances disclosure of the prosecuting department's allegations, which would inure to the benefit of the respondents and further increases the fairness of the proceeding.[36] Last, FINRA noted that all of these objectives are served by authorizing Hearing Officers to order a party to furnish other pre-hearing submissions.[37]

FINRA also proposed Rule 9840(e), which is a delivery requirement that requires a member firm that is the subject of a temporary cease and desist order to provide a copy of the order to its associated persons, within one business day of receiving it. Considering the significant nature of the harm that a temporary cease and desist order is aimed at stopping, FINRA believed that there is a heightened need to ensure that the persons who may act on behalf of the member firm are made aware of the contents of a temporary cease and desist order imposed against the member firm and the delivery requirement furthers that goal.[38]

FINRA's rule change clarified the following additional three issues: (1) How settlements may be approved in temporary cease and desist proceedings; (2) which Hearing Panel has jurisdiction to preside over applications filed under FINRA Rule 9850 to modify, set aside, limit or suspend temporary cease and desist orders that are filed after a

[30] *See supra* note 14 at 38786.

[31] *Id.*

[32] Like FINRA's Rule 9559(d)(2), Rule 9559(d)(2) provides for the same pool for Rule 9556 expedited proceedings) [sic]. *Supra* note 26.

[33] *See* By-Laws of NASDAQ BX, Inc., Article VII, Exchange Review Council.

[34] As defined by Rule 9120(n).

[35] *See supra* note 14 at 38787.

[36] *Id.*

[37] *Id.*

[38] Similarly, FINRA made related amendments to FINRA Rules 9269, 9270, and 9840 to require that the Office of Hearing Officers, the Department of Enforcement, the Department of Market Regulation, or the General Counsel, as appropriate, disseminate default decisions, orders of acceptance of settlement, and temporary cease and desist orders to each member of FINRA with which a respondent is associated. FINRA noted that these dissemination requirements are intended to ensure that a respondent's member firm is made aware of the disciplinary history of its associated persons, regardless of the specific disciplinary procedure involved. *See supra* note 14 at 38787, n. 15. FINRA also noted that the amendments are consistent with other FINRA Rules that already require the Office of Hearing Officers, the National Adjudicatory Council, or the Board of Governors of FINRA to provide copies of a decision issued by a Hearing Panel, an Extended Hearing Panel, the National Adjudicatory Council, or the Board of Governors of FINRA to each member firm with which a respondent is associated. *Id.; see also* FINRA Rules 9268(d), 9349(c), 9351(e). The Exchange is adopting these amendments to Rules 9269, 9270, and 9840.

Hearing Panel has already been appointed in the underlying disciplinary proceeding; and (3) whether temporary and permanent cease and desist orders imposed against a firm also apply to successors of that firm.

With respect to the first issue, new FINRA Rule 9810(c) established that, if the parties agree to the terms of a proposed temporary cease and desist order, the Hearing Officer has the authority to approve and issue the order. On the second issue, amended FINRA Rule 9850 provided that the Hearing Panel that presided over the temporary cease and desist order proceeding shall retain jurisdiction to review a FINRA Rule 9850 application unless at the time the application is filed a Hearing Panel has already been appointed in the underlying disciplinary proceeding commenced under FINRA Rule 9211, in which case the Hearing Panel appointed in the disciplinary proceeding has jurisdiction. As to the third issue, amended FINRA Rule 9840(b) and new Rule 9291(a) established that when a temporary or permanent cease and desist order is imposed against a member firm, it also applies to any successor of the member firm.

Finally, FINRA amended certain provisions of FINRA Rule 9120. FINRA amended FINRA Rule 9120(s), ''Hearing Panel,'' to include an Adjudicator that is constituted under Rule 9231 to conduct a disciplinary proceeding governed by the Rule 9800 Series. The Exchange is adopting this amendment in its Rule 9120(s).

FINRA also amended FINRA Rule 9120(t), ''Interested Staff,'' to: (1) Insert ''or petition'' under paragraph (2)(A) of the rule, thus expanding the definition to include FINRA staff that filed a petition in a proceeding under the Rule 9520 Series or Rule 9550 Series; and (2) include a new paragraph (4) to list FINRA staff that are defined as Interested Staff in a proceeding under the FINRA Rule 9800 Series. The Exchange is also adopting the amendment to its Rule 9120(t) ''Interested Staff,'' but is expanding the definition to also include BX Regulation employees who directly participated in the authorization of the notice that initiates a temporary cease and desist proceeding, or directly participated in an examination, investigation, prosecution, or litigation related to a specific temporary cease and desist proceeding, under new paragraphs (t)(4)(C) and (D) of the rule.

FINRA also amended FINRA Rule 9120(w), ''Panelists,'' to include references to Panelists in the Rule 9550 Series, and the Rule 9800 Series within the definition provided by the rule. The Exchange is adopting this amendment in Rule 9120(z). FINRA also amended Rule 9120(z) ''Respondent'' to define a Respondent in a proceeding governed by the Rule 9800 Series to mean a FINRA member or associated person that has been served a notice initiating a cease and desist proceeding. The Exchange is adopting this amendment in Rule 9120(bb) ''Respondent.''

The Exchange believes that the changes made by FINRA in 2011 and 2015, as described above, improve the cease and desist authority as well as the service provisions. Consequently, the Exchange is proposing to adopt the changes, as described above, as its own.

Other Non-Substantive Changes

The Exchange is also proposing to make other non-substantive changes to its rules to correct misuse of the word ''FINRA,'' which were introduced erroneously when the Exchange adopted the rules. Specifically, the Exchange is proposing to amend Rule 9555(g) to remove reference to FINRA and replace it with reference to the Exchange to make clear that it is BX's departments that should be contacted. The Exchange is also replacing references to FINRA's rules under new Rule 9810 with references to analogous rules of BX. Specifically, BX is replacing reference to FINRA Rule 2010 with reference to Equity Rule 2110, reference to FINRA Rule 2020 with reference to Equity Rule 2120, and FINRA Rule 4330 with reference to Equity Rule 2150.[39] The Exchange is also replacing the word ''FINRA'' with ''Exchange'' in adopting Rule 9840(d) to make it clear that the rule applies to BX members. Last, the Exchange is proposing not to include the word ''FINRA'' prior to ''Rule 9211'' in adopting Rule 9850 to make it clear that the rule referenced is BX's rule, not FINRA's.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[40] in general, and furthers the objectives of Section 6(b)(5) of the Act,[41] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange also believes that the proposed rule is consistent with Section 6(b)(6) of the Act,[42] which requires the rules of an exchange provide that its members be appropriately disciplined for violations of the Act as well as the rules and regulations thereunder, or the rules of the Exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction.

The Exchange believes that the proposed rule change is consistent with these provisions because the proposed changes are based on the cease and desist authority that FINRA has adopted, which the Exchange believes furthers the objectives of the Act by providing it with ability to stop violative conduct that is likely to cause dissipation or conversion of assets or other significant harm to investors, and on other changes to its related rules that clarify, harmonize, and improve its disciplinary process.

The proposed rule change will improve the Exchange's capacity to enforce compliance with applicable laws and rules by its members and persons associated with members and improving [sic] the Exchange's capability to prevent fraudulent and manipulative acts and practices. Thus, this authority is a vitally important tool to have to protect market participants.

The Exchange acknowledges that, when used, the cease and desist authority proposed herein would significantly impact a respondent. The Exchange, however, notes that the proposed rules incorporate numerous procedural protections for respondents to ensure that the proceedings initiated under these rules are fair, including

[39] BX notes that the BX rules cited in new Rule 9810 are the same as those that were cited under old Rule 9810(a). BX further notes that under FINRA Rule 9810(a), FINRA cites to FINRA Rules 2010, 2020, and 4330. BX is replacing reference to the FINRA rules with reference to BX's analogous Equity Rules 2110, 2120 and 2150, as was the case in old Equity Rule 9810(a). While the provisions of Equity Rules 2110 and 2120 closely mirror FINRA Rules 2010 and 2020, Equity Rule 2150 is significantly different than FINRA Rule 4330. FINRA Rule 4330 concerns the permissible use of customers' margin securities while Equity Rule 2150 requires a member and persons associated with a member to comply with FINRA's Rule 2150. FINRA Rule 2150 is titled ''Improper Use of Customers' Securities or Funds; Prohibition Against Guarantees and Sharing in Accounts'' and, among other things, prohibits members or persons associated with a member from making improper use of a customer's securities or funds, guaranteeing a customer against loss in connection with any securities transaction or in any securities account of such customer, and setting forth what is permissible in terms of sharing in profits and losses in a customer account. BX believes that Equity Rule 2150 is the appropriate rule cite under new Rule 9810(a) for purposes of alleged violations concerning misuse or conversion of customer assets.

[40] 15 U.S.C. 78f(b).

[41] 15 U.S.C. 78f(b)(5).

[42] 15 U.S.C. 78f(b)(6).

notice and an opportunity to be heard before a neutral tribunal. Moreover, the Exchange anticipates using the authority provided by these rules sparingly.

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 changes are being proposed to provide an important regulatory tool to the Exchange and FINRA, acting on its behalf, which will protect investors when violative conduct is being taken by a member or person associated with a member, and time is of the essence to prevent harm, or further harm, to investors.

The proposed change does not impose a burden on competition among participants or other venues because it will only be used in circumstances where investor harm is imminent or is occurring. Thus, to the extent a burden on competition results from use of the authority provided by the proposed rules, such burden is necessary to protect investors, which is consistent with the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[43] and subparagraph (f)(6) of Rule 19b–4 thereunder.[44]

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative upon filing. The Exchange has stated that it is requesting this waiver so that the Exchange could apply, at the earliest time possible, the authority to issue temporary cease and desist orders and explicit authority to impose permanent cease and desist orders as a remedy in disciplinary cases. The Exchange explained that although it does not anticipate that it will be necessary to use this authority, when its cease and desist authority is needed, the Exchange must be able to move swiftly to prevent or stop investor harm. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because this waiver will enable the Exchange to utilize the temporary or permanent cease and desist authority described herein without delay in the unlikely event that circumstances arise that warrant its use. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[45]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2016–055 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2016–055. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2016–055, and should be submitted on or December 6, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[46]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27365 Filed 11–14–16; 8:45 am]

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[43] 15 U.S.C. 78s(b)(3)(A)(iii).

[44] 17 CFR 240.19b–4(f)(6).

[45] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[46] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79264; File No. SR-BatsEDGX–2016–60]

Self-Regulatory Organizations; Bats EDGX Exchange, Inc.; Notice of Filing of a Proposed Rule Change in Connection With the Proposed Corporate Transaction Involving Bats Global Markets, Inc. and CBOE Holdings, Inc.

November 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 2, 2016, Bats EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f(a).

change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposed rule change (the ''Proposed Rule Change'') in connection with the proposed corporate transaction (the ''Transaction''), as described in more detail below, involving its ultimate parent company, Bats Global Markets, Inc. (''BGM''), CBOE Holdings, Inc. (''CBOE Holdings''), and two wholly owned subsidiaries of CBOE Holdings, CBOE Corporation and CBOE V, LLC (''CBOE V''). CBOE Holdings is the parent company of Chicago Board Options Exchange, Incorporated (''CBOE'') and C2 Options Exchange, Incorporated (''C2''), each a national securities exchange registered with the Commission pursuant to Section 6(a) of the Act,[3] and CBOE Futures Exchange, LLC (''CBOE Futures,'' and together with CBOE and C2, the ''CBOE Exchanges''), a national securities exchange that lists or trades security-futures products notice-registered with the Commission pursuant to Section 6(g) of the Act.[4]

Upon completion of the mergers described below that effectuate the Transaction (the ''Closing''), the business of BGM will be carried on by CBOE V. CBOE V, rather than BGM, will be the direct parent company of Direct Edge LLC (''Direct Edge''), which is the direct parent company of the Exchange. As a result, CBOE Holdings will become the ultimate parent company of Direct Edge and of the Exchange.

To effectuate the Transaction, the Exchange seeks to obtain the Commission's approval of: (i) The resolutions of BGM's board of directors (the ''BGM Board'') waiving certain provisions of the Amended and Restated Certificate of Incorporation of BGM (the ''BGM Charter'') and making certain related determinations regarding CBOE Holdings and the impact of the Transaction on the Exchange (the ''Resolutions''); (ii) the CBOE Holdings Second Amended and Restated Certificate of Incorporation (the ''CBOE Holdings Charter'') and the CBOE Holdings Third Amended and Restated Bylaws (the ''CBOE Holdings Bylaws''); (iii) the Certificate of Formation of CBOE V (the ''CBOE V Certificate'') and the Limited Liability Company Operating Agreement of CBOE V (the ''CBOE V Operating Agreement''); (iv) the proposed amendments to the Amended and Restated Limited Liability Company Operating Agreement of Direct Edge (the ''Direct Edge Operating Agreement''); (v) the proposed amendments to the Fifth Amended and Restated Bylaws of the Exchange (the ''Exchange Bylaws''); and (vi) the proposed amendments to EDGX Rules 2.3, 2.10 and 2.12 (the ''Exchange Rules'').

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange submits this Proposed Rule Change to seek the Commission's approval of the organizational and governance documents of the Exchange and its current and proposed future parent companies, and related actions that are necessary in connection with the Closing of the Transaction, as described below.

Other than as described herein and set forth in Exhibits 5A through 5H, the Exchange will continue to conduct its regulated activities (including operating and regulating its market and members) in the manner currently conducted, and will not make any changes to its regulated activities in connection with the Transaction. Except as set forth in this Proposed Rule Change, the Exchange is not proposing any amendments to its trading and regulatory rules at this time. If the Exchange determines to make any such changes, it will seek the approval of the Commission to the extent required by the Act, and the Commission's rules thereunder, and the Rules of the Exchange.

1. Current Corporate Structures

The Exchange, Bats BZX Exchange, Inc. (''BZX''), Bats BYX Exchange, Inc. (''BYX'') and Bats EDGA Exchange, Inc. (''EDGA,'' and together with the Exchange, BZX and BYX, the ''Bats Exchanges'') are each Delaware corporations that are national securities exchanges registered with the Commission pursuant to Section 6(a) of the Act.[5]

The Exchange and EDGA are each direct, wholly owned subsidiaries of Direct Edge, a Delaware limited liability company that is a direct, wholly owned subsidiary of BGM. BZX and BYX are direct, wholly owned subsidiaries of Bats Global Markets Holdings, Inc. (''BGM Holdings''), a Delaware corporation that is a direct, wholly owned subsidiary of BGM. In addition to certain other subsidiaries not registered with the Commission in any capacity, BGM Holdings also owns 100 percent of the equity interest in Bats Trading, Inc. (''Bats Trading''), a Delaware corporation that is a broker-dealer registered with the Commission that provides routing services outbound from, and in certain instances inbound to, each Bats Exchange. BGM, a Delaware corporation, is a publicly traded company listed on BZX.

CBOE Holdings, a Delaware corporation, is a publicly traded company listed on The NASDAQ Stock Market. CBOE Holdings owns 100 percent of the equity interest in the CBOE Exchanges.

In contemplation of the Transaction, CBOE Holdings formed two additional entities, CBOE Corporation, a Delaware corporation, and CBOE V, a Delaware limited liability company, each of which are direct, wholly owned subsidiaries of CBOE Holdings. Each of CBOE Corporation and CBOE V currently have no material assets or conduct any operations.

2. The Transaction

On September 25, 2016, BGM, CBOE Holdings, CBOE Corporation and CBOE V entered into an Agreement and Plan of Merger (the ''Merger Agreement''). Pursuant to and subject to the terms of the Merger Agreement, at the Closing, among other things:

(i) CBOE Corporation will be merged with and into BGM, whereupon the separate existence of CBOE Corporation will cease and BGM will be the surviving company (the ''Merger'');

[4] 15 U.S.C. 78f(g).

[5] 15 U.S.C. 78f(a).

(ii) by virtue of the Merger and without any action required on the part of BGM, CBOE Corporation or any holder of BGM or CBOE Corporation stock, each share of BGM common stock (whether voting or non-voting) issued and outstanding (with the exception of shares owned by CBOE Holdings, BGM or any of their respective subsidiaries and certain shares held by persons that are entitled to and properly demand appraisal rights) will be converted into the right to receive a particular number of shares of CBOE Holdings and/or cash, at the election of the holder of such share of BGM common stock (the ''Merger Consideration''), and each share of CBOE Corporation issued and outstanding will be converted into one share of BGM, such that BGM will become a wholly owned subsidiary of CBOE Holdings; and

(iii) immediately following the Merger, BGM will be merged with and into CBOE V, whereupon the separate existence of BGM will cease and CBOE V will be the surviving company (the ''Subsequent Merger'').

Upon the Closing, the Direct Edge Operating Agreement, the Exchange Bylaws and the Exchange Rules will be amended to take into account the post-Closing corporate structure, described below.

3. Post-Closing Corporate Structure

As a result of the Transaction, BGM will cease to exist and the business of BGM will be carried on by CBOE V, which is a wholly owned subsidiary of CBOE Holdings.[6] CBOE V will own 100 percent of the equity interest in Direct Edge and BGM Holdings. Direct Edge will continue to own 100 percent of the equity interest in the Exchange and EDGA. BGM Holdings will continue to own 100 percent of the equity interest in BZX, BYX, Bats Trading, and certain other subsidiaries not registered with the Commission in any capacity.[7]

4. Ownership and Voting Limitations of BGM; Resolutions

The BGM Charter provides that (i) no Person,[8] either alone or together with its Related Persons,[9] may own, directly or indirectly, of record or beneficially, shares constituting more than 40 percent of any class of its capital stock, and no Exchange Member, either alone or together with its Related Persons, may own, directly or indirectly, of record or beneficially, shares constituting more than 20 percent of any class of its capital stock (collectively, the ''BGM Ownership Limitation''); and (ii) subject to certain exceptions, no Person, either alone or together with its Related Persons, at any time, may, directly, indirectly or pursuant to any of various arrangements, vote or cause the voting of shares or give any consent or proxy with respect to shares representing more than 20 percent of the voting power of its then issued and outstanding capital stock (the ''BGM Voting Limitation'').[10] Purported transfers that would result in a violation of the BGM Ownership Limitation are not recognized by BGM to the extent of any ownership in excess of the BGM Ownership Limitation, and purported voting or voting arrangements in violation of the BGM Voting Limitation are not honored by BGM to the extent of any voting in excess of the limitation.[11]

However, the BGM Charter provides that each of the BGM Ownership Limitation and the BGM Voting Limitation may be waived (except with respect to Exchange Members and their Related Persons) pursuant to a resolution duly adopted by the BGM Board if, in connection with taking such action, the BGM Board states in such resolution that it is the determination of the BGM Board that the waiver:

- Will not impair the ability of each Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder;
- is otherwise in the best interests of BGM, its stockholders, and each Bats Exchange;
- will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder; and
- shall not be effective until it is filed with and approved by the Commission.[12]

In granting such a waiver, the BGM Board has the discretion to impose on the Person and its Related Persons, such conditions and restrictions that it deems necessary, appropriate or desirable in furtherance of the objectives of the Act and the rules and regulations promulgated thereunder, and the governance of each Bats Exchange.[13]

In addition, notwithstanding the above, the BGM Charter provides[14] that in any case where a Person, either alone or with its Related Persons, would own or vote more than the BGM Ownership Limitation or BGM Voting Limitation, respectively, upon consummation of any proposed sale, assignment or transfer of BGM's capital stock, such a transaction will not become effective until the BGM Board determines, by resolution, that such Person and its Related Persons are not subject to any ''statutory disqualification,'' as defined in Section 3(a)(39) of the Act.[15]

[6] In connection with the Transaction, CBOE Holdings agreed in the Merger Agreement to take all requisite actions so, as of the Closing, the CBOE Holdings Board will include three individuals designated by BGM who (1) are serving as BGM directors immediately prior to the Closing and (2) comply with the policies (including clarifications of the policies provided to BGM) of the Nominating and Governance Committee of the CBOE Holdings Board as in effect on the date of the Merger Agreement and previously provided to BGM (each of whom will be appointed to the CBOE Holdings Board as of the Closing). The CBOE Holdings Board currently consists of 14 directors. The Exchange expects three current CBOE Holdings directors to resign effective prior to the Closing and the remaining CBOE Holdings directors to fill those vacancies with the three BGM directors designated by BGM.

[7] As described above, the Transaction will result in a change of ownership of Bats Trading, which is a member of the Financial Industry Regulatory Authority, Inc. (''FINRA''). The Exchange understands that, pursuant to NASD Rule 1017, Bats Trading is seeking approval for this change of ownership from FINRA.

[8] The BGM Charter generally defines a ''Person'' as a natural person, partnership, corporation, limited liability company, entity, government, or political subdivision, agency or instrumentality of a government. *See* BGM Charter, Art. FIFTH, para. (a)(i).

[9] The BGM Charter generally defines a ''Related Person'' as, with respect to any Person, (i) any ''affiliate'' of such Person (as defined in Rule 12b-2 under the Act); (ii) any other Person with which such first Person has any agreement, arrangement or understanding (whether or not in writing) to act together for the purpose of acquiring, voting, holding or disposing of shares of the capital stock of BGM; (iii) in the case of a Person that is a company, corporation or similar entity, any executive officer (as defined under Rule 3b–7 under the Act) or director of such Person and, in the case of a Person that is a partnership or limited liability company, any general partner, managing member or manager of such Person, as applicable; (iv) in the case of any Person that is a registered broker or dealer that has been admitted to membership in any of the Bats Exchanges (for purposes of this definition of ''Related Person,'' each such national securities exchange shall be referred to generally as an ''Exchange'' and any member of such Exchange, an ''Exchange Member''), any Person that is associated with the Exchange Member (as determined using the definition of ''person associated with a member'' as defined under Section 3(a)(21) of the Act); (v) in the case of a Person that is a natural person and Exchange Member, any broker or dealer that is also an Exchange Member with which such Person is associated; (vi) in the case of a Person that is a natural person, any relative or spouse of such Person, or any relative of such spouse who has the same home as such Person or who is a director or officer of BGM or any of its parents or subsidiaries; (vii) in the case of a Person that is an executive officer (as defined under Rule 3b–7 under the Act) or a director of a company, corporation or similar entity, such company, corporation or entity, as applicable; and (viii) in the case of a Person that is a general partner, managing member or manager of a partnership or limited liability company, such partnership or limited liability company, as applicable. *See* BGM Charter, Art. FIFTH, para. (a)(ii).

[10] *See* BGM Charter, Art. FIFTH, para. (b).

[11] *See* BGM Charter, Art. FIFTH, para. (d).

[12] *See* BGM Charter, Art. FIFTH, para. (b)(ii)(B).

[13] *Id.*

[14] *See* BGM Charter, Art. FIFTH, para. (b)(iii).

[15] 15 U.S.C. 78c(a)(39).

As described above, as a result of the Merger (and prior to its separate existence ceasing as a result of the Subsequent Merger), BGM will become a wholly owned subsidiary of CBOE Holdings, such that CBOE Holdings will possess ownership and voting rights in BGM in excess of the Ownership Limitation and the Voting Limitation. In addition, as a result of the Subsequent Merger, BGM will merge with and into CBOE V, terminating the BGM Charter and becoming an entity whose ownership and voting is held entirely by CBOE Holdings, in excess of the BGM Ownership Limitation and the BGM Voting Limitation that would otherwise apply.

The BGM Board therefore determined that in order to effect the Transaction, a waiver of the BGM Ownership Limitation and the BGM Voting Limitation with respect to CBOE Holdings would be required. To do so, the BGM Board adopted the Resolutions, attached as Exhibit 5A, making certain determinations with respect to CBOE Holdings and the Transaction that are necessary to waive the BGM Ownership Limitation and BGM Voting Limitation. Specifically, the BGM Board determined that:

- The acquisition of the proposed ownership by CBOE Holdings in BGM will not impair the ability of each Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder, is otherwise in the best interests of BGM, its stockholders and the Bats Exchanges, and will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder;
- the acquisition or exercise of the proposed voting rights by CBOE Holdings in BGM will not impair the ability of each Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder, is otherwise in the best interests of BGM, its stockholders and the Bats Exchanges, and will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder;
- neither CBOE Holdings nor any of its Related Persons is subject to ''statutory disqualification'' within the meaning of Section 3(a)(39) of the Act; [16] and
- neither CBOE Holdings nor any of its Related Persons is an Exchange Member.[17]

The Exchange has reviewed such Resolutions and requests that the Commission approve such Resolutions. The Exchange believes that the Commission should approve the Resolutions, as the Transaction will not impair the ability of any Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder, or the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder. The Bats Exchanges will continue to operate and regulate their markets and members as they have done prior to the Transaction. Thus, each Bats Exchange will continue to enforce the Act, the Commission's rules thereunder, and each Exchange's own rules, in the manner it does today. Further, the Commission will continue to have plenary regulatory authority over the Bats Exchanges, as is currently the case with these entities.

The Exchange also notes that the Resolutions reflect the determination by the BGM Board that the Transaction and CBOE Holdings' resulting ownership and voting rights in BGM following the Merger, and CBOE V's ownership and voting rights following the Subsequent Merger, are otherwise in the best interests of BGM, its stockholders and the Bats Exchanges. The Bats Exchanges will be ultimately held by an entity, CBOE Holdings, that already owns other national securities exchanges and is subject to governance documents that similarly restrict concentration of ownership and voting rights.

As described in more detail below, the Exchange is also requesting approval of the adoption of the CBOE Holdings Charter and the CBOE Holdings Bylaws. The CBOE Holdings Charter includes a number of provisions relating to the Commission's regulatory oversight that have a similar effect as those in the BGM Charter, including the BGM Ownership Limitation and the BGM Voting Limitation. Therefore, notwithstanding the Resolutions and the Transaction, provisions similar (and, in some cases, more stringent) to the BGM Ownership Limitation and the BGM Voting Limitation will remain in place with respect to potential future transactions involving the ultimate parent company of the Bats Exchanges. This means that the Exchange ownership structure will continue to provide the Commission with appropriate oversight tools to ensure that the Commission will have the ability to enforce the Act with respect to the Exchange, its direct and indirect parent companies, and its directors, officers, employees and agents to the extent they are involved in the activities of the Exchange, and protect the independence of the Exchange's self-regulatory activities.

The Exchange therefore requests that the Commission approve the Resolutions, attached as Exhibit 5A.

5. CBOE Holdings Charter and CBOE Holdings Bylaws

CBOE Holdings currently holds a direct ownership interest in the CBOE Exchanges. The Commission has previously approved the CBOE Holdings Charter and the CBOE Holdings Bylaws (collectively, the ''CBOE Holdings Organizational Documents''), attached as Exhibits 5B and 5C, respectively.[18]

In connection with the Transaction, upon the Closing, CBOE Holdings will become the indirect owner (through CBOE V and Direct Edge) of the Exchange and EDGA and the indirect owner (through CBOE V and BGM Holdings) of BZX, BYX and Bats Trading (and certain other subsidiaries not registered with the Commission in any capacity).

The CBOE Holdings Organizational Documents include various provisions relating to any ''Regulated Securities Exchange Subsidiary,'' which is defined as any national securities exchange controlled, directly or indirectly, by CBOE Holdings. Upon the Closing, the Exchange will be covered by the

[16] *Id.*

[17] In addition, the Resolutions contain a determination that the execution and delivery of the Merger Agreement by CBOE Holdings constituted notice of CBOE Holdings' intention to acquire ownership and voting rights in excess of the BGM Ownership Limitation and BGM Voting Limitation, respectively, in writing and not less than 45 days before the Closing. *See* BGM Charter, Art. FIFTH, para. (b)(iv). The Exchange notes that Art. FIFTH, para. (c)(i) of the BGM Charter further requires that any Person that, either alone or together with its Related Persons, owns, directly or indirectly (whether by acquisition or by a change in the number of shares outstanding), of record or beneficially, five percent or more of the then outstanding shares of capital stock of BGM must immediately upon acquiring knowledge of its ownership of five percent or more give written notice of such ownership to the BGM Board. The Merger Agreement provides that the Merger Agreement constitutes such notice with respect to certain voting agreements entered into concurrently with the Merger Agreement. *See* Merger Agreement, Section 5.21.

[18] *See* Securities Exchange Act Release No. 62158 (May 24, 2010), 75 FR 30082 (May 28, 2010) (SR–CBOE–2008–88). The CBOE Organizational Documents have been subsequently amended from time to time pursuant to proposed rule changes that were filed with the Commission for immediate effectiveness. *See, e.g.,* Securities Exchange Act Release No. 76282 (October 27, 2015), 80 FR 67464 (November 2, 2015) (SR–CBOE–2015–092).

definition of Regulated Securities Exchange Subsidiary for purposes of the CBOE Holdings Organizational Documents. As a result, no amendments to the CBOE Holdings Organizational Documents will be necessary to reflect CBOE Holdings' indirect ownership of the Exchange.

The Exchange believes that the CBOE Holdings Organizational Documents will protect and maintain the integrity of the self-regulatory functions of the Exchange and facilitate the ability of the Exchange and the Commission to carry out their regulatory and oversight obligations under the Act, as the CBOE Organizational Documents do with respect to the CBOE Exchanges.

In addition, the CBOE Organizational Documents contain provisions, including those with respect to the following, that are similar to those contained in the BGM Charter and BGM's Amended and Restated Bylaws (the ''BGM Bylaws''), which the Commission has previously found to be consistent with the Act: [19]

• *Ownership and Voting Limitations.* Similar to the BGM Voting Limitation and the BGM Ownership Limitation contained in the BGM Charter, the CBOE Holdings Charter limits the extent of ownership and voting rights which certain persons may possess or exercise.[20] Like the BGM Charter, the CBOE Holdings Charter similarly prohibits any Person,[21] together with its Related Persons,[22] from exercising voting rights with respect to more than 20 percent of the then outstanding votes entitled to be cast on such matter.[23] However, with respect to ownership limitations, the CBOE Holdings Charter contains a more stringent threshold than contained in the BGM Charter. Under the CBOE Holdings Charter, no Person, together with its Related Persons, is permitted at any time to beneficially own directly or indirectly shares of stock of CBOE Holdings representing in the aggregate more than 20 percent of the then outstanding shares of stock of CBOE Holdings.[24] In contrast, the BGM Ownership Limitation only applies a 20 percent threshold to any Exchange Member together with its Related Persons, while applying a 40 percent threshold to any other Person together with its Related Persons. As a result, the CBOE Holdings Charter should be at least as effective as the BGM Charter at preventing any stockholder from exercising undue control over the operation of the Exchange.

• *Independence and Non-Interference.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that for so long as CBOE Holdings controls, directly or indirectly, a Regulated Securities Exchange Subsidiary, each officer, director and employee of CBOE Holdings must give due regard to the preservation of the independence of the self-regulatory function of the Regulated Securities Exchange Subsidiaries and may not take any actions that he or she knows or reasonably should have known would interfere with the effectuation of any decisions by the board of directors of any Regulated Securities Exchange Subsidiary relating to such Regulated Securities Exchange Subsidiary's regulatory functions (including disciplinary matters) or that would adversely affect the ability of the Regulated Securities Exchange Subsidiary to carry out such Regulated Securities Exchange Subsidiary's responsibilities under the Act.[25]

• *Confidentiality.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that, to the fullest extent permitted by applicable law, all confidential information pertaining to the self-regulatory function of Regulated Securities Exchange Subsidiaries contained in the books and records of any Regulated Securities Exchange Subsidiary that shall come into the possession of the CBOE Holdings must be retained in confidence by CBOE Holdings and its officers, directors, employees and agents and must not be used for any commercial purposes.[26]

• *Books and Records.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that, for so long as CBOE Holdings directly or indirectly controls any Regulated Securities Exchange Subsidiary, the books, records, premises, officers, directors and employees of CBOE Holdings shall be deemed to be the books, records, premises, officers, directors and employees of the Regulated Securities Exchange Subsidiary for purposes of and subject to oversight pursuant to the Act, but only to the extent that such books, records, premises, officers, directors and employees of the Corporation relate to the business of such Regulated Securities Exchange Subsidiary.[27]

• *Compliance With Securities Laws; Cooperation With the Commission.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that CBOE Holdings shall comply with the federal securities laws and the rules and regulations thereunder and shall cooperate with the Commission, and each Regulated Securities Exchange Subsidiary pursuant to and to the extent of its regulatory authority, and shall take reasonable steps necessary to cause its agents to cooperate with the Commission and, where applicable, the Regulated Securities Exchange Subsidiaries pursuant to their regulatory authority, with respect to such agents' activities related to the Regulated Securities Exchange Subsidiaries.[28]

• *Consent to Jurisdiction.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that CBOE Holdings, its directors, officers, agents and employees, irrevocably submit to the jurisdiction of the U.S. federal courts, the Commission, and the Regulated Securities Exchange Subsidiaries, for the purposes of any suit, action or proceeding pursuant to U.S. federal securities laws or the rules or regulations thereunder, commenced or initiated by the Commission arising out of, or relating to, the Regulated Securities Exchange Subsidiaries' activities.[29]

• *Amendments.* Similar to provisions contained in the BGM Charter and BGM Bylaws, the CBOE Organizational Documents provide that for so long as CBOE Holdings controls, directly or indirectly, Regulated Securities Exchange, before any amendment to or repeal of the CBOE Holdings Charter or CBOE Holdings Bylaws may be effective, such amendment or repeal must be submitted to the board of directors of each such exchange, and if the amendment or repeal is required to

[19] *See* Securities Exchange Act Release No. 77464 (March 29, 2016), 81 FR 19252 (April 4, 2016) (File Nos. SR–BATS–2016–10, SR–BYX–2016–02, SR–EDGX–2016–04, and SR–EDGA–2016–01).

[20] *Compare* CBOE Holdings Charter, Art. SIXTH *with* BGM Charter, Art. FIFTH.

[21] ''Person'' mean an individual, partnership (general or limited), joint stock company, corporation, limited liability company, trust or unincorporated organization, or any governmental entity or agency or political subdivision thereof. *See* CBOE Holdings Charter, Art. FIFTH, para. (a)(iv).

[22] ''Related Person'' is defined in the CBOE Holdings Charter in a manner substantially the same as it is defined in the BGM Charter. *See supra* note 9; CBOE Holdings Charter, Art. FIFTH, para. (a)(vi).

[23] *See* CBOE Holdings Charter, Art. SIXTH, para. (a).

[24] *See* CBOE Holdings Charter, Art. SIXTH, para. (b).

[25] *Compare* CBOE Holdings Charter, Art. SIXTEENTH, para. (c) *with* BGM Bylaws, Section 12.01.

[26] *Compare* CBOE Holdings Charter, Art. FIFTEENTH *with* BGM Bylaws, Section 12.02.

[27] *Compare* CBOE Holdings Charter, Art. FIFTEENTH *with* BGM Bylaws, Section 12.03.

[28] *Compare* CBOE Holdings Charter, Art. SIXTEENTH, para. (a) *with* BGM Bylaws, Section 12.04.

[29] *Compare* CBOE Holdings Charter, Art. FOURTEENTH *with* BGM Bylaws, Section 12.05.

be filed with, or filed with and approved by the Commission, then such change shall not be effective until filed with, or filed with and approved by, the Commission, as the case may be.[30] As stated above, the Exchange believes that the foregoing provisions will assist the Exchange in fulfilling its self-regulatory obligations and in administering and complying with the requirements of the Act.

6. CBOE V Certificate and CBOE V Operating Agreement

Effective as of the Closing of the Transaction, CBOE V will hold direct ownership of (i) Direct Edge, which will continue to hold direct ownership of the Exchange and EDGA and (ii) BGM Holdings, which will continue to hold direct ownership of BZX, BYX and Bats Trading (and certain other subsidiaries not registered with the Commission in any capacity). However, unlike BGM currently, CBOE V will not be the ultimate holding company under the post-Closing corporate structure, but rather will be an intermediate holding company owned by CBOE Holdings. The Exchange believes that the CBOE V Operating Agreement contains provisions relating to its indirect ownership of one or more national securities exchanges, including such exchanges' regulatory functions and Commission oversight, that are appropriate for an intermediate holding company in the ownership chain of a national securities exchange. Many of the provisions of the CBOE V Operating Agreement relating to these matters are similar to the organizational documents of Direct Edge, which currently is, and following the Subsequent Merger will be, similarly situated as an intermediate holding company of the Exchange. The Commission has previously found the Direct Edge organizational documents to be consistent with the Act.[31]

Although CBOE V will not carry out any regulatory functions, the Exchange notes that its activities with respect to the operation of the Bats Exchanges must be consistent with, and must not interfere with, the self-regulatory obligations of each Bats Exchange. The CBOE V Operating Agreement therefore includes certain provisions that are designed to maintain the independence of the Bats Exchanges' self-regulatory functions, enable the Bats Exchanges to operate in a manner that complies with the federal securities laws, including the objectives of Sections 6(b)[32] and 19(g)[33] of the Act, and facilitate the ability of each Bats Exchange and the Commission to fulfill their respective regulatory and oversight obligations under the Act.

a. CBOE V Certificate of Formation

The CBOE V Certificate, attached as Exhibit 5D, includes the following provisions required under Delaware law: (i) The full name of CBOE V as ''CBOE V, LLC'', and (ii) the name and address of CBOE V's registered office in the State of Delaware and the name of CBOE V's registered agent at such address.[34] In addition, the CBOE V Certificate contains a provision providing that CBOE V shall indemnify members of its board of directors and certain other persons, subject to certain conditions.

As the Exchange believes is customary for limited liability companies formed in the State of Delaware, other substantive provisions governing the ownership, operation and management of CBOE V are set forth in the CBOE V Operating Agreement, discussed below.

b. CBOE V Operating Agreement

With respect to ownership and control of CBOE V, the CBOE V Operating Agreement, attached as Exhibit 5E, specifically provides that CBOE V's sole member is CBOE Holdings, until the CBOE V Operating Agreement is amended (subject to Commission approval, as described below).[35] Further, for so long as CBOE V controls, directly or indirectly, a subsidiary that is registered with the Commission as a national securities exchange (an ''Exchange Subsidiary''), CBOE Holdings may not sell, assign, transfer, convey, gift, exchange or otherwise dispose of any or all of its member interest in CBOE V, except pursuant to an amendment to the CBOE V Operating Agreement that is filed with and approved by the Commission.[36] These restrictions are designed to ensure that any change to the ownership or control of any Exchange Subsidiary, including without limitation the Bats Exchanges, may only occur through a change in the ownership or control of CBOE Holdings. As such, any purported change of such ownership or control (unless pursuant to a Commission-approved change of ownership of CBOE V) would need to comply with the CBOE Holdings Charter and CBOE Holdings Bylaws, including the ownership and voting limitations discussed above (or a Commission-approved waiver therefrom).

The CBOE V Operating Agreement also contains several provisions designed to protect the independence of the self-regulatory functions of the Bats Exchanges. The CBOE V Operating Agreement requires that, for so long as CBOE V, directly or indirectly, controls any Exchange Subsidiary, CBOE Holdings, as the sole member of CBOE V, and officers, employees and agents of CBOE V must give due regard to the preservation of independence of the self-regulatory functions of such Exchange Subsidiary, as well as to its obligations to investors and the general public, and not interfere with the effectuation of any decisions by the board of directors of an Exchange Subsidiary relating to its regulatory functions (including disciplinary matters) or which would interfere with the ability of such Exchange Subsidiary to carry out its responsibilities under the Act.[37]

The CBOE V Operating Agreement also would require that CBOE V comply with the U.S. federal securities laws and rules and regulations thereunder and cooperate with the Commission and each Exchange Subsidiary, as applicable, pursuant to and to the extent of their respective regulatory authority.[38] Further, CBOE V's officers, directors, employees and agents shall be deemed to agree to (i) comply with the U.S. federal securities laws and the rules and regulations thereunder; and (ii) cooperate with the Commission and each Exchange Subsidiary in respect of the Commission's oversight responsibilities regarding such Exchange Subsidiary and the self-regulatory functions and responsibilities of the Exchange Subsidiaries, and CBOE V will take reasonable steps to cause its officers, employees and agents to so cooperate.[39]

Furthermore, to the fullest extent permitted by law, CBOE V and its officers, directors, employees and agents will be deemed to irrevocably submit to the jurisdiction of the U.S. federal courts, the Commission, and each Exchange Subsidiary, as applicable, for purposes of any suit, action, or proceeding pursuant to the U.S. federal securities laws or the rules or

[30] *Compare* CBOE Holdings Charter, Arts. ELEVENTH, TWELFTH and CBOE Holdings Bylaws, Section 10.2 *with* BGM Charter, Art. FOURTEENTH and BGM Bylaws, Article XI.

[31] *See* Securities Exchange Act Release No. 71449 (January 30, 2014), 79 FR 6961 (February 5, 2014) (SR–EDGA–2013–34; SR–EDGX–2013–43).

[32] 15 U.S.C. 78f(b).

[33] 15 U.S.C. 78s(g).

[34] Delaware Limited Liability Company Act § 18–201.

[35] CBOE V Operating Agreement, Section 1.1.

[36] CBOE V Operating Agreement, Section 5.1.

[37] *See* CBOE V Operating Agreement, Section 10.1(a).

[38] *See* CBOE V Operating Agreement, Section 10.2(a).

[39] *Id.*

regulations thereunder arising out of, or relating to, the activities of such Exchange Subsidiary.[40]

The proposed CBOE V Operating Agreement also contains a number of provisions designed to ensure that the Exchange will have sufficient access to the books and records of CBOE V as they relate to any Exchange Subsidiary. Pursuant to the CBOE V Operating Agreement, to the extent they are related to the operation or administration of an Exchange Subsidiary, the books, records, premises, officers, agents, and employees of CBOE V are deemed to be the books, records, premises, officers, agents and employees of such Exchange Subsidiary for the purposes of, and subject to oversight pursuant to, the Act.[41] In addition, for as long as CBOE V controls, directly or indirectly, an Exchange Subsidiary, CBOE V's books and records shall be subject at all times to inspection and copying by the Commission and the applicable Exchange Subsidiary, provided that such books and records are related to the operation or administration of an Exchange Subsidiary.[42]

The proposed CBOE V Operating Agreement also provides that, to the fullest extent permitted by law, all books and records of any Exchange Subsidiary reflecting confidential information pertaining to the self-regulatory function of such Exchange Subsidiary (including disciplinary matters, trading data, trading practices and audit information) that comes into the possession of CBOE V, shall be retained in confidence by CBOE V, CBOE V's officers, employees and agents and CBOE Holdings, and not used for any non-regulatory purposes.[43] The proposed CBOE V Operating Agreement provides, however, that the foregoing shall not limit or impede the rights of the Commission or an Exchange Subsidiary to access and examine such confidential information pursuant to the U.S. federal securities laws and the rules and regulations thereunder, or limit or impede the ability of CBOE Holdings or any of CBOE V's officers, employees or agents to disclose such confidential information to the Commission or an Exchange Subsidiary.[44]

In addition, the CBOE V Operating Agreement provides that for so long as CBOE V controls, directly or indirectly, any Exchange Subsidiary, before any amendment to or repeal of any provision of the CBOE V Operating Agreement will be effective, those changes must be submitted to the board of directors of each Exchange Subsidiary, and if the same must be filed with, or filed with and approved by, the Commission before the changes may be effective under Section 19 of the Act [45] and the rules promulgated thereunder, then the proposed changes shall not be effective until filed with, or filed with and approved by, the Commission, as the case may be.[46]

7. Direct Edge Operating Agreement

The Direct Edge Operating Agreement currently provides that the sole member of Direct Edge is BGM. However, as a result of the Transaction, CBOE V will become the sole member of Direct Edge. The Exchange proposes to amend the Direct Edge Operating Agreement to reflect this change, as set forth in Exhibit 5F.

8. Bylaws of the Exchange

In connection with the Transaction, the Exchange proposes to amend and restate its Fifth Amended and Restated Bylaws and adopt the amended Exchange Bylaws as its Sixth Amended and Restated Bylaws, attached as Exhibit 5G. Specifically, the Exchange proposes to (i) expand the prohibition contained in Section 2 of Article XI of the Exchange Bylaws and (ii) add a definition of ''Trading Permit Holder'' to Article I.

Currently, Section 2 of Article XI of the Exchange Bylaws prohibits directors of BGM or Direct Edge who are not also directors, officers, staff, counsel or advisors of the Exchange from participating in any meetings of the Exchange's board of directors (or any committee thereof) pertaining to the self-regulatory function of the Exchange (including disciplinary matters). This provision refers to BGM and Direct Edge because they are currently the only direct and indirect owners of the Exchange. However, following the Transaction, the Exchange will be owned indirectly by CBOE V and CBOE Holdings (in addition to its direct ownership by Direct Edge). Therefore, the Exchange is proposing to remove the reference to BGM and insert references to CBOE V and CBOE Holdings, so that CBOE V and CBOE Holdings will both be covered by this prohibition. The Exchange believes that this amendment will protect the independence of the Exchange's self-regulatory activities.

In addition, as noted above, the CBOE Holdings Charter currently prohibits certain persons from owning or exercising voting rights over certain percentages of ownership of CBOE Holdings. The CBOE Holdings Charter permits the board of directors of CBOE Holdings to waive the limitation on the exercise of voting rights in excess of 20 percent of the then outstanding votes entitled to be cast on such matter only if, among other things, ''for so long as [CBOE Holdings] directly or indirectly controls any Regulated Securities Exchange Subsidiary, neither such Person nor any of its Related Persons is a 'Trading Permit Holder' (as defined in the Bylaws of any Regulated Securities Exchange Subsidiary as they may be amended from time to time).'' [47]

The Exchange does not issue ''trading permits,'' but admits members. The Exchange believes the provisions of the CBOE Holdings Charter that refer to Trading Permit Holders of its Regulated Securities Exchange Subsidiaries should apply equally to members of the Exchange once it becomes a Regulated Securities Exchange Subsidiary of CBOE Holdings. As a result, the Exchange proposes to add clause (ff) to Article I of the Exchange Bylaws, providing that '' 'Trading Permit Holder' shall have the same meaning as Exchange Member.'' This will ensure that the Exchange's members will be considered Trading Permit Holders of a Regulated Securities Exchange Subsidiary for purposes of the CBOE Holdings Charter.

9. Exchange Rules

a. Exchange Rule 2.3—Member Eligibility

Pursuant to Exchange Rule 2.3, in order to be eligible for membership in the Exchange, a registered broker or dealer is currently required to be a member of at least one other national securities association or national securities exchange. However, membership in the Exchange's affiliated national securities exchanges, BZX, BYX or EDGA, is not sufficient for purposes of eligibility for Exchange membership. The Exchange adopted this because the Bats Exchanges have historically not functioned as the designated examining authority for any of its members, and the Exchange wanted to be sure that any member would be appropriately supervised by another national securities association or national securities exchange that has

[40] *See* CBOE V Operating Agreement, Section 10.3(a).

[41] *See* CBOE V Operating Agreement, Section 8.4(b).

[42] *Id.*

[43] *See* CBOE V Operating Agreement, Section 8.4(a).

[44] *Id.*

[45] 15 U.S.C. 78s.

[46] *See* CBOE V Operating Agreement, Section 11.2.

[47] *See* CBOE Holdings Charter, Art. SIXTH, para. (a)(ii)(C).

the capacity to function as the member's designated examining authority.

As a result of the Transaction, the Exchange will additionally become affiliated with the CBOE Exchanges. As with the Bats Exchanges, C2 does not currently serve as the designated examination authority for any of its members. CBOE, however, does act as the designated examining authority for certain of its members. Therefore, the Exchange proposes to amend Exchange Rule 2.3 to specify that a registered broker or dealer will be eligible for membership only if it is a member of a national securities association or national securities exchange other than or in addition to the following affiliates of the Exchange: BZX, BYX, EDGA and C2.

In addition, to ensure there is no confusion with respect to the possibility that a broker or dealer could qualify for membership in the Exchange based solely on membership in CBOE Futures or any other national securities exchange notice—registered with the Commission pursuant to Section 6(g) of the Act [48] that lists or trades security-futures products, the Exchange proposes to also specify that eligibility for membership requires membership in a national securities association registered pursuant to Section 15A of the Act or a national securities exchange registered with the Commission pursuant to Section 6(a) of the Act, so as to exclude a national securities exchange registered solely under Section 6(g) of the Act. The proposed amendments to Exchange Rule 2.3 are set forth in Exhibit 5H.

b. Exchange Rule 2.10—Affiliation Between Exchange and a Member

Exchange Rule 2.10 provides that, without prior approval of the Commission, neither the Exchange, nor any of its affiliates, shall directly or indirectly acquire or maintain an ownership interest in a member of the Exchange. This restriction is intended to address potential conflicts of interest that could result from affiliation between the Exchange and a member. Notwithstanding this general restriction, Exchange Rule 2.10 provides that it does not prohibit a member or its affiliate from acquiring or holding an equity interest in BGM that is permitted by the ownership and voting limitations contained in the BGM Charter and the BGM Bylaws. In addition, Exchange Rule 2.10 states that it does not prohibit a member from being or becoming an affiliate of the Exchange, or an affiliate of any affiliate of the Exchange, solely by reason of such member or any officer, director, manager, managing member, partner or affiliate of such member being or becoming either (a) a director of the Exchange pursuant to the Bylaws of the Exchange, or (b) a director of the Exchange serving on the board of directors of BGM. The Exchange proposes to replace the references to BGM in Rule 2.10 with references to CBOE Holdings to reflect the fact that following the Transaction, CBOE Holdings will replace BGM as the ultimate parent holding company of the Exchange.

Exchange Rule 2.10 also clarifies that it does not prohibit the Exchange from being an affiliate of its routing broker-dealer Direct Edge ECN LLC d/b/a DE Route (''DE Route'') or of EDGA, BZX, BYX, or Bats Trading, each of which are affiliated with the Exchange. The Exchange proposes to remove the reference to DE Route to reflect the fact that Bats Trading previously replaced DE Route as the Exchange's routing broker-dealer.[49] The Exchange also proposes to add references to the CBOE Exchanges, as the CBOE Exchanges will become new affiliated exchanges following the Transaction. The proposed amendments to Exchange Rule 2.10 are set forth in Exhibit 5H.

c. Exchange Rule 2.12—Bats Trading, Inc. as Inbound Router

Exchange Rule 2.12 provides that the Exchange, on behalf of BGM, shall establish and maintain procedures and internal controls reasonably designed to ensure that Bats Trading does not develop or implement changes to its systems on the basis of nonpublic information obtained as a result of its affiliation with the Exchange until such information is available generally to similarly situated members of the Exchange in connection with the provision of inbound order routing to the Exchange. The Exchange proposes to replace the reference to BGM with a reference to ''the holding company indirectly owning the Exchange and Bats Trading.'' This change would reflect the fact that BGM would no longer be the ultimate holding company of the Exchange following the Transaction and would also make this language consistent with the language used in Rule 2.12 of the BZX and BYX rulebooks. The proposed amendments to Exchange Rule 2.12 are set forth in Exhibit 5H.

2. Statutory Basis

The Exchange believes that the Proposed Rule Change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[50] In particular, the proposal is consistent with Section 6(b)(1) of the Act [51] in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the Rules of the Exchange.

The Proposed Rule Change is designed to enable the Exchange to continue to have the authority and ability to effectively fulfill its self-regulatory duties pursuant to the Act and the rules promulgated thereunder. In particular, the Proposed Rule Change includes in the CBOE Holdings Charter and CBOE Holdings Bylaws, like the BGM Charter and BGM Bylaws, various provisions intended to protect and maintain the integrity of the self-regulatory functions of the Exchange upon Closing. For example, the CBOE Holdings Charter, as described above, is drafted to preserve the independence of the Exchange's self-regulatory function and carry out its regulatory responsibilities under the Act. In addition, the CBOE Holdings Charter imposes limitations similar to the BGM Ownership Limitation and BGM Voting Limitation to preclude undue influence over or interference with the Exchange's self-regulatory functions and fulfillment of its regulatory duties under the Act.

Moreover, notwithstanding the Proposed Rule Change, including the change to the indirect ownership of the Exchange, the Commission will continue to have regulatory authority over the Exchange, as is currently the case, as well as jurisdiction over the Exchange's direct and indirect parent companies with respect to activities related to the Exchange.[52] As a result, the Proposed Rule Change will facilitate an ownership structure that will provide the Commission with appropriate oversight tools to ensure that the Commission will have the ability to enforce the Act with respect to the Exchange, its direct and indirect parent

[48] 15 U.S.C. 78f(g).

[49] *See* Securities Exchange Act Release No. 71449 (January 30, 2014), 79 FR 6961 (February 5, 2014) (SR–EDGA–2013–34; SR–EDGX–2013–43).

[50] 15 U.S.C. 78f(b).

[51] 15 U.S.C. 78f(b)(1).

[52] *See, e.g.*, CBOE Holdings Charter, Art. FOURTEENTH; CBOE V Operating Agreement, Section 10.3; Direct Edge Operating Agreement, Section 10.3.

companies and their directors, officers, employees and agents to the extent they are involved in the activities of the Exchange.

The Exchange also believes that the Proposed Rule Change furthers the objectives of Section 6(b)(5) of the Act [53] because the Proposed Rule Change would be consistent with and facilitate a governance and regulatory structure that is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

In addition, as discussed further in the Exchange's Statement on Burden on Competition below, the Exchange expects that the Transaction will foster further innovation while facilitating efficient, transparent and well-regulated markets for issuers and investors, removing impediments to, and perfecting the mechanism of a free and open market and a national market system. The Transaction will benefit investors and the securities market as a whole by, among other things, enhancing competition among securities venues and reducing costs.

Furthermore, the Exchange is not proposing any significant changes to its existing operational and trading structure in connection with the change in ownership; the Exchange will operate in essentially the same manner upon Closing as it operates today. Therefore, the Exchange believes that it will continue to satisfy the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange. The changes that the Exchange is proposing to the Exchange Rules are designed to reflect the prospective affiliation with CBOE Holdings and the CBOE Exchanges. The Exchange believes that the proposed change to its Rules is consistent with the requirements of the Act and the rules and regulations thereunder.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the Proposed Rule Change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Indeed, the Exchange believes that the Proposed Rule Change will enhance competition among trading venues, as the Exchange believes that the Transaction will result in various synergies and efficiencies. For example, the Transaction will allow the Bats Exchanges and the CBOE Exchanges to utilize a single technology platform, which the Exchange expects will reduce Bats Exchanges' and the CBOE Exchanges' combined costs, creating the opportunity to further reduce costs to their respective members and other constituents. The potential use of a single technology platform may also reduce investors' costs of connecting to and using the Bats Exchanges and the CBOE Exchanges, including through the combination of data centers and market data services. Combining the expertise of the CBOE Exchanges' personnel with the expertise of the Bats Exchanges' personnel will also facilitate ongoing innovation, including through new product creation and platform improvements.

The Exchange notes that the Bats Exchanges and the CBOE Exchanges generally operate with different business models, target different customer bases and primarily focus on different asset classes, limiting any concern that the Transaction could burden competition. Therefore, the Exchange expects that the Transaction will benefit investors, issuers, shareholders and the market as a whole. The Exchange will continue to conduct regulated activities (including operating and regulating its market and members) of the type it currently conducts, but will be able to do so in a more efficient manner to the benefit of its members. These efficiencies will pass through to the benefit of investors and issuers, promoting further efficiencies, competition and capital formation, placing no burden on competition not necessary or appropriate in furtherance of the Act.

Furthermore, the Exchange's conclusion that the Proposed Rule Change would not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act is consistent with the Commission's prior conclusions about similar combinations involving multiple exchanges in a single corporate family.[54]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited or received written comments on the Proposed Rule Change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BatsEDGX–2016–60 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsEDGX–2016–60. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be

[53] 15 U.S.C. 78f(b)(5).

[54] *See, e.g.,* Securities Exchange Act Release Nos. 71375 (January 23, 2014), 79 FR 4771 (January 29, 2014) (SR–BATS–2013–059; SR–BYX–2013–039); 66071 (December 29, 2011), 77 FR 521 (January 5, 2012) (SR–CBOE–2011–107 and SR–NSX–2011–14); 58324 (August 7, 2008), 73 FR 46936 (August 12, 2008) (SR–BSE–2008–02; SR–BSE–2008–23; SR–BSE–2008–25; SR–BSECC–2008–01); 53382 (February 27, 2006), 71 FR 11251 (March 6, 2006) (SR–NYSE–2005–77).

available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsEDGX–2016–60, and should be submitted on or before December 6, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[55]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27369 Filed 11–14–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79262; File No. SR–BX–2016–153]

Self-Regulatory Organizations; NASDAQ BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Commentary .14 to Rule 4770 (Compliance With Regulation NMS Plan To Implement a Tick Size Pilot)

November 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 31, 2016, NASDAQ BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Commentary .14 to Rule 4770 (Compliance with Regulation NMS Plan to Implement a Tick Size Pilot) to provide the SEC with notice of its efforts to re-program its systems to eliminate a re-pricing functionality for certain orders in Test Group Three securities in connection with the Regulation NMS Plan to Implement a Tick Size Pilot Program (''Plan'' or ''Pilot'').[3]

The text of the proposed rule change is set forth below. Proposed new language is underlined; deleted text is in brackets.

* * * * *

NASDAQ BX Rules

* * * * *

4770. Compliance With Regulation NMS Plan To Implement a Tick Size Pilot

(a) through (d) No Change.

Commentary

.01–.13 No change.

.14 Until [October 31, 2016] *November 14, 2016,* the treatment of Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols in Test Group Three securities shall be as follows:

Following entry, and if market conditions allow, a Price to Comply Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Comply Order is able to be ranked and displayed at its original entered limit price.

Following entry, and if market conditions allow, a Price to Display Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Display Order is able to be ranked and displayed at its original entered limit price.

Following entry, and if market conditions allow, a Non-Displayed Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO up (down) to the Order's limit price.

Following entry, and if market conditions allow, the Post-Only Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO or the best price on the Exchange Book, as applicable until such time as the Post-Only Order is able to be ranked and displayed at its original entered limit price.

* * * * *

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

On September 7, 2016, the Exchange filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change (''Proposal'') to adopt paragraph (d) to Exchange Rule 4770 to describe changes to system functionality necessary to implement the Plan. The Exchange also proposed amendments to Rule 4770(a) and (c) to clarify how the Trade-at exception may be satisfied. The SEC published the Proposal in the **Federal Register** for notice and comment on September 20, 2016.[4] BX subsequently filed three Partial Amendments to clarify aspects of the Proposal. The Commission approved the Proposal, as amended, on October 7, 2016.[5]

In SR–BX–2016–050, BX had initially proposed a re-pricing functionality for Price to Comply Orders, Non-Displayed Orders, and Post-Only Orders entered through the OUCH and FLITE protocols in Group Three securities.[6] BX subsequently determined that it would not offer this re-pricing functionality for

[55] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) (''Approval Order'').

[4] *See* Securities Exchange Act Release No. 78838 (September 14, 2016), 81 FR 64566 (September 20, 2016) (SR–BX–2016–050).

[5] *See* Securities Exchange Act Release No. 79076 (October 7, 2016) (SR–BX–2016–050).

[6] As originally proposed, Rule 4770(d)(2) stated that Price to Comply Orders in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Comply Order is able to be ranked and displayed at its original entered limit price. Rule 4770(d)(3) stated that, if market conditions allow, a Non-Displayed Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO up (down) to the Order's limit price. Rule 4770(d)(4) stated that, if market conditions allow, the Post-Only Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO or the best price on the BX Book, as applicable until such time as the Post-Only Order is able to be ranked and displayed at its original entered limit price.

Price to Comply Orders, Non-Displayed Orders, and Post-Only Orders entered through the OUCH and FLITE protocols in Group Three securities. As part of Partial Amendment No. 2 to SR–BX–2016–050, BX proposed to delete the relevant language from Rule 4770 related to this re-pricing functionality.

In that amendment, BX noted that this change would only impact the treatment of Price to Comply Orders, Non-Displayed Orders, and Post-Only orders that are submitted through the OUCH and FLITE protocols in Test Group Three Pilot Securities, as these types of Orders that are currently submitted to BX through the RASH or FIX protocols are already subject to this re-pricing functionality and will remain subject to this functionality under the Pilot.

In the Amendment, BX further noted that its systems are currently programmed so that Price to Comply Orders, Non-Displayed Orders and Post-Only Orders entered through the OUCH and FLITE protocols in Test Group Three Securities may be adjusted repeatedly to reflect changes to the NBBO and/or the best price on the BX book. BX stated that it is re-programming its systems to remove this functionality for Price to Comply Orders, Non-Displayed Orders and Post-Only Orders entered through the OUCH and FLITE protocols in Test Group Three Securities. In the Amendment, BX stated that it anticipated that this re-programming shall be completed no later than November 30, 2016. If it appears that this functionality will remain operational by October 17, 2016, BX indicated that it would file a proposed rule change with the SEC and will provide notice to market participants sufficiently in advance of that date to provide effective notice. The rule change and the notice to market participants will describe the current operation of the BX systems in this regard, and the timing related to the re-programming.

On October 17, 2016, BX filed a proposal to extend the date by which it would complete the re-programing of its systems to eliminate the re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols.[7] In that proposal, BX stated that it anticipated that this re-programming shall be complete on or before October 31, 2016.[8]

At this time, BX is still determining how to modify its systems to eliminate the current re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols. BX is therefore submitting this proposal to extend the date by which the current re-pricing functionality will be eliminated. BX anticipates that the re-programming to eliminate the current re-pricing functionality shall be completed on or before November 14, 2016.

Therefore, the current treatment of Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols in Test Group Three securities shall be as follows:

Following entry, and if market conditions allow, a Price to Comply Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Comply Order is able to be ranked and displayed at its original entered limit price.

Following entry, and if market conditions allow, a Price to Display Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Display Order is able to be ranked and displayed at its original entered limit price.

Following entry, and if market conditions allow, a Non-Displayed Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO up (down) to the Order's limit price.

Following entry, and if market conditions allow, a Post-Only Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO or the best price on the BX Book, as applicable until such time as the Post-Only Order is able to be ranked and displayed at its original entered limit price.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The purpose of this filing is to inform the SEC and market participants of the status of BX's attempts to re-program its systems to remove the re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols, and the current treatment of such orders pending the removal of this functionality. This proposal is consistent with the Act because it provides the SEC and market participants with notice of BX's efforts in this regard, and is being submitted in connection with the statements made by BX in SR–BX–2016–050 and SR–BX–2016–054 in proposing the removal of this functionality.

BX also believes that the proposal is consistent with the Act because the re-pricing functionality will not significantly impact the data gathered pursuant to the Pilot. BX notes that this re-pricing functionality only affects Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols for Test Group Three securities until the re-pricing functionality is eliminated, and only becomes relevant when an Order in a Test Group Three security would cross a Protected Quotation of another market center. BX has analyzed data relating to the frequency with which Orders in Test Group Three securities are entered with a limit price that would cross a Protected Quotation of another market center, and believes that the re-pricing functionality will be triggered infrequently once Test Group Three becomes fully operational.[11] The Exchange also notes that it is diligently working to eliminate the current re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols, and that it anticipates this re-programming to be complete on or before November 14, 2016.

[7] *See* Securities Exchange Act Release No. 79154 (October 25, 2016) (SR–BX–2016–054).

Subsequent to the approval of SR–BX–2016–050, BX become aware that this re-pricing functionality also applies to Price to Display Orders that are entered through the OUCH and FLITE protocols in Test Group Three Securities, and included those Orders as part of SR–BX–2016–054 accordingly. Price to Display Orders will be treated in the same manner as Price to Comply Orders under the re-pricing functionality.

[8] *Id.*

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] For example, on October 31, 2016, in the one hundred Test Group Three securities that are currently live, 0.06% of orders that were entered on the NASDAQ Stock Market LLC in those securities were entered at a price that crossed the NBBO.

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 purpose of this proposal is to provide the SEC and market participants with notice of BX's efforts to remove its re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols, consistent with its statements in SR–BX–2016–050 and SR–BX–2016–054.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[12] and subparagraph (f)(6) of Rule 19b–4 thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing. Rule 19b–4(f)(6)(iii), however, permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay contained in Rule 19b–4(f)(6)(iii) so that this proposed change will be in operative as of October 31, 2016, the date that Test Group Three securities are fully implemented and are subject to the quoting and trading restrictions of the Plan and, therefore, the relevant language in Rule 4770.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to implement the proposed rules immediately thereby preventing delays in the implementation of the Plan. The Commission notes that the Pilot started implementation on October 3, 2016, Test Group Three securities were fully phased into the Pilot on October 31, 2016, and waiving the 30-day operative delay would ensure that the rules of the Exchange would be in place during implementation. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2016–153 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2016–153. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2016–153, and should be submitted on or before December 6, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27367 Filed 11–14–16; 8:45 am]

BILLING CODE 8011–01–P

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79258; File No. SR–BOX–2016–50]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing of Proposed Rule Change To Amend Rule 5050 Series of Options Contracts Open for Trading To Provide for the Listing and Trading on the Exchange of RealDay™ Options Pursuant to a Pilot Program

November 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 26, 2016, 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 5050 to provide for the listing and trading on the Exchange of RealDay™ Options pursuant to a pilot program. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules to provide for the listing and trading on the Exchange of a new type of standardized option product on the SPDR® S&P 500® Exchange Traded Fund (''ETF'') (this security is known by its symbol ''SPY'') called RealDay™ Options (''RealDay Options'') pursuant to a pilot program ending 12 months after approval of all necessary changes to the applicable BOX Rules has been received from the Securities and Exchange Commission (the ''SEC'' or ''Commission''). RealDay Options will possess many of the characteristics of existing standardized options with some important variations. Most notably, at the commencement of trading of a particular RealDay Option and until the close of trading on the last trading day before its expiration, the numerical value of the strike price will not be known. However, the formula used to calculate the strike price will be fixed and known from the time of listing.[3]

RealDay Options are a propriety product that are designed and exclusively licensed by the RealDay Options Corporation.[4] RealDay Options will be exclusively listed on BOX. RealDay Options are designed to have an active period, where the numerical value of the strike prices is known, for exactly one trading day but can be listed far in advance of their expiration date. Although the active period is only one trading day, RealDay options can still be traded during the anticipatory period which is the period of time from listing until the close of trading on the trading day prior to expiration. The Exchange believes that there is interest for options designed to cover a single trading day across all market participants, including institutional investors and the public. RealDay Options are true, or real, one-day options, because they are forward-start (or delayed start[5]) options whose strike increments and strike price setting formula are fixed from the time they are listed, but whose numerical strike prices are determined based on the formula which uses the closing price of SPY from the last trading day before expiration. This unique structure of having the strike intervals and strike price setting formula fixed from the time they are listed but not knowing the numerical value of the strike price until the exercise price setting date—which is after the close of trading on the last trading day before expiration—is what makes these options one-day options.

Initially, RealDay Options will only be listed on SPY but the Exchange may seek to list RealDay Options on additional securities in the future,[6] provided that the Exchange receives the necessary approval from the Commission. The Exchange has selected SPY as the initial security to list RealDay Options on due to the vast liquidity in the security. Specifically, SPY is the largest and most actively traded ETF in the United States. According to State Street Global Advisor, the Trustee of SPY, as of October 5, 2016, the total net assets of SPY were approximately $198 billion, and the weighted average market capitalization of the portfolio components was approximately $146 billion.[7] For the three months ending October 5, 2016, the average daily volume in SPY shares was approximately 85 million.[8]

RealDay Options will be P.M. cash-settled and have European-style exercise provisions.[9] These options may expire every trading day, including days on which monthly options series, Short Term Options Series, and Quarterly Options Series on SPY expire. The Exchange believes that cash settlement is more appropriate than physical settlement and therefore is best suited for this product. Physical settlement possesses certain risks with respect to volatility and movement of the underlying security at expiration that the recipient may need to hedge against. Cash settlement does not have any of these risks associated with the underlying security. If an issue with the delivery of the underlying security arises, it may become more expensive to reverse due to a change in the price of the underlying security; such risk does not exist with reversing a cash payment. Additionally, with physical settlement, the recipient has to sell the underlying security if they desire cash, which would cause them to incur costs associated with liquidating the position and has risks related to movement of the underlying price before it can be liquidated. Further, if RealDay Options were physically settled, an investor would need to carry the security overnight and liquidate the next trading day; this would defeat the purpose of having an option where the active period is designed to cover only a single trading day. If an investor had to liquate the next trading day, there would be a risk that the price of the security could change overnight before the investor would be able to liquidate their position.[10] The Exchange notes that there are still certain risks with cash settlement, however, these risks are minimal and will continue to be monitored. The Exchange notes that cash settlement for options is not a unique feature and other options exchanges have cash settled options.[11] Additionally, the Exchange has discussed RealDay Options with market participants and they have expressed

[3] The Exchange notes that this is not a new concept. *See* Chicago Board Options Exchange, Incorporated (''CBOE'') Rule 24.1(aa).

[4] The RealDay Options Corporation is a design and product development company specializing in innovative exchange-listed derivative instruments. For more information visit *http://realdayoptions.com/.*

[5] Delayed start options are options that do not have an exercise price when first introduced for trading, but instead have an exercise price setting formula pursuant to which the exercise price will be fixed on a specified future date. The price setting formula is fixed and known from the time of listing.

[6] The Exchange would use the SEC's form 19b–4 approval process in order to list RealDay Options on additional securities.

[7] *See https://www.spdrs.com/product/fund.seam?ticker=SPY.*

[8] Calculated using data from Yahoo as of October 5, 2016.

[9] *See* Proposed Rule 5050(f)(4).

[10] If an investor was required to wait until the next trading day to liquidate, RealDay Options would essentially be A.M.-settled options instead of P.M.-settled, as designed.

[11] *See e.g.* NASDAQ's FX Options and CBOE's SPX Options.

their preference for the product to be cash-settled.

RealDay Options are P.M.-settled due to the nature of the product. Specifically, RealDay Options are designed to cover a single trading day due to the fact they are only active for one trading day. The only way to ensure that the option covers one trading day is to have it be P.M.-settled, as opposed to A.M.-settlement where additional factors may have an effect on the settlement price. Specifically, A.M.-settled options use the opening price for settlement which means they will price in after-hours news and events and therefore do not cover only one trading day. If RealDay Options were A.M.-settled, they would not cover only a single trading day because the settlement price would include events occurring after the close, which is not the intended goal of RealDay Options. Additionally, the Exchange notes that standard options in SPY are already P.M.-settled.

Listing

Although RealDay Options are designed to cover one trading day, they will be listed at least two weeks prior to their expiration but no greater than nine (9) months prior to their expiration.[12] The options are in essence divided into two periods: The anticipatory period and the active period.[13] The anticipatory period is the period of time from the day the option is listed up until the close of trading on the last trading day before expiration. The active period is the expiration day of the option. During the anticipatory period the strike intervals and strike price setting formula are known, but not the numerical value of the strike prices, because they depend on the closing price of SPY from the last trading day before expiration. RealDay Options may still be traded in the anticipatory period in the same manner as standard options on SPY. The fact that the numerical strike prices will only be known for the active period, which is one trading day, is how RealDay Options are designed to be active for one trading day.

Strike Prices

The numerical value of the strike prices for RealDay Options will not be known until the close of trading on the last trading day before expiration, although the strike intervals and strike price setting formula will be fixed from inception.[14] As described in greater detail below, the formula will involve multiplying the closing price of SPY from the last trading day before expiration (''Strike Setting Price'') by the Strike Multiplier.[15] The Exchange notes that calculating strike prices based on a previous close is not an entirely new concept.[16] In effect, the strike price will stay at the same percentage relationship to the price of SPY from the time of listing. Further, the Exchange may only list up to a maximum of seven strike prices for each expiration date. The seven strike prices will consist of up to three (3) strike prices with a price greater than the Strike Setting Price, three (3) strike prices with a price less than the Strike Setting Price, and one (1) strike price equal to the Strike Setting Price.[17] The Exchange will have discretion in determining the number of strike prices it will list per expiration, provided that the strike prices listed satisfy the restrictions above. Additionally, the Exchange must list the strike price that is equal to the Strike Setting Price for every RealDay Option expiration. For example, the Exchange could not list four (4) strike prices at a price greater than the Strike Setting Price, one (1) strike price equal to the Strike Setting Price and two (2) options that have a strike price less than the Strike Setting Price. However, the Exchange could list three (3) strike prices at a price greater than the Strike Setting Price, one (1) strike price equal to the Strike Setting Price and two (2) strike prices that are less than the Strike Setting Price.

The Exchange may, in its sole discretion, determine to not list in-the-money (''ITM'') put or call options for any of the seven (7) strike prices.[18] The ITM puts that the Exchange may decide to not list are those corresponding to the three strike prices that are greater than the Strike Setting Price and the ITM call options are those corresponding to the three strike prices that are less than the Strike Setting Price. The Exchange notes that nothing in its Rules prohibits the Exchange from deciding to list only a put or call option for a specific strike price. The Exchange also notes that the listing of only a put or call option for a specific strike price will allow for quote mitigation. Additionally, the Exchange believes it will be beneficial to have this discretion because it will allow the Exchange to limit the number of instruments listed. Additionally, the Exchange believes that the value of RealDay Options is in the instruments that are at-the-money (''ATM'') and out-of-the-money (''OTM'').

As is the case with other options that the Exchange lists, the Exchange may add additional strike prices after the initial listing of a RealDay Option, provided that the Exchange does not list more than the seven strike prices as described above. For example, if the Exchange lists a RealDay Option at the beginning of March with only the strike price equal to the Strike Setting Price that expires on June 29, 2017, the Exchange could list up to six additional strike prices at the beginning of June for the same expiration.[19] When listing the additional strike prices, the Exchange must follow the guidelines above with respect to only being allowed to list up to three strike prices above and three strike prices below the Strike Setting Price.

The strike price formula will be used after the close of trading on the last trading day before expiration in order to calculate the numerical values of the strike prices. Specifically, the strike prices will be determined by multiplying the Strike Setting Price by the Strike Multiplier. Additionally, the strike prices will have fixed strike intervals of 0.50%; therefore the Exchange's general strike price interval rules shall not apply to RealDay Options.[20] This means there will be one strike price equal to 100% of the Strike Setting Price.[21] The three strike prices greater than then Strike Setting Price will be determined by adding 0.5%, 1.0%, and 1.5%,[22] respectively, to the Strike Setting Price. The three strike prices less than the Strike Setting Price will be determined by subtracting 0.5%, 1.0%, and 1.5%,[23] respectively, from the Strike Setting Price. The strike prices will be rounded to the nearest

[12] *See* Proposed Rule 5050(f).

[13] *See* Exhibit 3–2 for a chart illustrating the two periods.

[14] *See* Proposed Rule 5050(f)(8).

[15] The ''Strike Multiplier'' is the decimal equivalent of the percentage strike of the specific option. The Strike Multiplier will be expressed with three decimal places. For example, an option that is equal to the Strike Setting price would be 100%, making the Strike Multiplier 1.000.

[16] *See* CBOE Rule 24.9(d). The exercise price of CBOE Delayed Start Options Series is determined in relation to the closing price of the underlying index on the date on which the exercise price is fixed.

[17] *See* Proposed Rule 5050(f)(2).

[18] *See* Proposed Rule 5050(f)(2)(ii).

[19] For example, on June 1, 2017, the Exchange could list three strike prices greater than the Strike Setting Price and three strike prices lower than the Strike Setting Price. The threes [sic] strike prices greater than the Strike Setting Price will be the strike prices calculated by adding 0.5%, 1.0%, and 1.5%, respectively, to the Strike Setting Price. The three strike prices less than the strike Setting Price will be the strike prices calculated by subtracting 0.5%, 1.0%, and 1.5%, respectively, from the Strike Setting Price.

[20] *See* Proposed Rule 5050(f)(3).

[21] The Strike Multiplier would be 1.000.

[22] The Strike Multipliers would be 1.005, 1.010 and 1.015, respectively.

[23] The Strike Multiplies would be 0.995, 0.990 and 0.985 respectively.

minimum trading increment, if necessary.

Example #1

On Tuesday, SPY's closing price is 180.15, which will be the Strike Setting Price. RealDay Options on SPY expiring on the next trading day, Wednesday, may have the following strike prices computed by multiplying the Strike Setting Price by the Strike Multiplier.

Option	Formula (strike setting price * strike multiplier)	Strike prices
Strike Setting Price +1.5%	180.15 * 1.015	182.85
Strike Setting Price +1.0%	180.15 * 1.010	181.95
Strike Setting Price +0.5%	180.15 * 1.005	181.05
Strike Setting Price	180.15 * 1.000	180.15
Strike Setting Price −0.5%	180.15 * 0.995	179.25
Strike Setting Price −1.0%	180.15 * 0.990	178.35
Strike Setting Price −1.5%	180.15 * 0.985	177.45

If SPY does not open for trading on the trading day before the options expiration date, then the last available closing price for SPY will be the Strike Setting Price. For Example, if a RealDay Option is expiring on Friday but SPY does not open for trading on Thursday, which is the last trading day before the expiration date, the Strike Setting Price used for the RealDay Option expiring on Friday will be the closing price of SPY from Wednesday, provided that SPY is open for trading on Wednesday.

The Exchange is proposing to list RealDay Options on SPY with the symbol ''SPYZ.'' During the anticipatory period, the strike prices will be listed as the Strike Multiplier, since the numerical value of the strike price is not yet known. The table below illustrates how this will work.

Option	Strike price during anticipatory period (strike multiplier)
Strike Setting Price +1.5%	1.015
Strike Setting Price +1.0%	1.010
Strike Setting Price +0.5%	1.005
Strike Setting Price	1.000
Strike Setting Price −0.5%	0.995
Strike Setting Price −1.0%	0.990
Strike Setting Price −1.5%	0.985

The Exchange believes that using three decimal places will minimize the potential for investor confusion.[24] Specifically, since three decimal places is unique and not currently used for options, investors will be on notice and aware that the Strike Multiplier does not represent a strike price of a typical standard option. The Exchange notes that it will also provide information and education to market participants via circular prior to the launch of RealDay Options to further minimize any investor confusion. Additionally, since the Exchange will never list RealDay Options on an underlying security with a price below $10.00, there will be no confusion that the decimal equivalent is actually a strike price around $1.00. For example, if the underlying security was trading around $2.00, a strike price of 1.005 during the anticipatory period may be confused as a strike price equal to $1.005 instead of .05% above the Strike Setting Price. Below is an example of how RealDay Options will be listed.

	Symbol	Strike (%)	CALL/PUT	Expiration date
SPYZ 161021C1.000	SPYZ	100	CALL	10/21/2016
SPYZ 161021C.995	SPYZ	99.50	CALL	10/21/2016

After the close of trading on the last trading day before expiration, the decimal will be converted into the numerical strike price by multiplying the Strike Setting Price by the Strike Multiplier.[25] For example, if SPY closes at $190.00 on the last trading day before expiration, the 1.005 strike price will be converted to $190.95 ($190.00 * 1.005).

Although the Exchange will have some discretion in determining the exact number of strike prices that can be listed, the Exchange will follow additional procedures[26] based on the price of the underlying security. Specifically, if the underlying security is at or above $25.00 per share, the Exchange may list all seven strike prices. If the underlying security is at or below $10.00 per share, the Exchange will not list any RealDay Option on the underlying security. If the underlying security is between $10.00 and $25.00 per share, the Exchange will only list one strike price. In such a case, the one strike price will be equal to the Strike Setting Price.

These unique strike price features are designed to minimize excessive quoting traffic that would come from listing standard options that expire every trading day and are listed at least two weeks prior to their expiration. If the Exchange were to list standard options on an underlying security that expire every trading day, there would be an enormous increase in quoting trading traffic due to the sheer number of strike prices that would have to be listed for each series. This is in part due to the fact that the price of the underlying security will fluctuate between when a standard option is listed and its expiration date. For example, on March 1, 2016 there were 127 strike prices listed for the weekly SPY option expiring on March 4, 2016 and 232 strike prices listed for the standard SPY option expiring on March 18, 2016. The number of strike prices further increases as the options expiration date

[24] The Exchange notes that it has confirmed with data vendors, the Options Clearing Corporation and various market participants to confirm that they will be able to handle three decimal places when RealDay Options are launched. The Exchange also explained what the three decimal places would represent.

[25] An adjustment to the Strike Setting Price may be needed in order to remove the effects of corporate actions, such as cash dividends. If a dividend is declared, the Strike Setting Price would be adjusted by subtracting the declared dividend before multiplying it by the Strike multiplier.

[26] *See* Proposed Rule 5050(f)(2).

approaches, as well as in response to any price swings. Listing a maximum of seven strike prices, instead of over 100 strike prices for each expiration date, is designed to mitigate issues associated with RealDay Option quoting traffic interfering with Exchange messaging by minimizing the additional quoting traffic. Additionally, having the strike prices based on a percentage of the underlying security up to the expiration date will eliminate any issue around the underlying security moving drastically from the period of time between listing and expiration, which would lead to the need to list additional strike prices so that there are strike prices near the price of the underlying security.

Exercise and Settlement

The exercise and settlement price will be calculated based on the closing price of SPY on the trading day of expiration. The exercise-settlement amount is equal to the difference between the settlement price and the exercise price of the option multiplied by 100. Exercise will result in the delivery of cash on the business day following expiration.

Example #2

On Monday, a trader purchased a 1.005 (0.50%) call for expiration on Thursday. The Strike Multiplier is 1.005. When he purchased the call he did not know the numerical value of the strike price, only that he will get a call option whose strike price is fixed at 0.50% above the close of SPY on Wednesday. On Wednesday, SPY closed at 177.43 (the Strike Setting Price). All RealDay strike prices for expiration on Thursday are determined as follows:

Option	Strike multiplier	Strike price
Strike Setting Price +1.5%	1.015	180.09
Strike Setting Price +1.0%	1.010	179.20
Strike Setting Price +0.5%	1.005	178.32
Strike Setting Price	1.000	177.43
Strike Setting Price −0.5%	0.995	176.54
Strike Setting Price −1.0%	0.990	175.66
Strike Setting Price −1.5%	0.985	174.77

Since the trader purchased the RealDay SPY 1.005 call, the strike price is now set at 178.32. Upon the close on Thursday, if SPY has risen above 178.32, the option expires in the money. Assume that SPY closes at 178.75 on Thursday, the call option purchased by the trader will be $0.43 in the money (178.75 − 178.32 = 0.43), and the trader will receive $43.00 (100 * 0.43).

If SPY does not open for trading on the trading day of expiration, then the last available closing price for SPY will be used to determine the settlement price of the expiring RealDay Options. Specifically, if SPY does not open for trading, at the close of trading on expiration, RealDay Options will have an exercise price that is equal to the closing price from the last trading day before expiration. This will result in all RealDay Options expiring either ATM, OTM, or ITM; depending on whether an ATM, OTM, or ITM option was purchased. This is due to the nature of options that are designed to have an active period of one trading day. For example, if a trader purchases an ATM RealDay call option, which is equal to the closing price of SPY from the last trading day before expiration (1.000 call), and SPY does not open for trading on the expiration day of that RealDay Options, then the call option purchased by the trader would expire ATM. This is because the exercise price would be equal to the closing price which, in this case, is equal to the closing price from the last trading day before expiration, since SPY did not open for trading on the expiration day. This is the same procedure used for standard options. Specifically, when an option does not open for trading on an expiration date, the last available closing price is used for settlement purposes.

Contract Specifications

The contract specifications for RealDay Options are set forth in Exhibit 3–1. RealDay Options will be European-style and P.M. cash-settled. As mentioned above, the Exchange believes that having a P.M. settlement is the best way to adequately represent the goal of RealDay Options, which are designed to cover one trading day. The Exchange does not believe that having a P.M. settlement will raise any issues since the market for SPY is so large that any attempt to alter the closing price would be extremely difficult and would subject the manipulator to regulatory scrutiny. As previously mentioned, BOX is only proposing to list RealDay Options on SPY, the most actively traded ETF in the U.S. Due to the vast liquidity and diversity in market participants trading SPY, any attempt to manipulate the closing price of SPY would be near impossible to accomplish. Additionally, the Exchange has surveillance measures in place to monitor such behavior. RealDay Options will overlie 100 shares of SPY in the same manner as standard options on SPY. The Exchange's standard trading hours for SPY options will apply to trading in RealDay Options.

With respect to margin requirements[27] for RealDay Options, the Exchange proposes to apply margin requirements for the purchase and sale of RealDay Options that are identical to the margin requirements for standard options on SPY.[28] Margin requirements for RealDay Options will be calculated in the same manner as margins for standard options on SPY. Margins should be calculated in the same manner during the anticipatory and active periods. The Exchange notes that even though the numerical value of the strike price is not known until the close of trading on the trading day before expiration, the margins will still be calculated the same way as standard options. Specifically, the strike price used for calculating the margin will just be the numerical value of the strike price using the current price of SPY for the strike setting formula. For example, if on Monday, a RealDay SPY Call Option with a strike of 100% expiring on Friday is purchased where the price of SPY is $200, the strike price used for calculating margins will be $200 (100% * current SPY price).

The minimum trading increments for RealDay Options will be the same as the minimum trading increments applicable to standard options on SPY.[29] Specifically, RealDay Options on SPY will have a minimum trading increment

[27] Options Participants and associated persons are bound by the initial and maintenance margin requirements of either the CBOE or the New York Stock Exchange. *See* Rule 10120, *see also* CBOE Rule 12.3.

[28] *See* Proposed Rule 5050(f)(6).

[29] *See* Proposed Rule 5050(f)(5).

of $0.01. The Exchange believes that, since SPY options have a minimum trading increment of $0.01, also having a minimum trading increment of $0.01 for RealDay Options on SPY will avoid investor confusion. The Exchange notes that this is similar to the treatment of Mini Options for which the minimum trading increment is the same as the minimum trading increment permitted for standard options on the same underlying security.[30]

Position Limits

The Exchange proposes that the position limits for RealDay Options will be the same as the position limits for standard options on SPY.[31] For example, the Exchange proposes that there shall be no position or exercise limits for RealDay Options on SPY. As noted above, RealDay Options will settle using the published closing price from SPY. Given that there are currently no position limits for SPY options,[32] the Exchange believes it is appropriate for there to be no position or exercise limits for RealDay Options on SPY. Since the removal of any position limits on SPY is subject to a pilot program, if the pilot is discontinued or cancelled and therefore SPY becomes subject to position limits, then RealDay Options would become subject to the same position limits as SPY options. Positions in RealDay Options shall be aggregated with positions in all other options on SPY.

Customer Trading

Section 4000 of the Exchange's rules is designed to protect public customer trading and shall apply to trading in RealDay Options. Specifically, Rules 4020(a) and (b) prohibit Order Flow Providers (''OFP'') [33] from accepting a Public Customer order to purchase or write an option, including RealDay Options, unless such customer's account has been approved in writing by a designated Options Principal of the OFP. Additionally, Rule 4040 regarding suitability is designed to ensure that options, including RealDay Options, are sold only to customers capable of evaluating and bearing the risks associated with trading in the instrument. Further, Rule 4050 permits OFPs to exercise discretionary power with respect to trading options, including RealDay Options, in a Public Customer's account only if the OFP has received prior written authorization from the customer and the account has been accepted in writing by a designated Options Principal. Finally, Rule 4030 Supervision of Accounts, Rule 4060 Confirmation to Public Customers, and Rule 4100 Delivery of Current Options Disclosure Documents and Prospectus, will also apply to trading in RealDay Options.

Surveillance

The Exchange has an adequate surveillance program in place for RealDay Options and intends to apply the same program procedures that it applies to the Exchange's other options products. The Exchange does not believe that it will have any issues with the surveillance of RealDay Options. Although there are certain differences with RealDay Options as compared to standard options, the Exchange believes its current surveillance procedures will adequately monitor RealDay Options. Additionally, the Exchange is also a member of the Intermarket Surveillance Group (''ISG'') under the Intermarket Surveillance Group Agreement dated June 20, 1994. The ISG members work together to coordinate surveillance and investigative information sharing in the stock and options markets.

Per the proposed rule change, RealDay Options will be settled using a calculation based on the daily closing prices of SPY. The Exchange believes that manipulating the settlement price will be difficult based on the size of the market for SPY. As discussed above, the Exchange is only proposing to list RealDay Options on SPY, which is the most actively traded ETF in the United States. The vast liquidity of the equities markets ensures a multitude of market participants at any given time. Due to the high level of participation among market makers that can enter quotes in SPY, the Exchange believes it would be very difficult for a single participant to alter the closing price in any significant way without exposing the would-be manipulator to regulatory scrutiny and financial costs. This is especially true for SPY given the vast amount of liquidity in the ETF.

The Exchange believes that there is no additional risk of manipulation of RealDay Options as compared to other P.M.-settled options. RealDay Options will be listed on the most actively traded ETF and should dispel any concerns of manipulation. Due to the vast liquidity in SPY and the diverse group of market participants that trade SPY, any potential manipulator would be subject to regulatory scrutiny.

The Exchange represents that it has the necessary system capacity to support additional quotations and messages that will result from the listing and trading of RealDay Options. The Exchange believes that by limiting the listing of RealDay Options to only seven (7) strike prices per expiration, the Exchange will minimize the system capacity required to list them. Additionally, the Exchange believes that having the discretion to not list ITM call or put options will further minimize the required system capacity.

Standardized Options

Rule 9b–1 under the Act establishes a disclosure framework for standardized options that are traded on a national securities exchange and cleared through a registered clearing agency.[34] The exchange on which a standardized option is listed and traded must prepare an Options Disclosure Document (''ODD'') that, among other things, identifies the issuer and describes the uses, mechanics, and risk of options trading, in language that can be easily understood by the investing public. The ODD is treated as a substitute for the traditional prospectus. Pursuant to Rule 9b–1 of the Act, use of the ODD is limited to standardized options. The Exchange believes that RealDay Options are covered by the current language of the ODD. Specifically, the June 2008 Supplement to the ODD added a definition for delayed start options.[35] The ODD describes delayed start options as ''an option that does not have an exercise price when first introduced for trading but instead has an exercise price setting formula pursuant to which the exercise price will be fixed on a specified future date.'' [36] Although the Exchange believes that RealDay Options are covered by the current language of the ODD, BOX respectfully requests that the Commission designate RealDay Options as standardized options. The Exchange notes that the Commission has previously designated options

[30] *See* IM–5050–10(d) to Rule 5050.

[31] *See* Proposed Rule 5050(f)(10).

[32] *See* Securities Exchange Act Release No. 67936 (September 27, 2012), 77 FR 60491 (October 3, 2012) (Notice of Filing and Immediate Effectiveness of SR–BOX–2012–013).

[33] *See* Rule 100(a)(45). The terms ''Order Flow Provider'' or ''OFP'' mean those Options Participants representing as agent Customer Orders on BOX and those non-Market Maker Participants conducting proprietary trading.

[34] ''Standardized options'' are defined in Rule 9b–1(a)(4) as ''options contracts trading on a national securities exchange, an automated quotation system of a registered securities association, or a foreign securities exchange which relate to options classes the terms of which are limited to specific expiration dates and exercise prices, or such other securities as the Commission may, by order, designate.'' *See* 17 CFR 240.9b–1(a)(4).

[35] *See* pg. 129 of the Characteristics & Risks of Standardized Options, located at *http://www.optionsclearing.com/about/publications/character-risks.jsp.*

[36] *Id.*

similar to RealDay Options as standardized options.[37]

Market Participation

The Exchange believes that RealDay Options will be a useful tool for all market participants. The unique strike price setting structure and the fact that RealDay Options may expire every trading day will allow investors to hedge single day events, including the release of an economic report or a company's earnings release (''event days''). Although the Exchange believes that these event days will be more active as compared to the non-event days, the Exchange still believes that investors will see value, including obtaining exposure to implied volatility, as described in greater detail below, and trade RealDay Options expiring on non-event days. Additionally, market participants can capture interday realized volatility when they are bundled as consecutive at-the-money straddles.

Additionally, the Exchange believes that market participants will find value in trading RealDay Options during both the anticipatory period and active period. During the anticipatory period investors can trade RealDay Options in order to get exposure to implied volatility and during the active period RealDay Options will act and be traded in the same manner as standard options. Market participants can obtain exposure to implied volatility by initiating a position and then liquidating it prior to the expiration day.

The Exchange believes that Market Makers will be able to price and quote RealDay Options effectively. Since RealDay Options will not have their strike prices set until the day before expiration, the Exchange believes that the models Market Makers use to price and quote RealDay Options will be simpler than the models they use for standard options. Specifically, Market Makers will not have to account for price movements in SPY or time to expiration; basically Market Makers will just have to deal with implied volatility when pricing RealDay Options.

Pilot Program

As proposed, the proposal would become effective on a pilot program basis for a period of twelve months.[38] If the Exchange were to propose an extension of the program or should the Exchange propose to make the program permanent, then the Exchange would submit a filing to the Commission proposing such amendments to the program. The Exchange notes that any positions established under the pilot would not be impacted by the expiration of the pilot. For example, a position in a RealDay Option series that expires beyond the conclusion of the pilot period could be established during the 12-month pilot. If the pilot program were not extended, then the position could continue to exist. However, the Exchange notes that any further trading in the series would be restricted to transactions where at least one side of the trade is a closing transaction.

The Exchange proposes to submit a pilot program report to the Commission two months prior to the expiration date of the Pilot Program (the ''pilot report''). The pilot report would contain an analysis of volume, open interest, and trading patterns. The analysis would examine trading in RealDay Options. In addition, for certain series, the pilot report would provide analysis of price volatility and trading activity in additional option series. In addition to the pilot report, the Exchange would provide the Commission with periodic interim reports while the pilot is in effect that would contain some, but not all, of the information contained in the pilot report. The pilot report would be provided to the Commission on a confidential basis.

The pilot report would contain the following volume and open interest data for RealDay Options:

(1) Daily contract trading volume aggregated for all trades, for all option series with less than 31 days until expiration;

(2) daily contract trading volume aggregated by expiration date, for all option series with less than 31 days until expiration;

(3) daily contract trading volume for each individual series;

(4) daily open interest aggregated for all series, for all option series with less than 31 days until expiration;

(5) daily open interest aggregated for all series by expiration date, for all option series with less than 31 days until expiration;

(6) daily open interest for each individual series;

(7) statistics on the distribution of trade sizes;

(8) type of market participant trading (*e.g.,* contract trading volume for each market participant type); and

(9) 5-minute returns, level changes, and trading volume for the S&P 500 Index, VIX, SPY, IVV, and expiring RealDay options between open and close for the first and second Wednesday of the month that is a trading day and trading days when standard SPY options expire.

In addition to the pilot report, the Exchange would periodically provide the Commission with interim reports of the information listed in items (1) through (9) above as required by the Commission while the pilot is in effect. These interim reports would also be provided on a confidential basis.

Additional Changes

The Exchange also proposes to amend Rule 5050(a). Specifically, the Exchange proposes to amend the rule to state that the Exchange will fix a specific expiration date and exercise price for RealDay Options, as provided in proposed Rule 5050(f).

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[39] in general, and furthers the objectives of Section 6(b)(5) of the Act[40] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. Specifically, the Exchange believes that the introduction of RealDay Options will attract order flow to the Exchange, increase the variety of listed options to investors, and provide a valuable hedge tool to investors.

The Exchange believes the proposed rule change will further the Exchange's goal of introducing new and innovative products to the marketplace. The Exchange believes that listing RealDay Options will provide an opportunity for investors to hedge, or speculate on, the market risk associated with single day events. The proposed rule change will allow the Exchange to list options that will allow traders to manage risk associated with certain events, such as a company's earnings or the release of an economic report. The Exchange believes that RealDay Options will give traders an unprecedented ability to hedge against single day events. As the Exchange previously noted, the concept of a delayed start options is not a new proposal. Specifically, CBOE has rules covering delayed start options.[41] Additionally, the ODD already has language covering delayed start options.[42]

[37] *See* Securities Exchange Act Release No. 56855 (November 28, 2007), 72 FR 68613 (December 5, 2007)(Order Approving Proposed Rule Change as Modified by Amendment No. 1 Thereto to List and Trade Delayed Start Option Series).

[38] *See* Proposed Rule 5050(f)(9).

[39] 15 U.S.C. 78f(b).

[40] 15 U.S.C. 78f(b)(5).

[41] *See supra* notes 3 and 16.

[42] *See supra* note 35.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in RealDay Options. The Exchange believes that by initially limiting RealDay Options to only SPY, it will reduce the chances of manipulation due to the robust market and liquidity in SPY. The Exchange also represents that it has the necessary systems capacity to support the new options series; and as stated in the filing, the Exchange has rules in place designed to protect public customer trading.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of a novel option product that will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov. Please include File Number SR–BOX–2016–50 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-*2016–50.* This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BOX–2016–50 and should be submitted on or before December 6, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27363 Filed 11–14–16; 8:45 am]

BILLING CODE 8011–01–P

[43] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79267; File No. SR–C2–2016–022]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing of a Proposed Rule Change in Connection With a Proposed Corporate Transaction Involving CBOE Holdings, Inc. and Bats Global Markets, Inc.

November 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 4, 2016, C2 Options Exchange, Incorporated (the ''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange submits this rule filing in connection with a proposed corporate transaction (the ''Transaction'') involving its ultimate parent company, CBOE Holdings, Inc. (''CBOE Holdings''), two wholly owned subsidiaries of CBOE Holdings, CBOE Corporation and CBOE V, LLC (''CBOE V''), and Bats Global Markets, Inc. (''BGM''). BGM is the ultimate parent company of Bats BZX Exchange, Inc. (''Bats BZX''), Bats BYX Exchange, Inc. (''Bats BYX''), Bats EDGX Exchange, Inc. (''Bats EDGX''), and Bats EDGA Exchange, Inc. (''Bats EDGA'' and, together with Bats BZX, Bats BYX, and Bats EDGX, the ''Bats Exchanges''). Upon completion of the Transaction (the ''Closing''), CBOE Holdings will become the ultimate parent of the Bats Exchanges.

On September 25, 2016, CBOE Holdings, CBOE Corporation, CBOE V, and BGM entered into an Agreement and Plan of Merger, as it may be amended from time to time (the ''Merger Agreement''). In connection with the Transaction, the Exchange seeks the Commission's approval of a provision in the Merger Agreement regarding the composition of the CBOE Holdings Board of Directors (''CBOE Holdings Board'') upon the Closing. There are no

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

proposed changes to Exchange rules or governing documents of CBOE Holdings or the Exchange.

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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange submits this filing for Commission approval of a provision in the Merger Agreement regarding the composition of the CBOE Holdings Board upon Closing. Other than as described herein, the Exchange will continue to conduct its regulated activities (including operating and regulating its market and Trading Permit Holders) in essentially the same manner it conducts them today, and will not make any changes to its regulated activities in connection with the Transaction. The Exchange is not proposing any amendments to its trading and regulatory rules or organizational and governance documents at this time. If the Exchange determines to make any such changes, it will submit rule filings to the Commission proposing such changes to the extent required by the Act and the rules and regulations thereunder.

Current Corporate Structures

Each of C2 and Chicago Board Options Exchange, Incorporated (''CBOE'' and, together with the Exchange, the ''CBOE Exchanges'') is a Delaware corporation that is a national securities exchange registered with the Commission pursuant to Section 6(a) of the Act.[3] Each CBOE Exchange is a direct, wholly owned subsidiary of CBOE Holdings, a publicly traded Delaware corporation. CBOE V is a Delaware limited liability company and direct, wholly owned subsidiary of CBOE Holdings, which currently has no material assets and conducts no operations.

Each Bats Exchange is a Delaware corporation that is a national securities exchange registered with the Commission pursuant to Section 6(a) of the Act.[4] BGM is a publicly traded Delaware corporation and the ultimate parent of the Bats Exchanges.

The Transaction

Pursuant to and subject to the terms of the Merger Agreement, at the Closing, among other things, each share of BGM common stock (whether voting or non-voting) issued and outstanding (other than shares owned by CBOE Holdings, BGM or any of their respective subsidiaries, and certain shares held by BGM stockholders that are entitled to and properly demand appraisal rights) will be converted into the right to receive a particular number of shares of CBOE Holdings common stock, an amount of cash, or a combination of both, at the election of the holder of such share of BGM common stock. BGM will ultimately merge with and into CBOE Holdings' wholly owned subsidiary CBOE V, at which time the separate existence of BGM will cease and CBOE V will be the surviving company.

Post-Closing Corporate Structure

As a result of the Transaction, CBOE Holdings will be the ultimate parent of the Bats Exchanges, each of which will continue to operate separately. CBOE Holdings will continue to be a publicly owned company and the ultimate parent of the CBOE Exchanges, each of which will continue to operate separately.

Post-Closing CBOE Holdings Board

In connection with the Transaction, CBOE Holdings agreed in the Merger Agreement to take all requisite actions so, as of the Closing, the CBOE Holdings Board will include three individuals designated by BGM who (1) are serving as BGM directors immediately prior to the Closing and (2) comply with the policies (including clarifications of the policies provided to BGM) of the Nominating and Governance Committee of the CBOE Holdings Board as in effect on the date of the Merger Agreement and previously provided to BGM (each of whom will be appointed to the CBOE Holdings Board as of the Closing). The CBOE Holdings Board currently consists of 14 directors.[5] The Exchange expects three current CBOE Holdings directors to resign effective prior to the Closing and the remaining CBOE Holdings directors to fill the vacancies created by those resignations with the three BGM directors designated by BGM.[6]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[7] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed rule change is consistent with CBOE Holdings' organizational and governing documents previously filed with the Commission.[10] The Exchange will continue to have the authority and ability to effectively fulfill its self-regulatory duties pursuant to the Act and the rules promulgated thereunder. CBOE Holdings' governing documents will not change at the Closing and, therefore, will continue to include various provisions intended to protect and maintain the integrity of the self-regulatory functions of the Exchange. Additionally, the Commission will

[3] 15 U.S.C. 78f(a).

[4] 15 U.S.C. 78f(a).

[5] Pursuant to the Second Amended and Restated Certificate of Incorporation of CBOE Holdings (''CBOE Holdings Certificate'') and the Third Amended and Restated Bylaws of CBOE Holdings (''CBOE Holdings Bylaws''), the CBOE Holdings Board will consist of no less than 11 and no more than 23 directors, the exact number to be fixed by the CBOE Holdings Board from time to time pursuant to resolution adopted by the Board. *See* CBOE Holdings Certificate Article Seventh (b) and CBOE Holdings Bylaws Section 3.2.

[6] *See* Sections 3.4 and 3.5 of the CBOE Holdings Bylaws.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *Id.*

[10] *See, e.g.,* Securities Exchange Act Release Nos. 34–76282 (October 27, 2015), 80 FR 67464 (November 2, 2015) (SR–CBOE–2015–092); and 34–76281 (October 27, 2015), 80 FR 67461 (November 2, 2015) (SR–C2–2015–022) (notices of filing and immediate effectiveness of recent proposed rule changes to amend the CBOE Holdings Certificate and Bylaws); *see also supra* notes 5 and 6.

continue to have regulatory authority over the Exchange, as is currently the case, as well as jurisdiction over CBOE Holdings with respect to activities related to the Exchange.[11]

The Exchange is proposing no changes to its existing operational and trading structure in connection with the Transaction. Upon Closing, the Exchange will operate in essentially the same manner as it operates today. Therefore, the Exchange believes it will continue to satisfy the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change relates to the corporate governance of CBOE Holdings—specifically a change in composition of the CBOE Holdings Board in connection with a corporate transaction—and not the operations of the Exchange. This is not a competitive filing and, therefore, imposes no burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–C2–2016–022 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–C2–2016–022. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from ubmissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–C2–2016–022, and should be submitted on or before December 6, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27372 Filed 11–14–16; 8:45 am]

BILLING CODE 8011–01–P

[11] *See, e.g.,* CBOE Holdings Certificate Article Fourteenth.

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79261; File No. SR–Phlx–2016–110]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Commentary .14 to Rule 3317 (Compliance With Regulation NMS Plan To Implement a Tick Size Pilot)

November 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 31, 2016, NASDAQ PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Commentary .14 to Rule 3317 (Compliance with Regulation NMS Plan to Implement a Tick Size Pilot) to provide the SEC with notice of its efforts to re-program its systems to eliminate a re-pricing functionality for certain orders in Test Group Three securities in connection with the Regulation NMS Plan to Implement a Tick Size Pilot Program (''Plan'' or ''Pilot'').[3]

The text of the proposed rule change is set forth below. Proposed new language is underlined; deleted text is in brackets.

* * * * *

NASDAQ PHLX Rules

* * * * *

3317. Compliance With Regulation NMS Plan To Implement a Tick Size Pilot

(a) through (d) No Change.

Commentary

.01–.13 No change.

.14 Until [October 31, 2016] *November 14, 2016,* the treatment of Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) (''Approval Order'').

Post-Only Orders that are entered through the OUCH or FLITE protocols in Test Group Three securities shall be as follows:

Following entry, and if market conditions allow, a Price to Comply Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Comply Order is able to be ranked and displayed at its original entered limit price.

Following entry, and if market conditions allow, a Price to Display Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Display Order is able to be ranked and displayed at its original entered limit price.

Following entry, and if market conditions allow, a Non-Displayed Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO up (down) to the Order's limit price.

Following entry, and if market conditions allow, the Post-Only Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO or the best price on the Exchange Book, as applicable until such time as the Post-Only Order is able to be ranked and displayed at its original entered limit price.

* * * * *

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

On September 7, 2016, the Exchange filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change (''Proposal'') to adopt paragraph (d) and Commentary .12 to Exchange Rule 3317 to describe changes to system functionality necessary to implement the Plan. The Exchange also proposed amendments to Rule 3317(a) and (c) to clarify how the Trade-at exception may be satisfied. The SEC published the Proposal in the **Federal Register** for notice and comment on September 20, 2016.[4] Phlx subsequently filed three Partial Amendments to clarify aspects of the Proposal. The Commission approved the Proposal, as amended, on October 7, 2016.[5]

In SR–Phlx–2016–92, Phlx had initially proposed a re-pricing functionality for Price to Comply Orders, Non-Displayed Orders, and Post-Only Orders entered through the OUCH and FLITE protocols in Group Three securities.[6] Phlx subsequently determined that it would not offer this re-pricing functionality for Price to Comply Orders, Non-Displayed Orders, and Post-Only Orders entered through the OUCH and FLITE protocols in Group Three securities. As part of Partial Amendment No. 2 to SR–Phlx–2016–92, Phlx proposed to delete the relevant language from Rule 3317 related to this re-pricing functionality.

In that amendment, Phlx noted that this change would only impact the treatment of Price to Comply Orders, Non-Displayed Orders, and Post-Only orders that are submitted through the OUCH and FLITE protocols in Test Group Three Pilot Securities, as these types of Orders that are currently submitted to Phlx through the RASH or FIX protocols are already subject to this re-pricing functionality and will remain subject to this functionality under the Pilot.

In the Amendment, Phlx further noted that its systems are currently programmed so that Price to Comply Orders, Non-Displayed Orders and Post-Only Orders entered through the OUCH and FLITE protocols in Test Group Three Securities may be adjusted repeatedly to reflect changes to the NBBO and/or the best price on the Phlx book. Phlx stated that it is re-programming its systems to remove this functionality for Price to Comply Orders, Non-Displayed Orders and Post-Only Orders entered through the OUCH and FLITE protocols in Test Group Three Securities. In the Amendment, Phlx stated that it anticipated that this re-programming shall be completed no later than November 30, 2016. If it appears that this functionality will remain operational by October 17, 2016, Phlx indicated that it would file a proposed rule change with the SEC and will provide notice to market participants sufficiently in advance of that date to provide effective notice. The rule change and the notice to market participants will describe the current operation of the Phlx systems in this regard, and the timing related to the re-programming.

On October 17, 2016, Phlx filed a proposal to extend the date by which it would complete the re-programing of its systems to eliminate the re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols.[7] In that proposal, Phlx stated that it anticipated that this re-programming shall be complete on or before October 31, 2016.[8]

At this time, Phlx is still determining how to modify its systems to eliminate the current re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols. Phlx is therefore submitting this proposal to extend the date by which the current re-pricing functionality will be eliminated. Phlx anticipates that the re-programming to eliminate the current re-pricing functionality shall be completed on or before November 14, 2016.

Therefore, the current treatment of Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols

[4] *See* Securities Exchange Act Release No. 78835 (September 14, 2016), 81 FR 64552 (September 20, 2016) (SR–Phlx–2016–92).

[5] *See* Securities Exchange Act Release No. 79074 (October 7, 2016) (SR–Phlx–2016–92).

[6] As originally proposed, Rule 3317(d)(2) stated that Price to Comply Orders in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Comply Order is able to be ranked and displayed at its original entered limit price. Rule 3317(d)(3) stated that, if market conditions allow, a Non-Displayed Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO up (down) to the Order's limit price. Rule 3317(d)(4) stated that, if market conditions allow, the Post-Only Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO or the best price on the Phlx Book, as applicable until such time as the Post-Only Order is able to be ranked and displayed at its original entered limit price.

[7] *See* Securities Exchange Act Release No. 79156 (October 25, 2016) (SR–Phlx–2016–106). Subsequent to the approval of SR–Phlx–2016–92, Phlx become aware that this re-pricing functionality also applies to Price to Display Orders that are entered through the OUCH and FLITE protocols in Test Group Three Securities, and included those Orders as part of SR–Phlx–2016–106 accordingly. Price to Display Orders will be treated in the same manner as Price to Comply Orders under the re-pricing functionality.

[8] *Id.*

in Test Group Three securities shall be as follows:

Following entry, and if market conditions allow, a Price to Comply Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Comply Order is able to be ranked and displayed at its original entered limit price.

Following entry, and if market conditions allow, a Price to Display Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Display Order is able to be ranked and displayed at its original entered limit price.

Following entry, and if market conditions allow, a Non-Displayed Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO up (down) to the Order's limit price.

Following entry, and if market conditions allow, a Post-Only Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO or the best price on the Phlx Book, as applicable until such time as the Post-Only Order is able to be ranked and displayed at its original entered limit price.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The purpose of this filing is to inform the SEC and market participants of the status of Phlx's attempts to re-program its systems to remove the re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols, and the current treatment of such orders pending the removal of this functionality. This proposal is consistent with the Act because it provides the SEC and market participants with notice of Phlx's efforts in this regard, and is being submitted in connection with the statements made by Phlx in SR–Phlx–2016–92 and SR–Phlx–2016–106 in proposing the removal of this functionality.

Phlx also believes that the proposal is consistent with the Act because the re-pricing functionality will not significantly impact the data gathered pursuant to the Pilot. Phlx notes that this re-pricing functionality only affects Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols for Test Group Three securities until the re-pricing functionality is eliminated, and only becomes relevant when an Order in a Test Group Three security would cross a Protected Quotation of another market center. Phlx has analyzed data relating to the frequency with which Orders in Test Group Three securities are entered with a limit price that would cross a Protected Quotation of another market center, and believes that the re-pricing functionality will be triggered infrequently once Test Group Three becomes fully operational.[11] The Exchange also notes that it is diligently working to eliminate the current re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols, and that it anticipates this re-programming to be complete on or before November 14, 2016.

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 purpose of this proposal is to provide the SEC and market participants with notice of Phlx's efforts to remove its re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols, consistent with its statements in SR–Phlx–2016–92 and SR–Phlx–2016–106.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[12] and subparagraph (f)(6) of Rule 19b–4 thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing. Rule 19b–4(f)(6)(iii), however, permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay contained in Rule 19b–4(f)(6)(iii) so that this proposed change will be in operative as of October 31, 2016, the date that Test Group Three securities are fully implemented and are subject to the quoting and trading restrictions of the Plan and, therefore, the relevant language in Rule 3317.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to implement the proposed rules immediately thereby preventing delays in the implementation of the Plan. The Commission notes that the Pilot started implementation on October 3, 2016, Test Group Three securities were fully phased into the Pilot on October 31, 2016, and waiving the 30-day operative delay would ensure that the rules of the Exchange would be in place during implementation. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] For example, on October 31, 2016, in the one hundred Test Group Three securities that are currently live, 0.06% of orders that were entered on the NASDAQ Stock Market LLC in those securities were entered at a price that crossed the NBBO.

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2016–110 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–Phlx–2016–110. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2016–110, and should be submitted on or before December 6, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27366 Filed 11–14–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79270; File No. SR–NASDAQ–2016–153]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7014 and the Nasdaq Growth Program

November 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 1, 2016, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Nasdaq Rule 7014, Market Quality Incentive Programs, to modify the volume threshold for the method under which members may currently qualify for the Nasdaq Growth Program (''Program''). The Exchange also proposes to add another method through which members may qualify for the Program, and to modify the manner in which a member's Growth Baseline is updated.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Nasdaq Rule 7014, Market Quality Incentive Programs, to modify the volume threshold for the method under which members may currently qualify for the Program. The Exchange also proposes to add another method through which members may qualify for the Nasdaq Growth Program (''Program''), and to modify the manner in which a member's Growth Baseline is updated.

Nasdaq recently introduced the Nasdaq Growth Program.[3] The purpose of the Program is to provide a credit per share executed for members that meet certain growth criteria. The credit is designed to provide an incentive to members that do not qualify for other credits under Rule 7018 in excess of the Program credit to increase their participation on the Exchange. The Program will provide a member a $0.0025 per share executed credit in securities priced $1 or more per share if the member meets certain criteria. The credit will be provided in lieu of other credits provided to the member for displayed quotes/orders (other than Supplemental Orders or Designated Retail Orders) that provide liquidity under Rule 7018, if the credit under the Nasdaq Growth Program is greater than the credit attained under Rule 7018. To be eligible for the credit a member must: (i) Add greater than 750,000 shares a day on average during the month through one or more of its Nasdaq Market Center MPIDs; and (ii) increase its shares of liquidity provided through one or more of its Nasdaq Market Center MPIDs as a percent of Consolidated Volume by 25% versus the member's Growth Baseline.[4]

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 78977 (September 29, 2016), 81 FR 69140 (October 5, 2016) (SR–NASDAQ–2016–132).

[4] As part of this proposed rule change, Nasdaq is amending the rule text to add the conjunctive ''and'' between these two conditions to make clear that a member must satisfy both conditions in order to qualify for the Program.

Rule 7014 defines the Growth Baseline as the member's shares of liquidity provided in all securities through one or more of its Nasdaq Market Center MPIDs as a percentage of Consolidated Volume during the last month a member qualified for the Program. If a member has not qualified for a credit under the Program, its August 2016 share of liquidity provided in all securities through one or more of its Nasdaq Market Center MPIDs as a percent of Consolidated Volume will be used to establish a baseline.

As noted above, Nasdaq is proposing to modify the volume requirement that members must satisfy in order to qualify for the Program under the current method. Nasdaq also proposes to add another method through which members may qualify for the Program. Nasdaq is therefore re-numbering Rule 7014(j)(ii) as Rule 7014(j)(ii)(A) and (B) accordingly.

Accordingly, Rule 7014(j)(ii)(A) will now state that, in order to be eligible for the rebate, the member must increase its shares of liquidity provided through one or more of its Nasdaq Market Center MPIDs as a percent of Consolidated Volume by 20% versus the member's Growth Baseline. Nasdaq notes that the purpose of the Program is to increase participation on the Exchange by incentivizing members to transact more volume on the Exchange. Nasdaq believes that changing the volume requirement from 25% to 20% will make it easier for members to qualify for the Program, thereby creating a greater incentive for members to increase their activity on the Exchange.

New Rule 7014(j)(ii)(B) provides that a member may qualify for the Program if it met the criteria set forth in Rule 7014(j)(ii)(A) in the preceding month and maintained or increased its shares of liquidity provided through one or more of its Nasdaq Market Center MPIDs as a percent of Consolidated Volume compared to the preceding month.

Previously, a member would have been required to increase its shares of liquidity by 25% (now 20%) each month versus the member's Growth Baseline in order to qualify for the Program. Assuming the member satisfied the criteria set forth in Rule 7014(j)(ii)(A) in the previous month, Rule 7014(j)(ii)(B) will allow a member to continue to qualify for the program as long as it maintains or increases its shares of liquidity in the current month. Since Rule 7014(j)(ii)(B) requires that the member met the criteria in Rule 7014(j)(ii)(A) in the preceding month, a member would not be able to use Rule 7014(j)(ii)(B) in successive months.

Third, Nasdaq proposes to modify the calculation of a member's baseline. As noted above, the Growth Baseline is defined as the member's shares of liquidity provided in all securities through one or more of its Nasdaq Market Center MPIDs as a percent of Consolidated Volume during the last month a member qualified for the Nasdaq Growth Program. If a member has not qualified for a credit under the Program, its August 2016 share of liquidity provided in all securities through one or more of its Nasdaq Market Center MPIDs as a percent of Consolidated Volume will be used to establish a baseline. Once the member qualifies for the Program, the August 2016 baseline is replaced by the volume of that qualifying month, which becomes the member's updated baseline.

Nasdaq is proposing to add language to the definition of the Growth Baseline to reflect the fact that a member's baseline will only be updated when a member qualifies for the rebate under Rule 7014(j)(ii)(A). A member may only qualify for the rebate under Rule 7014(j)(ii)(A) if it increases its volume by 20% over its baseline, whereas a member would qualify for the rebate under Rule 7014(j)(ii)(B) if it maintained or increased its volume in comparison to the previous month. Nasdaq believes that adjusting the member's baseline when the growth of the member's monthly volume meets or exceeds 20% is appropriate because this is a clearly defined threshold. Nasdaq also notes that members cannot qualify for the rebate under Rule 7014(j)(ii)(B) in successive months, so Nasdaq does not anticipate a scenario where a member qualifies for a rebate for several months without having its baseline adjusted accordingly.

The following example illustrates the proposed changes:

- In August 2016, the firm's shares of liquidity as a percentage of Consolidated Volume is 0.03%. This is the firm's Growth Baseline.
- In September 2016, the firm's shares of liquidity as a percentage of Consolidated Volume is 0.035%. The member does not qualify for an applicable rebate, and the member's Growth Baseline remains 0.03% (its August 2016 volume).
- In October 2016, the firm's shares of liquidity as a percentage of Consolidated Volume is 0.04%. Since the firm has increased its volume by more than 20% in comparison to its Growth Baseline, the firm qualifies for the credit. Since the firm has qualified for the credit, its Growth Baseline is now 0.04%.
- In November 2016, the firm's shares of liquidity as a percentage of Consolidated Volume is 0.041%. Although the firm did not increase its volume by 20% in comparison to its Growth Baseline, it still qualifies for the credit, since Rule 7014(j)(ii)(B) allows a member to continue to qualify for the Program if it met the criteria in Rule 7014(j)(ii)(A) in the previous month, and if it maintains or increases its shares of liquidity in the current month. Since the firm qualified for the credit under Rule 7014(j)(ii)(B), the Growth Baseline does not update.
- A member may only qualify for the rebate under Rule 7014(j)(ii)(B) if it satisfied the criteria of Rule 7014(j)(ii)(A) in the preceding month. In order to be eligible for the December 2016 rebate, the firm would therefore have to increase its volume by more than 20% in comparison to its Growth Baseline (which is October 2016).

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[6] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using its facilities which the Exchange operates or controls, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange notes that the amount of the credits provided under the Program is unchanged.[7] Nasdaq believes that the proposed changes are equitably allocated among members, and are not designed to permit unfair discrimination. Nasdaq notes that, in decreasing the volume threshold from 25% to 20% in order to qualify for the Program under Rule 7014(j)(ii)(A), and in proposing an alternate method under which members may qualify for the Program, Nasdaq is making the Program and its associated credits more accessible to members. At the same time, the purpose of the Program is to increase members' participation on the Exchange by offering a credit to members that meet the volume requirements. Nasdaq believes that the proposed changes strike an appropriate and equitable balance by expanding the number of members that may be eligible for the Program while continuing to

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4) and (5).

[7] *See* Securities Exchange Act Release No. 78977 (September 29, 2016), 81 FR 69140 (October 5, 2016) (SR–NASDAQ–2016–132) (establishing the Nasdaq Growth Program and its credit structure).

incentivize other members that may not currently qualify for the Program to transact greater volume in order to become eligible for the Program.

In amending Rule 7014(j)(ii)(A) so that members may qualify for the Program by increasing their volume in a given month by 20% over their baseline, Nasdaq also notes that this proposed change merely changes the member's trading volume necessary to qualify for the program under Rule 7014(j)(ii)(A), and does not otherwise differentiate among members who may qualify for the Program.

Nasdaq also believes that Rule 7014(j)(ii)(B) is equitably allocated and not unfairly discriminatory. In adopting Rule 7014(j)(ii)(B), Nasdaq is providing all members that otherwise qualify for the Program with an alternate way in which they may qualify for the Program's rebate in a given month by permitting members to either maintain or increase their volume in comparison to the preceding month. Given, however, that the purpose of the Program is to increase a member's trading activity on the Exchange, Nasdaq believes that it is equitable and not unfairly discriminatory to only permit members to qualify for the rebate in this manner if they have qualified for the rebate in the preceding month under Rule 7014(j)(ii)(A) (increasing their volume by 20% or more in comparison to the Growth Baseline). Similarly, the member will be required to satisfy the criteria in Rule 7014(j)(ii)(A) in order to qualify for the rebate in the following month, which means that it will be required to increase its volume by 20% in comparison to its Growth Baseline. Nasdaq believes this requirement is equitable and not unfairly discriminatory because it furthers the aims of the Program by encouraging increased volume on the Exchange. Nasdaq also notes that these requirements will apply equally to all members.

Nasdaq believes that updating a member's Growth Baseline when the member has qualified for the rebate pursuant to Rule 7014(j)(ii)(A) by increasing its volume by 20% over its previous Growth Baseline is equitable and not unfairly discriminatory because this is a clearly defined threshold that applies equally to all members that qualify for the rebate under Rule 7014(j)(ii)(A). Nasdaq also notes that members cannot qualify for the rebate under Rule 7014(j)(ii)(B) in successive months, so Nasdaq does not anticipate a scenario where a member qualifies for a rebate for several months without having its baseline adjusted accordingly.

Finally, Nasdaq notes that participation in the Program is voluntary, and that the proposed changes apply to all members that otherwise qualify for the Program, *e.g.*, [sic] members that add greater than 750,000 shares a day on average during the month through one or more of its [sic] Nasdaq Market Center MPIDs.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change will not result in a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.[8] In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or credit opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and credits to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges.

Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. In addition, the Exchange believes that the competition among exchanges and other venues will help to drive price improvement and overall execution quality higher for end retail investors.

In this instance, participation in the Program is voluntary. The proposed changes will lower the volume threshold for the current method of qualifying for the Program, and will provide members with another way in which they may qualify for the Program. These changes will apply equally to all members who otherwise qualify for the Program. Similarly, the proposed method of updating the Growth Baseline will be uniformly applied across members.

In sum, if the change proposed herein is unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed change will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[9]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov. Please include File Number SR–NASDAQ–2016–153 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–NASDAQ–2016–153. 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

[8] 15 U.S.C. 78f(b)(8).

[9] 15 U.S.C. 78s(b)(3)(A)(ii).

communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2016–153 and should be submitted on or before December 6, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27375 Filed 11–14–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79259; File No. SR–NASDAQ–2016–148]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Cease and Desist Authority Rules

November 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 27, 2016, The NASDAQ Stock Market LLC (''Nasdaq'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt Rules 9556 and 9800, which were previously adopted as a pilot the term of which has since expired, and to make related changes to the 9100, 9200, 9300, 9550, and 9800 Rule Series.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to adopt new Rules 9556 and 9800, which were previously adopted as a pilot the term of which has since expired, and to make related changes to the 9100, 9200, 9300, 9550, and 9800 Rule Series. In May 2003, the Commission approved, on a pilot basis, a rule change to adopt NASD Rules 9556 and 9800 that gave NASD, now known as FINRA, authority to issue temporary cease and desist orders and made explicit NASD's ability to impose permanent cease and desist orders as a remedy in disciplinary cases.[3] Because NASD was, and now FINRA is, the Exchange's regulatory services provider and administers the Exchange's disciplinary program under contract, the Exchange seeks to maintain comparability between its disciplinary procedure rules and those of NASD and now FINRA. As a consequence, the Exchange adopted Rules 9556 and 9800 to mirror the then-NASD rules to operate as a pilot in conjunction with the related NASD pilot.[4]

On June 23, 2009, the Exchange's Rule 9556 and 9800 pilot programs expired, at which time those rules and certain references thereto became obsolete, notwithstanding that they remained in the rulebook. The FINRA pilot program, however, continued and was approved on July 14, 2009 on a permanent basis.[5]

Neither the Exchange nor FINRA, acting on behalf of the Exchange pursuant to agreement, have [sic] used the cease and desist authority under Rules 9556 and 9800 during the time that the rules were effective. Nonetheless, the Exchange believes that, in addition to maintaining similar disciplinary rules, adoption of Rules 9556 and 9800 is important to the Exchange's disciplinary program. The authority under these rules will provide the Exchange and FINRA, operating on behalf of the Exchange, with a mechanism to take appropriate remedial action against a member or an associated person that has engaged (or is engaging) in violative conduct that could cause continuing harm to the investing public if not addressed expeditiously, such as dissipation or conversion of assets. It must be emphasized, however, that the cease and desist provisions contain numerous procedural protections for respondents to ensure that the proceedings are fair. Consequently, the Exchange believes that adoption of these rules is important to its regulatory program, notwithstanding that it anticipates exercising the authority provided by the rules sparingly.

The Exchange is proposing to delete Rules 9556 and 9800 (and related references in other rules[6]) because the pilot period for these rules has expired rendering them void, and adopt new

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 47925 (May 23, 2003) (File No. SR–NASD–98–80), 68 FR 33548 (June 4, 2003). *See also* Securities Exchange Act Release No. 51860 (June 16, 2005), 70 FR 36427 (June 23, 2005) (SR–NASD–2005–061) (extending the pilot to June 23, 2007 and making non-substantive changes); and Securities Exchange Act Release No. 55819 (May 25, 2007), 72 FR 30895 (June 4, 2007) (SR–NASD–2007–033) (extending the pilot to June 23, 2009 and making non-substantive changes).

[4] *See* Securities Exchange Act Release No. 53128 (January 13, 2006), 71 FR 3550 (January 23, 2006). *See also* Securities Exchange Act Release No. 56120 (July 24, 2007), 72 FR 41561 (July 30, 2007) (SR–NASDAQ–2007–060) (extending the pilot to June 23, 2009 and making conforming changes); and Securities Exchange Act Release No. 58069 (June 30, 2008), 73 FR 39360 (July 9, 2008) (SR–NASDAQ–2008–054) (making non-substantive changes).

[5] Securities Exchange Act Release No. 60306 (July 14, 2009), 74 FR 36292 (July 22, 2009) (SR–FINRA–2009–035). The Exchange notes that FINRA, in its rule change proposal to make its pilot program permanent, noted that it had used the authority under Rules 9556 and 9800 sparingly. *Id.* at 36293.

[6] The Exchange is deleting text from related provisions of Rules 8310, IM–8310–3(c)(1), 9120(r), 9241(c), 9290, 9311(b), 9312(b), and 9360 that also expired on June 23, 2009 and is inserting new text identical to what was deleted.

Rules 9556 and 9800 (and related references in other rules) [7] based on FINRA's analogous cease and desist rules, which include amendments to the former Nasdaq cease and desist rules to reflect changes that FINRA has made to its cease and desist rules in 2011 and 2015 after they were made permanent.[8] The Exchange is also proposing to amend other Rules under the 9000 Series to incorporate changes that FINRA made to its analogous rules in 2015, as discussed below. These proposed changes include significant amendments made by FINRA to not only its Rules 9556 and 9800, but also to its 9100, 9200, 9300, 9550, and 9800 Rule Series in 2015. Unless otherwise noted, Nasdaq is adopting the FINRA Rules with only minor changes to reflect the Exchange's committee structure and rules,[9] as described below.

2011 FINRA Rule Changes

In 2011, FINRA amended Rules 9552(b), 9553(b), 9554(b), 9555(b), and 9556(b), all of which concern service of notice.[10] Each of these rules concern [sic] the process followed when a person or entity subject to FINRA's jurisdiction fail [sic] to comply with various requirements under its rules. FINRA amended the rule provisions noted above to allow notice of failure to comply with a temporary or permanent cease and desist order to be served on counsel representing the member or person, or other person authorized to represent others under FINRA Rule 9141,[11] when counsel or other person authorized to represent others under FINRA Rule 9141 agrees to accept service for the member or person.

2015 FINRA Rule Changes

In 2015, FINRA made significant changes to its temporary and permanent cease and desist rules.[12] FINRA lowered the evidentiary standard to obtain a temporary cease and desist order, adopted a new expedited proceedings [sic] to address situations involving repeated violations of temporary or permanent cease and desist orders, and made a series of rule amendments to the temporary cease and desist order rules under FINRA Rule Series 9800, the expedited proceedings rules under FINRA Rule Series 9550,[13] and FINRA's Code of Procedure (FINRA Rule Series 9000) that harmonize service provisions in temporary cease and desist proceedings and expedited proceedings, ease administrative burdens in temporary cease and desist proceedings, and clarify the process by which permanent cease and desist orders may be imposed.

(i) Evidentiary Standard for Imposing a Temporary Cease and Desist Order

FINRA amended FINRA Rule 9840(a)(1) to change the evidentiary standard applied by Hearing Panels in issuing a temporary cease and desist order. Specifically, FINRA changed the standard for issuing a temporary cease and desist order from ''by a preponderance of the evidence that the alleged violation specified in the notice has occurred'' to a ''showing of a likelihood of success on the merits.'' FINRA noted that it believed that the ''preponderance of the evidence'' standard set too high an evidentiary threshold for this critical investor-protection tool, and noted that it is the identical standard for proving a violation in the underlying disciplinary proceeding that must be pursued at the same time.[14] Thus, to obtain a temporary cease and desist order—and thereby prevent the likely and significant dissipation or conversion of assets or other significant harm to investors—FINRA's prosecuting department had to make an evidentiary presentation in the temporary cease and desist proceeding that is similar in extent to its evidentiary presentation in the subsequent underlying disciplinary proceeding, but in an expedited manner.

FINRA also made a corresponding amendment to FINRA Rule 9840(a)(2). Prior to the amendment, FINRA Rule 9840(a)(2) provided that a temporary cease and desist order shall be imposed if the Hearing Panel finds that the violative conduct or continuation thereof is likely to result in significant dissipation or conversion of assets or other significant harm to investors prior to the completion of the underlying proceeding. The 2015 rule change modified this requirement to apply to the ''alleged'' violative conduct or continuation thereof, to be consistent with the proposed change to the evidentiary standard.

(ii) Failures To Comply With Temporary Cease and Desist Orders and Permanent Cease and Desist Orders (FINRA Rule 9556)

FINRA also made amendments to FINRA Rule 9556, which sets forth expedited procedures for enforcing violations of FINRA-issued temporary and permanent cease and desist orders. FINRA was concerned that their [sic] existing expedited procedures may permit cease and desist orders to be circumvented without any real threat of a sanction.[15] Thus, FINRA amended FINRA Rule 9556 to adopt a new paragraph (h) to permit its staff (with prior authorization from FINRA's Chief Executive Officer or other designated senior officer) to institute a new kind of expedited proceeding if the subject of a temporary or permanent cease and desist order fails to comply with that order and has previously been served with a notice under Rule 9556(a) for

[7] As a consequence of the expiration of the pilot rendering the existing related rule text void, in certain cases the Exchange is deleting the void text and reinserting identical rule text thereafter so the text may have effect once again. For example, the Exchange is deleting Rule 8310(a)(6), concerning imposition of a temporary or permanent cease and desist order, and adopting a new Rule 8310(a)(6) identical to what was deleted.

[8] In 2013, FINRA consolidated the publication standards for expedited proceeding decisions, including under FINRA Rule 9556, in FINRA Rule 8313(a)(3) and consequently amended FINRA Rule 9556 to remove paragraph (h) ''Notice to Membership'' from the rule. *See* Securities Exchange Act Release No. 69825 (June 21, 2013), 78 FR 38771 (June 27, 2013) (SR–FINRA–2013–018). The Exchange did not have such a provision in its Rule 9556. The Exchange's disclosure obligations are provided under IM–8310–3, including the Exchange's disclosure obligations related to expedited proceedings. *See* IM–8310–3(c).

[9] The Exchange is replacing references to FINRA and FINRA staff with references to Nasdaq and Nasdaq staff, which are the appropriate analogous parties at Nasdaq. The Exchange is also replacing FINRA text that states ''Chief Executive Officer or such other senior officer as the Chief Executive Officer may designate'' with ''Chief Regulatory Officer,'' which is the Exchange officer vested with the authority described under the rules. For example, old Rules 9556(a) and 9860 vested authority with the Chief Regulatory Officer to authorize notice and initiation of proceedings, respectively, whereas the analogous FINRA rules authorize its Chief Executive Officer or such other senior officer as the Chief Executive Officer may designate instead. Last, the Exchange is adding clarifying language to Rule 9810 to make it clear that initiation of a proceeding must not only be authorized by FINRA's Chief Executive Officer or such other senior officer as the Chief Executive Officer may designate, but also Nasdaq's Chief Regulatory Officer. As a practical matter, the Chief Regulatory Officer must agree that such a proceeding should be brought pursuant to Nasdaq rules.

[10] Securities Exchange Act Release No. 60306 (January 4, 2012), 77 FR 1524 (January 10, 2012) (SR–FINRA–2011–044). FINRA also amended other rules in the FINRA Rule 9000 Series not addressed in this filing. *Id.*

[11] FINRA Rule 9141, entitled ''Appearance and Practice; Notice of Appearance,'' provides, among other things, what is permissible in terms of representation before an Adjudicator. Exchange Rule 9141 is consistent with FINRA Rule 9141.

[12] Securities Exchange Act Release No. 75629 (August 6, 2015), 80 FR 48379 (August 12, 2015) (SR–FINRA–2015–019).

[13] FINRA amended its Rule 9551 ''Failure to Comply with Public Communications Standards.'' Nasdaq does not have such a rule (Nasdaq Rule 9551 is held in reserve) and is thus not incorporating those changes. In a related change, the Exchange is also amending its Rule 9559 to delete the references to Rule 9551, which were erroneously included in the rule.

[14] *See* Securities Exchange Act Release No. 75333 (June 30, 2015), 80 FR 38783 (July 7, 2015) (Notice of Filing File No. SR–FINRA–2015–019) at 38784.

[15] *Id.* at 38785.

failure to comply with any provision of the same temporary or permanent cease and desist order. FINRA adopted the change to prevent a respondent from abusing the existing process by repeatedly violating a cease and desist order and curing that violation before the effective date of any FINRA Rule 9556 notice,[16] without being subject to the immediate sanctions or review by the Office of Hearing Officers for a prolonged period. FINRA noted in its filing that the new FINRA Rule 9556(h) proceeding differs from other FINRA Rule 9556 expedited proceedings in other respects that reflect the response that FINRA believes is warranted for situations involving repeated violations of temporary or permanent cease and desist orders.[17] These differences include the following:

- a FINRA Rule 9556(h) proceeding could be initiated only if the respondent has previously been served, under FINRA Rule 9556(a), with a notice for failing to comply with any provision of the same temporary or permanent cease and desist order;
- FINRA's prosecuting department would initiate a FINRA Rule 9556(h) proceeding by filing a petition with FINRA's Office of Hearing Officers (and serving the respondent) that seeks the imposition of sanctions for the violation (rather than issuing a notice to the respondent);
- FINRA's prosecuting department would seek the imposition of any fitting sanction at the outset of the FINRA Rule 9556(h) proceeding (in contrast to other FINRA Rule 9556 expedited proceedings, where the recipient of a notice is not subject to the imposition of any fitting sanction unless such recipient opts for a hearing);
- a hearing is required in a FINRA Rule 9556(h) proceeding;
- the hearing for a FINRA Rule 9556(h) proceeding must be held in a condensed time frame (ten business days after a respondent is served the petition, versus other Rule 9556 proceedings which require a respondent to request a hearing within seven business days after service of a notice instituting a proceeding and require hearings to be held within 14 days after a request for a hearing is filed); [18]
- a FINRA Rule 9556(h) proceeding is presided over by a Hearing Officer,[19] rather than a Hearing Panel; [20] and
- the Hearing Officer may issue default decisions in FINRA Rule 9556(h) proceedings.[21]

Under amended FINRA Rule 9556(h)(4), the FINRA department that filed the petition can withdraw it without prejudice and shall be permitted to refile a petition based on allegations concerning the same facts and circumstances that are set forth in the withdrawn petition. FINRA noted that this provision provides it the flexibility to withdraw the petition where, for instance, the respondent evidences a good faith intent to comply with the temporary or permanent cease and desist order without the need to adjudicate the petition, while preserving FINRA's right to refile the petition if the respondent fails to do so.[22]

(iii) Service Provisions in Temporary Cease and Desist Proceedings and Expedited Proceedings

FINRA also made the rules that govern service of documents in temporary cease and desist proceedings and the eight different types of expedited proceedings under the Rule 9550 Series more consistent.[23] Prior to the changes, some provisions of these rules explicitly addressed service by facsimile and on counsel, while some did not. FINRA's amendments explicitly allow service by facsimile and on counsel across all temporary cease and desist and expedited proceedings, noting that doing so removed unnecessary burdens and inefficiencies. FINRA also amended its rules to permit service by email for all temporary cease and desist proceedings and expedited proceedings. FINRA noted that email service would allow parties to receive information quickly, which is particularly important in these types of proceedings, considering the short time frames involved.[24] As part of the changes allowing service by email, FINRA also now requires duplicate service through some other means such as overnight courier or personal delivery and made changes to its Rule 9550 Series to reflect this requirement.

(iv) Clarifying FINRA's Authority to Impose Permanent Cease and Desist Orders

FINRA clarified its rules concerning the process for imposing permanent cease and desist orders in disciplinary proceedings. FINRA noted that when it obtained the authority to impose temporary cease and desist orders, it also obtained the authority to impose permanent cease and desist orders.[25] Thus, the clarifying changes were procedural in nature and did not reflect any change to FINRA's prior representations concerning the context in which it would seek permanent cease and desist orders.

(v) Administrative Changes to Temporary Cease and Desist Proceedings

FINRA also expanded the pool of persons eligible to serve on hearing panels to include those who may serve on hearing panels for disciplinary matters, as provided under FINRA Rules 9231(b) and 9559(d)(2).[26] Specifically, FINRA amended its Rule 9820 to provide that the potential panelists for the Hearing Panels that preside over temporary cease and desist proceedings to [sic] include persons who currently serve or previously served on a District Committee; [27] previously served on the

[16] Under the then-current FINRA Rule 9556, if a member or person failed to comply with a temporary or permanent cease and desist order, FINRA staff (with prior authorization from FINRA's Chief Executive Officer or other designated senior officer) may have issued a notice stating that the failure to comply within seven days will result in a suspension or cancellation of membership or a suspension or bar from associating with any member and also would have stated what the respondent must do to avoid such action.

[17] *See supra* note 14 at 38785.

[18] *See* FINRA Rule 9559(f)(2) and (3); FINRA Rule 9556(e).

[19] As defined by FINRA Rule 9120(r).

[20] As defined by FINRA Rule 9120(s). *See* FINRA Rule 9559(d)(1) and (2) for a description of the appointment and authority [sic] of a Hearing Officer and/or Hearing Panel in expedited proceedings.

[21] *See* FINRA Rule 9559(m)(2).

[22] *See supra* note 14 at 38785.

[23] The Exchange notes that in SR–FINRA–2015–019 FINRA replaced references to ''contact questionnaires'' with reference to the ''FINRA Contact System,'' FINRA's proprietary system that facilitates member firm reporting of key contacts to FINRA. Exchange members are required to use the FINRA Contact System to report to Nasdaq all contact information required by Nasdaq and update its required contact information promptly. *See* Rule 1160. Under the FINRA Rule 9550 Series, the rules cite Article 4, Section III of the FINRA By-Laws as the authority pursuant to which its members have an obligation to report required contact information to it via the FINRA Contact System, whereas the Exchange's authority is pursuant to Rule 1160, as noted above. Thus, the Exchange is instead referencing Rule 1160 in the Rule 9550 Series as the authority pursuant to which members have the reporting obligation.

[24] *See supra* note 14 at 38785–6.

[25] *See supra* note 14 at 38786.

[26] FINRA harmonized the categories of individuals eligible for appointment as a Hearing Panelist under FINRA Rule 9820 with FINRA Rule 9231(b) (providing that each panelist shall be associated with a member of FINRA or retired therefrom and that the pool of panelists for disciplinary proceedings includes current or previous members of District Committees, former members of the National Adjudicatory Council, past members of disciplinary subcommittees of the National Adjudicatory Council or the National Business Conduct Committee, past members of the Board of Directors of FINRA Regulation or past members of the Board of Governors of FINRA, and current or previous members of committees appointed or approved by the Board of Governors of FINRA); FINRA Rule 9559(d)(2) (providing for the same pool for FINRA Rule 9556 expedited proceedings).

[27] As defined by FINRA Rule 9120(g).

National Adjudicatory Council; [28] previously served on a disciplinary subcommittee of the National Adjudicatory Council or the National Business Conduct Committee; [29] previously served as a member of the Board of Directors of FINRA Regulation or of the Board of Governors of FINRA; or currently serve or previously served on a committee appointed or approved by the Board of Governors of FINRA, but do not serve currently on the National Adjudicatory Council or as a member of the Board of Directors of FINRA Regulation or of the Board of Governors of FINRA. The amendment to FINRA Rule 9820 also required that each panelist be associated with a member of FINRA or retired therefrom. FINRA noted that, while its Office of Hearing Officers has presided over only a limited number of temporary cease and desist proceedings, those experiences have revealed that the narrowly circumscribed set of potential panelists can impede the recruitment of Hearing Panel members, especially considering that the expedited nature of temporary cease and desist proceedings will already preclude many from being able to serve.[30] FINRA also noted that it had concerns that the small pool of potential panelists will often make it difficult to recruit hearing panelists who can serve on both the temporary cease and desist proceeding and the subsequent underlying disciplinary proceeding, as well as any related expedited proceeding under FINRA Rule 9556.[31]

The Exchange is proposing to, likewise, expand the categories of individuals eligible to participate as Hearing Panelists. Like FINRA, the Exchange is harmonizing the categories of eligible individuals with the criteria under Rules 9231(b) and 9559(d)(2).[32] Thus, the Exchange is allowing the Chief Hearing Officer to select as a Panelist pursuant to proposed Rule 9820(a) a person who: Previously served on the Nasdaq's Review Council; [33] previously served on a disciplinary subcommittee of the Nasdaq Review Council, including a Subcommittee, an Extended Proceeding Committee,[34] or their predecessor subcommittees; previously served as a Director, but does not serve currently in that position; served on the FINRA National Adjudicatory Council or on a disciplinary subcommittee of the FINRA National Adjudicatory Council prior to the date that Nasdaq commenced operating as a national securities exchange; or is a FINRA Panelist approved by the Nasdaq Board at least annually, or is drawn from other sources the Board deems appropriate given the responsibilities of Panelists.

FINRA's proposed changes also eased other administrative burdens created by the shortened time frame of a temporary cease and desist proceeding. Those proposed changes were aimed at improving Hearing Panels' and parties' ability to prepare for hearings and giving Hearing Officers some needed flexibility. For example, under FINRA Rule 9830(a) prior to the 2015 amendments a Hearing Officer was not able to extend a hearing date in a temporary cease and desist proceeding unless all parties consented to the extension. The requirement to obtain the parties' consent was problematic in instances whereby the Office of Hearing Officers, rather than one of the parties, had a need for an extension, such as when it encounters difficulty in quickly appointing a Hearing Panel. To address this problem, FINRA amended its Rule 9830(a) to allow hearing deadlines to be extended by the Chief Hearing Officer or Deputy Chief Hearing Officer for good cause shown.

FINRA also made similar amendments to the process by which extensions are obtained to the deadlines for issuing decisions in temporary cease and desist proceedings and responding to requests to modify, set aside, limit, or suspend a temporary cease and desist order. Before the amendments to FINRA Rule 9840(a), the Hearing Panel's deadline for issuing its written decision could not be extended, even where there was good cause, without the consent of the parties. Likewise, prior to amending FINRA Rule 9850, a Hearing Panel's deadline for responding to an application to have a temporary cease and desist order modified, set aside, limited, or suspended could not be extended, even where there was a good cause, without the consent of the Parties. To allow a Hearing Panel some flexibility where there is a need for additional time to prepare its decision or respond to a FINRA Rule 9850 request (*e.g.,* when a member of the Hearing Panel becomes ill, where the temporary cease and desist proceeding is highly complex), FINRA amended FINRA Rules 9840(a) and 9850 to permit the deadlines for issuing decisions and responding to FINRA Rule 9850 applications to be extended by the Chief Hearing Officer or Deputy Chief Hearing Officer for good cause shown.

To further address the burdens created by the short time frame of temporary cease and desist proceedings, FINRA amended its rules to: (i) Require FINRA's prosecuting department to file a memorandum of points and authorities with the notice initiating a temporary cease and desist proceeding; and (ii) permit the Hearing Officer to order a party to furnish to all other parties and the Hearing Panel such information as deemed appropriate, including any or all of the pre-hearing submissions described in FINRA Rule 9242(a). FINRA noted that requiring its prosecuting department to file a memorandum of points and authorities at the initiation of the proceeding provides more context to the allegations and set [sic] forth legal authorities on which the notice seeking a temporary cease and desist order is premised.[35] FINRA believed that the change would, in turn, facilitate a more efficient process and improve the quality of the hearing through more thorough preparation, which are the same goals of the pre-hearing processes in FINRA disciplinary proceedings. FINRA also noted that requiring the filing of a memorandum of points and authorities at the initiation of a temporary cease and desist proceeding also enhances disclosure of the prosecuting department's allegations, which would inure to the benefit of the respondents and further increases the fairness of the proceeding.[36] Last, FINRA noted that all of these objectives are served by authorizing Hearing Officers to order a party to furnish other pre-hearing submissions.[37]

FINRA also proposed Rule 9840(e), which is a delivery requirement that requires a member firm that is the subject of a temporary cease and desist order to provide a copy of the order to its associated persons, within one business day of receiving it. Considering the significant nature of the harm that a temporary cease and desist order is aimed at stopping, FINRA believed that there is a heightened need to ensure that the persons who may act on behalf of the member firm are made aware of the contents of a temporary cease and desist order imposed against the member firm and the delivery requirement furthers that goal.[38]

[28] *See* By-Laws of FINRA Regulation, Inc., Article V National Adjudicatory Council.

[29] The predecessor to the FINRA National Adjudicatory Council.

[30] *See supra* note 14 at 38786.

[31] *Id.*

[32] Like FINRA's Rule 9559(d)(2), Rule 9559(d)(2) provides for the same pool for Rule 9556 expedited proceedings) [sic]. *Supra* note 26.

[33] *See* By-Laws of The Nasdaq Stock Market LLC, Article VI, Nasdaq Review Council.

[34] As defined by Rule 9120(n).

[35] *See supra* note 14 at 38787.

[36] *Id.*

[37] *Id.*

[38] Similarly, FINRA made related amendments to FINRA Rules 9269, 9270, and 9840 to require that

Continued

FINRA's rule change clarified the following additional three issues: (1) How settlements may be approved in temporary cease and desist proceedings; (2) which Hearing Panel has jurisdiction to preside over applications filed under FINRA Rule 9850 to modify, set aside, limit or suspend temporary cease and desist orders that are filed after a Hearing Panel has already been appointed in the underlying disciplinary proceeding; and (3) whether temporary and permanent cease and desist orders imposed against a firm also apply to successors of that firm.

With respect to the first issue, new FINRA Rule 9810(c) established that, if the parties agree to the terms of a proposed temporary cease and desist order, the Hearing Officer has the authority to approve and issue the order. On the second issue, amended FINRA Rule 9850 provided that the Hearing Panel that presided over the temporary cease and desist order proceeding shall retain jurisdiction to review a FINRA Rule 9850 application unless at the time the application is filed a Hearing Panel has already been appointed in the underlying disciplinary proceeding commenced under FINRA Rule 9211, in which case the Hearing Panel appointed in the disciplinary proceeding has jurisdiction. As to the third issue, amended FINRA Rule 9840(b) and new Rule 9291(a) established that when a temporary or permanent cease and desist order is imposed against a member firm, it also applies to any successor of the member firm.

Finally, FINRA amended certain provisions of FINRA Rule 9120. FINRA amended FINRA Rule 9120(s), ''Hearing Panel,'' to include an Adjudicator that is constituted under Rule 9231 to conduct a disciplinary proceeding governed by the Rule 9800 Series. The Exchange is adopting this amendment in its Rule 9120(s).

FINRA also amended FINRA Rule 9120(t), ''Interested Staff,'' to: (1) Insert ''or petition'' under paragraph (2)(A) of the rule, thus expanding the definition to include FINRA staff that filed a petition in a proceeding under the Rule 9520 Series or Rule 9550 Series; and (2) include a new paragraph (4) to list FINRA staff that are defined as Interested Staff in a proceeding under the FINRA Rule 9800 Series. The Exchange is also adopting the amendment to its Rule 9120(t) ''Interested Staff,'' but is expanding the definition to also include Nasdaq Regulation employees who directly participated in the authorization of the notice that initiates a temporary cease and desist proceeding, or directly participated in an examination, investigation, prosecution, or litigation related to a specific temporary cease and desist proceeding, under new paragraphs (t)(4)(C) and (D) of the rule.

FINRA also amended FINRA Rule 9120(w), ''Panelists,'' to include references to Panelists in the Rule 9550 Series, and the Rule 9800 Series within the definition provided by the rule. The Exchange is adopting this amendment in Rule 9120(z). FINRA also amended Rule 9120(z) ''Respondent'' to define a Respondent in a proceeding governed by the Rule 9800 Series to mean a FINRA member or associated person that has been served a notice initiating a cease and desist proceeding. The Exchange is adopting this amendment in Rule 9120(bb) ''Respondent.''

The Exchange believes that the changes made by FINRA in 2011 and 2015, as described above, improve the cease and desist authority as well as the service provisions. Consequently, the Exchange is proposing to adopt the changes, as described above, as its own.

Other Non-Substantive Changes

The Exchange is also proposing to make other non-substantive changes to its rules to correct misuse of the word ''FINRA,'' which were introduced erroneously when the Exchange adopted the rules. Specifically, the Exchange is proposing to amend Rule 9555(g) to remove reference to FINRA and replace it with reference to Nasdaq to make clear that it is Nasdaq's departments that should be contacted. The Exchange is also replacing references to FINRA's rules under new Rule 9810 with references to analogous rules of Nasdaq. Specifically, Nasdaq is replacing reference to FINRA Rule 2010 with reference to Nasdaq Rule 2010A, reference to FINRA Rule 2020 with reference to Nasdaq Rule 2120, and FINRA Rule 4330 with reference to Nasdaq Rule 2150.[39] The Exchange is also replacing the word ''FINRA'' with ''Nasdaq'' in adopting Rule 9840(d) to make it clear that the rule applies to Nasdaq members. The Exchange is proposing not to include the word ''FINRA'' prior to ''Rule 9211'' in adopting Rule 9850 to make it clear that the rule referenced is Nasdaq's rule, not FINRA's. Last, the Exchange is proposing to correct references to Nasdaq's rule concerning ''Restrictions on Affiliation'' in Rules 9270(e) and (f)(1), and Rule 9360. Specifically, Rules 9270(e) and (f)(1), and Rule 9360 erroneously reference Rule 2140 as providing the meaning of the term ''affiliate of Nasdaq.'' Rule 2160 is titled ''Restrictions on Affiliation'' and is the appropriate reference under Rules 9270(e) and (f)(1), and Rule 9360, and accordingly the Exchange replacing references to Rule 2140 with references to Rule 2160 under those rules.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[40] in general, and furthers the objectives of Section 6(b)(5) of the Act,[41] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange also believes that the proposed rule is consistent with Section 6(b)(6) of the Act,[42] which requires the

the Office of Hearing Officers, the Department of Enforcement, the Department of Market Regulation, or the General Counsel, as appropriate, disseminate default decisions, orders of acceptance of settlement, and temporary cease and desist orders to each member of FINRA with which a respondent is associated. FINRA noted that these dissemination requirements are intended to ensure that a respondent's member firm is made aware of the disciplinary history of its associated persons, regardless of the specific disciplinary procedure involved. *See supra* note 14 at 38787, n. 15. FINRA also noted that the amendments are consistent with other FINRA Rules that already require the Office of Hearing Officers, the National Adjudicatory Council, or the Board of Governors of FINRA to provide copies of a decision issued by a Hearing Panel, an Extended Hearing Panel, the National Adjudicatory Council, or the Board of Governors of FINRA to each member firm with which a respondent is associated. *Id.; see also* FINRA Rules 9268(d), 9349(c), 9351(e). The Exchange is adopting these amendments to Rules 9269, 9270, and 9840.

[39] Nasdaq notes that the Nasdaq rules cited in new Rule 9810(a) are the same as those that were cited under old Rule 9810(a). Nasdaq further notes that under FINRA Rule 9810(a), FINRA cites to FINRA Rules 2010, 2020, and 4330. Nasdaq is replacing reference to the FINRA rules with reference to Nasdaq's analogous Rules 2010A, 2120, and 2150, as was the case in old Rule 9810(a). While the provisions of Nasdaq Rules 2010A and 2120 closely mirror FINRA Rules 2010 and 2020, Nasdaq Rule 2150 is significantly different than FINRA Rule 4330. FINRA Rule 4330 concerns the permissible use of customers' margin securities while Nasdaq Rule 2150 requires a member and persons associated with a member to comply with FINRA's Rule 2150. FINRA Rule 2150 is titled ''Improper Use of Customers' Securities or Funds; Prohibition Against Guarantees and Sharing in Accounts'' and, among other things, prohibits members or persons associated with a member from making improper use of a customer's securities or funds, guaranteeing a customer against loss in connection with any securities transaction or in any securities account of such customer, and setting forth what is permissible in terms of sharing in profits and losses in a customer account. Nasdaq believes that Nasdaq Rule 2150 is the appropriate rule cite under new Rule 9810(a) for purposes of alleged violations concerning misuse or conversion of customer assets.

[40] 15 U.S.C. 78f(b).

[41] 15 U.S.C. 78f(b)(5).

[42] 15 U.S.C. 78f(b)(6).

rules of an exchange provide that its members be appropriately disciplined for violations of the Act as well as the rules and regulations thereunder, or the rules of the Exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction.

The Exchange believes that the proposed rule change is consistent with these provisions because the proposed changes are based on the cease and desist authority that FINRA has adopted, which the Exchange believes furthers the objectives of the Act by providing it with ability to stop violative conduct that is likely to cause dissipation or conversion of assets or other significant harm to investors, and on other changes to its related rules that clarify, harmonize, and improve its disciplinary process.

The proposed rule change will improve the Exchange's capacity to enforce compliance with applicable laws and rules by its members and persons associated with members and improving [sic] the Exchange's capability to prevent fraudulent and manipulative acts and practices. Thus, this authority is a vitally important tool to have to protect market participants.

The Exchange acknowledges that, when used, the cease and desist authority proposed herein would significantly impact a respondent. The Exchange, however, notes that the proposed rules incorporate numerous procedural protections for respondents to ensure that the proceedings initiated under these rules are fair, including notice and an opportunity to be heard before a neutral tribunal. Moreover, the Exchange anticipates using the authority provided by these rules sparingly.

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 changes are being proposed to provide an important regulatory tool to the Exchange and FINRA, acting on its behalf, which will protect investors when violative conduct is being taken by a member or person associated with a member, and time is of the essence to prevent harm, or further harm, to investors.

The proposed change does not impose a burden on competition among participants or other venues because it will only be used in circumstances where investor harm is imminent or is occurring. Thus, to the extent a burden on competition results from use of the authority provided by the proposed rules, such burden is necessary to protect investors, which is consistent with the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[43] and subparagraph (f)(6) of Rule 19b–4 thereunder.[44]

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative upon filing. The Exchange has stated that it is requesting this waiver so that the Exchange could apply, at the earliest time possible, the authority to issue temporary cease and desist orders and explicit authority to impose permanent cease and desist orders as a remedy in disciplinary cases. The Exchange explained that although it does not anticipate that it will be necessary to use this authority, when its cease and desist authority is needed, the Exchange must be able to move swiftly to prevent or stop investor harm. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because this waiver will enable the Exchange to utilize the temporary or permanent cease and desist authority described herein without delay in the unlikely event that circumstances arise that warrant its use. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[45]

[43] 15 U.S.C. 78s(b)(3)(A)(iii).

[44] 17 CFR 240.19b–4(f)(6).

[45] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2016–148 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2016–148. 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–NASDAQ–2016–148, and should be submitted on or before December 6, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[46]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27364 Filed 11–14–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79265; File No. SR–BatsEDGA–2016–24]

Self-Regulatory Organizations; Bats EDGA Exchange, Inc.; Notice of Filing of a Proposed Rule Change in Connection With the Proposed Corporate Transaction Involving Bats Global Markets, Inc. and CBOE Holdings, Inc.

November 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 2, 2016, Bats EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposed rule change (the ''Proposed Rule Change'') in connection with the proposed corporate transaction (the ''Transaction''), as described in more detail below, involving its ultimate parent company, Bats Global Markets, Inc. (''BGM''), CBOE Holdings, Inc. (''CBOE Holdings''), and two wholly owned subsidiaries of CBOE Holdings, CBOE Corporation and CBOE V, LLC (''CBOE V''). CBOE Holdings is the parent company of Chicago Board Options Exchange, Incorporated (''CBOE'') and C2 Options Exchange, Incorporated (''C2''), each a national securities exchange registered with the Commission pursuant to Section 6(a) of the Act,[3] and CBOE Futures Exchange, LLC (''CBOE Futures,'' and together with CBOE and C2, the ''CBOE Exchanges''), a national securities exchange that lists or trades security-futures products notice-registered with the Commission pursuant to Section 6(g) of the Act.[4]

Upon completion of the mergers described below that effectuate the Transaction (the ''Closing''), the business of BGM will be carried on by CBOE V. CBOE V, rather than BGM, will be the direct parent company of Direct Edge LLC (''Direct Edge''), which is the direct parent company of the Exchange. As a result, CBOE Holdings will become the ultimate parent company of Direct Edge and of the Exchange.

To effectuate the Transaction, the Exchange seeks to obtain the Commission's approval of: (i) The resolutions of BGM's board of directors (the ''BGM Board'') waiving certain provisions of the Amended and Restated Certificate of Incorporation of BGM (the ''BGM Charter'') and making certain related determinations regarding CBOE Holdings and the impact of the Transaction on the Exchange (the ''Resolutions''); (ii) the CBOE Holdings Second Amended and Restated Certificate of Incorporation (the ''CBOE Holdings Charter'') and the CBOE Holdings Third Amended and Restated Bylaws (the ''CBOE Holdings Bylaws''); (iii) the Certificate of Formation of CBOE V (the ''CBOE V Certificate'') and the Limited Liability Company Operating Agreement of CBOE V (the ''CBOE V Operating Agreement''); (iv) the proposed amendments to the Amended and Restated Limited Liability Company Operating Agreement of Direct Edge (the ''Direct Edge Operating Agreement''); (v) the proposed amendments to the Fifth Amended and Restated Bylaws of the Exchange (the ''Exchange Bylaws''); and (vi) the proposed amendments to EDGA Rules 2.3, 2.10 and 2.12 (the ''Exchange Rules'').

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange submits this Proposed Rule Change to seek the Commission's approval of the organizational and governance documents of the Exchange and its current and proposed future parent companies, and related actions that are necessary in connection with the Closing of the Transaction, as described below.

Other than as described herein and set forth in Exhibits 5A through 5H, the Exchange will continue to conduct its regulated activities (including operating and regulating its market and members) in the manner currently conducted, and will not make any changes to its regulated activities in connection with the Transaction. Except as set forth in this Proposed Rule Change, the Exchange is not proposing any amendments to its trading and regulatory rules at this time. If the Exchange determines to make any such changes, it will seek the approval of the Commission to the extent required by the Act, and the Commission's rules thereunder, and the Rules of the Exchange.

1. Current Corporate Structures

The Exchange, Bats BZX Exchange, Inc. (''BZX''), Bats BYX Exchange, Inc. (''BYX'') and Bats EDGX Exchange, Inc. (''EDGX,'' and together with the Exchange, BZX and BYX, the ''Bats Exchanges'') are each Delaware corporations that are national securities exchanges registered with the Commission pursuant to Section 6(a) of the Act.[5]

The Exchange and EDGX are each direct, wholly owned subsidiaries of Direct Edge, a Delaware limited liability company that is a direct, wholly owned subsidiary of BGM. BZX and BYX are direct, wholly owned subsidiaries of Bats Global Markets Holdings, Inc. (''BGM Holdings''), a Delaware corporation that is a direct, wholly owned subsidiary of BGM. In addition

[46] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78S(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f(a).

[4] 15 U.S.C. 78f(g).

[5] 15 U.S.C. 78f(a).

to certain other subsidiaries not registered with the Commission in any capacity, BGM Holdings also owns 100 percent of the equity interest in Bats Trading, Inc. (''Bats Trading''), a Delaware corporation that is a broker-dealer registered with the Commission that provides routing services outbound from, and in certain instances inbound to, each Bats Exchange. BGM, a Delaware corporation, is a publicly traded company listed on BZX.

CBOE Holdings, a Delaware corporation, is a publicly traded company listed on The NASDAQ Stock Market. CBOE Holdings owns 100 percent of the equity interest in the CBOE Exchanges.

In contemplation of the Transaction, CBOE Holdings formed two additional entities, CBOE Corporation, a Delaware corporation, and CBOE V, a Delaware limited liability company, each of which are direct, wholly owned subsidiaries of CBOE Holdings. Each of CBOE Corporation and CBOE V currently have no material assets or conduct any operations.

2. The Transaction

On September 25, 2016, BGM, CBOE Holdings, CBOE Corporation and CBOE V entered into an Agreement and Plan of Merger (the ''Merger Agreement''). Pursuant to and subject to the terms of the Merger Agreement, at the Closing, among other things:

(i) CBOE Corporation will be merged with and into BGM, whereupon the separate existence of CBOE Corporation will cease and BGM will be the surviving company (the ''Merger'');

(ii) by virtue of the Merger and without any action required on the part of BGM, CBOE Corporation or any holder of BGM or CBOE Corporation stock, each share of BGM common stock (whether voting or non-voting) issued and outstanding (with the exception of shares owned by CBOE Holdings, BGM or any of their respective subsidiaries and certain shares held by persons that are entitled to and properly demand appraisal rights) will be converted into the right to receive a particular number of shares of CBOE Holdings and/or cash, at the election of the holder of such share of BGM common stock (the ''Merger Consideration''), and each share of CBOE Corporation issued and outstanding will be converted into one share of BGM, such that BGM will become a wholly owned subsidiary of CBOE Holdings; and

(iii) immediately following the Merger, BGM will be merged with and into CBOE V, whereupon the separate existence of BGM will cease and CBOE V will be the surviving company (the ''Subsequent Merger'').

Upon the Closing, the Direct Edge Operating Agreement, the Exchange Bylaws and the Exchange Rules will be amended to take into account the post-Closing corporate structure, described below.

3. Post-Closing Corporate Structure

As a result of the Transaction, BGM will cease to exist and the business of BGM will be carried on by CBOE V, which is a wholly owned subsidiary of CBOE Holdings.[6] CBOE V will own 100 percent of the equity interest in Direct Edge and BGM Holdings. Direct Edge will continue to own 100 percent of the equity interest in the Exchange and EDGX. BGM Holdings will continue to own 100 percent of the equity interest in BZX, BYX, Bats Trading, and certain other subsidiaries not registered with the Commission in any capacity.[7]

4. Ownership and Voting Limitations of BGM; Resolutions

The BGM Charter provides that (i) no Person,[8] either alone or together with its Related Persons,[9] may own, directly or indirectly, of record or beneficially, shares constituting more than 40 percent of any class of its capital stock, and no Exchange Member, either alone or together with its Related Persons, may own, directly or indirectly, of record or beneficially, shares constituting more than 20 percent of any class of its capital stock (collectively, the ''BGM Ownership Limitation''); and (ii) subject to certain exceptions, no Person, either alone or together with its Related Persons, at any time, may, directly, indirectly or pursuant to any of various arrangements, vote or cause the voting of shares or give any consent or proxy with respect to shares representing more than 20 percent of the voting power of its then issued and outstanding capital stock (the ''BGM Voting Limitation'').[10] Purported transfers that would result in a violation of the BGM Ownership Limitation are not recognized by BGM to the extent of any ownership in excess of the BGM Ownership Limitation, and purported voting or voting arrangements in violation of the BGM Voting Limitation are not honored by BGM to the extent of any voting in excess of the limitation.[11]

However, the BGM Charter provides that each of the BGM Ownership Limitation and the BGM Voting Limitation may be waived (except with respect to Exchange Members and their Related Persons) pursuant to a resolution duly adopted by the BGM Board if, in connection with taking such action, the BGM Board states in such resolution that it is the determination of the BGM Board that the waiver:

[6] In connection with the Transaction, CBOE Holdings agreed in the Merger Agreement to take all requisite actions so, as of the Closing, the CBOE Holdings Board will include three individuals designated by BGM who (1) are serving as BGM directors immediately prior to the Closing and (2) comply with the policies (including clarifications of the policies provided to BGM) of the Nominating and Governance Committee of the CBOE Holdings Board as in effect on the date of the Merger Agreement and previously provided to BGM (each of whom will be appointed to the CBOE Holdings Board as of the Closing). The CBOE Holdings Board currently consists of 14 directors. The Exchange expects three current CBOE Holdings directors to resign effective prior to the Closing and the remaining CBOE Holdings directors to fill those vacancies with the three BGM directors designated by BGM.

[7] As described above, the Transaction will result in a change of ownership of Bats Trading, which is a member of the Financial Industry Regulatory Authority, Inc. (''FINRA''). The Exchange understands that, pursuant to NASD Rule 1017, Bats Trading is seeking approval for this change of ownership from FINRA.

[8] The BGM Charter generally defines a ''Person'' as a natural person, partnership, corporation, limited liability company, entity, government, or political subdivision, agency or instrumentality of a government. *See* BGM Charter, Art. FIFTH, para. (a)(i).

[9] The BGM Charter generally defines a ''Related Person'' as, with respect to any Person, (i) any ''affiliate'' of such Person (as defined in Rule 12b–2 under the Act); (ii) any other Person with which such first Person has any agreement, arrangement or understanding (whether or not in writing) to act together for the purpose of acquiring, voting, holding or disposing of shares of the capital stock of BGM; (iii) in the case of a Person that is a company, corporation or similar entity, any executive officer (as defined under Rule 3b–7 under the Act) or director of such Person and, in the case of a Person that is a partnership or limited liability company, any general partner, managing member or manager of such Person, as applicable; (iv) in the case of any Person that is a registered broker or dealer that has been admitted to membership in any of the Bats Exchanges (for purposes of this definition of ''Related Person,'' each such national securities exchange shall be referred to generally as an ''Exchange'' and any member of such Exchange, an ''Exchange Member''), any Person that is associated with the Exchange Member (as determined using the definition of ''person associated with a member'' as defined under Section 3(a)(21) of the Act); (v) in the case of a Person that is a natural person and Exchange Member, any broker or dealer that is also an Exchange Member with which such Person is associated; (vi) in the case of a Person that is a natural person, any relative or spouse of such Person, or any relative of such spouse who has the same home as such Person or who is a director or officer of BGM or any of its parents or subsidiaries; (vii) in the case of a Person that is an executive officer (as defined under Rule 3b–7 under the Act) or a director of a company, corporation or similar entity, such company, corporation or entity, as applicable; and (viii) in the case of a Person that is a general partner, managing member or manager of a partnership or limited liability company, such partnership or limited liability company, as applicable. *See* BGM Charter, Art. FIFTH, para. (a)(ii).

[10] *See* BGM Charter, Art. FIFTH, para. (b).

[11] *See* BGM Charter, Art. FIFTH, para. (d).

• will not impair the ability of each Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder;

• is otherwise in the best interests of BGM, its stockholders, and each Bats Exchange;

• will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder; and

• shall not be effective until it is filed with and approved by the Commission.[12]

In granting such a waiver, the BGM Board has the discretion to impose on the Person and its Related Persons, such conditions and restrictions that it deems necessary, appropriate or desirable in furtherance of the objectives of the Act and the rules and regulations promulgated thereunder, and the governance of each Bats Exchange.[13]

In addition, notwithstanding the above, the BGM Charter provides [14] that in any case where a Person, either alone or with its Related Persons, would own or vote more than the BGM Ownership Limitation or BGM Voting Limitation, respectively, upon consummation of any proposed sale, assignment or transfer of BGM's capital stock, such a transaction will not become effective until the BGM Board determines, by resolution, that such Person and its Related Persons are not subject to any ''statutory disqualification,'' as defined in Section 3(a)(39) of the Act.[15]

As described above, as a result of the Merger (and prior to its separate existence ceasing as a result of the Subsequent Merger), BGM will become a wholly owned subsidiary of CBOE Holdings, such that CBOE Holdings will possess ownership and voting rights in BGM in excess of the Ownership Limitation and the Voting Limitation. In addition, as a result of the Subsequent Merger, BGM will merge with and into CBOE V, terminating the BGM Charter and becoming an entity whose ownership and voting is held entirely by CBOE Holdings, in excess of the BGM Ownership Limitation and the BGM Voting Limitation that would otherwise apply.

The BGM Board therefore determined that in order to effect the Transaction, a waiver of the BGM Ownership Limitation and the BGM Voting Limitation with respect to CBOE Holdings would be required. To do so, the BGM Board adopted the Resolutions, attached as Exhibit 5A, making certain determinations with respect to CBOE Holdings and the Transaction that are necessary to waive the BGM Ownership Limitation and BGM Voting Limitation. Specifically, the BGM Board determined that:

• The acquisition of the proposed ownership by CBOE Holdings in BGM will not impair the ability of each Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder, is otherwise in the best interests of BGM, its stockholders and the Bats Exchanges, and will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder;

• the acquisition or exercise of the proposed voting rights by CBOE Holdings in BGM will not impair the ability of each Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder, is otherwise in the best interests of BGM, its stockholders and the Bats Exchanges, and will not impair the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder;

• neither CBOE Holdings nor any of its Related Persons is subject to ''statutory disqualification'' within the meaning of Section 3(a)(39) of the Act; [16] and

• neither CBOE Holdings nor any of its Related Persons is an Exchange Member.[17]

The Exchange has reviewed such Resolutions and requests that the Commission approve such Resolutions. The Exchange believes that the Commission should approve the Resolutions, as the Transaction will not impair the ability of any Bats Exchange to carry out its functions and responsibilities as an ''exchange'' under the Act and the rules and regulations promulgated thereunder, or the ability of the Commission to enforce the Act and the rules and regulations promulgated thereunder. The Bats Exchanges will continue to operate and regulate their markets and members as they have done prior to the Transaction. Thus, each Bats Exchange will continue to enforce the Act, the Commission's rules thereunder, and each Exchange's own rules, in the manner it does today. Further, the Commission will continue to have plenary regulatory authority over the Bats Exchanges, as is currently the case with these entities.

The Exchange also notes that the Resolutions reflect the determination by the BGM Board that the Transaction and CBOE Holdings' resulting ownership and voting rights in BGM following the Merger, and CBOE V's ownership and voting rights following the Subsequent Merger, are otherwise in the best interests of BGM, its stockholders and the Bats Exchanges. The Bats Exchanges will be ultimately held by an entity, CBOE Holdings, that already owns other national securities exchanges and is subject to governance documents that similarly restrict concentration of ownership and voting rights.

As described in more detail below, the Exchange is also requesting approval of the adoption of the CBOE Holdings Charter and the CBOE Holdings Bylaws. The CBOE Holdings Charter includes a number of provisions relating to the Commission's regulatory oversight that have a similar effect as those in the BGM Charter, including the BGM Ownership Limitation and the BGM Voting Limitation. Therefore, notwithstanding the Resolutions and the Transaction, provisions similar (and, in some cases, more stringent) to the BGM Ownership Limitation and the BGM Voting Limitation will remain in place with respect to potential future transactions involving the ultimate parent company of the Bats Exchanges. This means that the Exchange ownership structure will continue to provide the Commission with appropriate oversight tools to ensure that the Commission will have the ability to enforce the Act with respect to the Exchange, its direct and indirect parent companies, and its directors, officers, employees and agents to the extent they are involved in the activities of the Exchange, and protect the independence of the Exchange's self-regulatory activities.

[12] *See* BGM Charter, Art. FIFTH, para. (b)(ii)(B).

[13] *Id.*

[14] *See* BGM Charter, Art. FIFTH, para. (b)(iii).

[15] 15 U.S.C. 78c(a)(39).

[16] *Id.*

[17] In addition, the Resolutions contain a determination that the execution and delivery of the Merger Agreement by CBOE Holdings constituted notice of CBOE Holdings' intention to acquire ownership and voting rights in excess of the BGM Ownership Limitation and BGM Voting Limitation, respectively, in writing and not less than 45 days before the Closing. *See* BGM Charter, Art. FIFTH, para. (b)(iv). The Exchange notes that Art. FIFTH, para. (c)(i) of the BGM Charter further requires that any Person that, either alone or together with its Related Persons, owns, directly or indirectly (whether by acquisition or by a change in the number of shares outstanding), of record or beneficially, five percent or more of the then outstanding shares of capital stock of BGM must immediately upon acquiring knowledge of its ownership of five percent or more give written notice of such ownership to the BGM Board. The Merger Agreement provides that the Merger Agreement constitutes such notice with respect to certain voting agreements entered into concurrently with the Merger Agreement. *See* Merger Agreement, Section 5.21.

The Exchange therefore requests that the Commission approve the Resolutions, attached as Exhibit 5A.

5. CBOE Holdings Charter and CBOE Holdings Bylaws

CBOE Holdings currently holds a direct ownership interest in the CBOE Exchanges. The Commission has previously approved the CBOE Holdings Charter and the CBOE Holdings Bylaws (collectively, the ''CBOE Holdings Organizational Documents''), attached as Exhibits 5B and 5C, respectively.[18]

In connection with the Transaction, upon the Closing, CBOE Holdings will become the indirect owner (through CBOE V and Direct Edge) of the Exchange and EDGX and the indirect owner (through CBOE V and BGM Holdings) of BZX, BYX and Bats Trading (and certain other subsidiaries not registered with the Commission in any capacity).

The CBOE Holdings Organizational Documents include various provisions relating to any ''Regulated Securities Exchange Subsidiary,'' which is defined as any national securities exchange controlled, directly or indirectly, by CBOE Holdings. Upon the Closing, the Exchange will be covered by the definition of Regulated Securities Exchange Subsidiary for purposes of the CBOE Holdings Organizational Documents. As a result, no amendments to the CBOE Holdings Organizational Documents will be necessary to reflect CBOE Holdings' indirect ownership of the Exchange.

The Exchange believes that the CBOE Holdings Organizational Documents will protect and maintain the integrity of the self-regulatory functions of the Exchange and facilitate the ability of the Exchange and the Commission to carry out their regulatory and oversight obligations under the Act, as the CBOE Organizational Documents do with respect to the CBOE Exchanges.

In addition, the CBOE Organizational Documents contain provisions, including those with respect to the following, that are similar to those contained in the BGM Charter and BGM's Amended and Restated Bylaws (the ''BGM Bylaws''), which the Commission has previously found to be consistent with the Act: [19]

- *Ownership and Voting Limitations.* Similar to the BGM Voting Limitation and the BGM Ownership Limitation contained in the BGM Charter, the CBOE Holdings Charter limits the extent of ownership and voting rights which certain persons may possess or exercise.[20] Like the BGM Charter, the CBOE Holdings Charter similarly prohibits any Person,[21] together with its Related Persons,[22] from exercising voting rights with respect to more than 20 percent of the then outstanding votes entitled to be cast on such matter.[23] However, with respect to ownership limitations, the CBOE Holdings Charter contains a more stringent threshold than contained in the BGM Charter. Under the CBOE Holdings Charter, no Person, together with its Related Persons, is permitted at any time to beneficially own directly or indirectly shares of stock of CBOE Holdings representing in the aggregate more than 20 percent of the then outstanding shares of stock of CBOE Holdings.[24] In contrast, the BGM Ownership Limitation only applies a 20 percent threshold to any Exchange Member together with its Related Persons, while applying a 40 percent threshold to any other Person together with its Related Persons. As a result, the CBOE Holdings Charter should be at least as effective as the BGM Charter at preventing any stockholder from exercising undue control over the operation of the Exchange.
- *Independence and Non-Interference.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that for so long as CBOE Holdings controls, directly or indirectly, a Regulated Securities Exchange Subsidiary, each officer, director and employee of CBOE Holdings must give due regard to the preservation of the independence of the self-regulatory function of the Regulated Securities Exchange Subsidiaries and may not take any actions that he or she knows or reasonably should have known would interfere with the effectuation of any decisions by the board of directors of any Regulated Securities Exchange Subsidiary relating to such Regulated Securities Exchange Subsidiary's regulatory functions (including disciplinary matters) or that would adversely affect the ability of the Regulated Securities Exchange Subsidiary to carry out such Regulated Securities Exchange Subsidiary's responsibilities under the Act.[25]
- *Confidentiality.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that, to the fullest extent permitted by applicable law, all confidential information pertaining to the self-regulatory function of Regulated Securities Exchange Subsidiaries contained in the books and records of any Regulated Securities Exchange Subsidiary that shall come into the possession of the CBOE Holdings must be retained in confidence by CBOE Holdings and its officers, directors, employees and agents and must not be used for any commercial purposes.[26]
- *Books and Records.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that, for so long as CBOE Holdings directly or indirectly controls any Regulated Securities Exchange Subsidiary, the books, records, premises, officers, directors and employees of CBOE Holdings shall be deemed to be the books, records, premises, officers, directors and employees of the Regulated Securities Exchange Subsidiary for purposes of and subject to oversight pursuant to the Act, but only to the extent that such books, records, premises, officers, directors and employees of the Corporation relate to the business of such Regulated Securities Exchange Subsidiary.[27]
- *Compliance with Securities Laws; Cooperation with the Commission.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that CBOE Holdings shall comply with the federal securities laws and the rules and regulations thereunder and shall cooperate with the Commission, and each Regulated Securities Exchange Subsidiary pursuant to and to the extent of its regulatory authority, and shall take reasonable steps necessary to cause its agents to cooperate with the Commission and, where applicable, the

[18] *See* Securities Exchange Act Release No. 62158 (May 24, 2010), 75 FR 30082 (May 28, 2010) (SR–CBOE–2008–88). The CBOE Organizational Documents have been subsequently amended from time to time pursuant to proposed rule changes that were filed with the Commission for immediate effectiveness. *See, e.g.,* Securities Exchange Act Release No. 76282 (October 27, 2015), 80 FR 67464 (November 2, 2015) (SR–CBOE–2015–092).

[19] *See* Securities Exchange Act Release No. 77464 (March 29, 2016), 81 FR 19252 (April 4, 2016) (File Nos. SR–BATS–2016–10, SR–BYX–2016–02, SR–EDGX–2016–04, and SR–EDGA–2016–01).

[20] *Compare* CBOE Holdings Charter, Art. SIXTH *with* BGM Charter, Art. FIFTH.

[21] ''Person'' mean an individual, partnership (general or limited), joint stock company, corporation, limited liability company, trust or unincorporated organization, or any governmental entity or agency or political subdivision thereof. *See* CBOE Holdings Charter, Art. FIFTH, para. (a)(iv).

[22] ''Related Person'' is defined in the CBOE Holdings Charter in a manner substantially the same as it is defined in the BGM Charter. *See supra* note 9; CBOE Holdings Charter, Art. FIFTH, para. (a)(vi).

[23] *See* CBOE Holdings Charter, Art. SIXTH, para. (a).

[24] *See* CBOE Holdings Charter, Art. SIXTH, para. (b).

[25] *Compare* CBOE Holdings Charter, Art. SIXTEENTH, para. (c) *with* BGM Bylaws, Section 12.01.

[26] *Compare* CBOE Holdings Charter, Art. FIFTEENTH *with* BGM Bylaws, Section 12.02.

[27] *Compare* CBOE Holdings Charter, Art. FIFTEENTH *with* BGM Bylaws, Section 12.03.

Regulated Securities Exchange Subsidiaries pursuant to their regulatory authority, with respect to such agents' activities related to the Regulated Securities Exchange Subsidiaries.[28]

• *Consent to Jurisdiction.* Similar to provisions contained in the BGM Bylaws, the CBOE Holdings Charter provides that CBOE Holdings, its directors, officers, agents and employees, irrevocably submit to the jurisdiction of the U.S. federal courts, the Commission, and the Regulated Securities Exchange Subsidiaries, for the purposes of any suit, action or proceeding pursuant to U.S. federal securities laws or the rules or regulations thereunder, commenced or initiated by the Commission arising out of, or relating to, the Regulated Securities Exchange Subsidiaries' activities.[29]

• *Amendments.* Similar to provisions contained in the BGM Charter and BGM Bylaws, the CBOE Organizational Documents provide that for so long as CBOE Holdings controls, directly or indirectly, Regulated Securities Exchange, before any amendment to or repeal of the CBOE Holdings Charter or CBOE Holdings Bylaws may be effective, such amendment or repeal must be submitted to the board of directors of each such exchange, and if the amendment or repeal is required to be filed with, or filed with and approved by the Commission, then such change shall not be effective until filed with, or filed with and approved by, the Commission, as the case may be.[30]

As stated above, the Exchange believes that the foregoing provisions will assist the Exchange in fulfilling its self-regulatory obligations and in administering and complying with the requirements of the Act.

6. CBOE V Certificate and CBOE V Operating Agreement

Effective as of the Closing of the Transaction, CBOE V will hold direct ownership of (i) Direct Edge, which will continue to hold direct ownership of the Exchange and EDGX and (ii) BGM Holdings, which will continue to hold direct ownership of BZX, BYX and Bats Trading (and certain other subsidiaries not registered with the Commission in any capacity). However, unlike BGM currently, CBOE V will not be the ultimate holding company under the post-Closing corporate structure, but rather will be an intermediate holding company owned by CBOE Holdings. The Exchange believes that the CBOE V Operating Agreement contains provisions relating to its indirect ownership of one or more national securities exchanges, including such exchanges' regulatory functions and Commission oversight, that are appropriate for an intermediate holding company in the ownership chain of a national securities exchange. Many of the provisions of the CBOE V Operating Agreement relating to these matters are similar to the organizational documents of Direct Edge, which currently is, and following the Subsequent Merger will be, similarly situated as an intermediate holding company of the Exchange. The Commission has previously found the Direct Edge organizational documents to be consistent with the Act.[31]

Although CBOE V will not carry out any regulatory functions, the Exchange notes that its activities with respect to the operation of the Bats Exchanges must be consistent with, and must not interfere with, the self-regulatory obligations of each Bats Exchange. The CBOE V Operating Agreement therefore includes certain provisions that are designed to maintain the independence of the Bats Exchanges' self-regulatory functions, enable the Bats Exchanges to operate in a manner that complies with the federal securities laws, including the objectives of Sections 6(b)[32] and 19(g)[33] of the Act, and facilitate the ability of each Bats Exchange and the Commission to fulfill their respective regulatory and oversight obligations under the Act.

a. CBOE V Certificate of Formation

The CBOE V Certificate, attached as Exhibit 5D, includes the following provisions required under Delaware law: (i) the full name of CBOE V as ''CBOE V, LLC'', and (ii) the name and address of CBOE V's registered office in the State of Delaware and the name of CBOE V's registered agent at such address.[34] In addition, the CBOE V Certificate contains a provision providing that CBOE V shall indemnify members of its board of directors and certain other persons, subject to certain conditions.

As the Exchange believes is customary for limited liability companies formed in the State of Delaware, other substantive provisions governing the ownership, operation and management of CBOE V are set forth in the CBOE V Operating Agreement, discussed below.

b. CBOE V Operating Agreement

With respect to ownership and control of CBOE V, the CBOE V Operating Agreement, attached as Exhibit 5E, specifically provides that CBOE V's sole member is CBOE Holdings, until the CBOE V Operating Agreement is amended (subject to Commission approval, as described below).[35] Further, for so long as CBOE V controls, directly or indirectly, a subsidiary that is registered with the Commission as a national securities exchange (an ''Exchange Subsidiary''), CBOE Holdings may not sell, assign, transfer, convey, gift, exchange or otherwise dispose of any or all of its member interest in CBOE V, except pursuant to an amendment to the CBOE V Operating Agreement that is filed with and approved by the Commission.[36] These restrictions are designed to ensure that any change to the ownership or control of any Exchange Subsidiary, including without limitation the Bats Exchanges, may only occur through a change in the ownership or control of CBOE Holdings. As such, any purported change of such ownership or control (unless pursuant to a Commission-approved change of ownership of CBOE V) would need to comply with the CBOE Holdings Charter and CBOE Holdings Bylaws, including the ownership and voting limitations discussed above (or a Commission-approved waiver therefrom).

The CBOE V Operating Agreement also contains several provisions designed to protect the independence of the self-regulatory functions of the Bats Exchanges. The CBOE V Operating Agreement requires that, for so long as CBOE V, directly or indirectly, controls any Exchange Subsidiary, CBOE Holdings, as the sole member of CBOE V, and officers, employees and agents of CBOE V must give due regard to the preservation of independence of the self-regulatory functions of such Exchange Subsidiary, as well as to its obligations to investors and the general public, and not interfere with the effectuation of any decisions by the board of directors of an Exchange Subsidiary relating to its regulatory functions (including disciplinary matters) or which would interfere with the ability of such Exchange Subsidiary

[28] *Compare* CBOE Holdings Charter, Art. SIXTEENTH, para. (a) *with* BGM Bylaws, Section 12.04.

[29] *Compare* CBOE Holdings Charter, Art. FOURTEENTH *with* BGM Bylaws, Section 12.05.

[30] *Compare* CBOE Holdings Charter, Arts. ELEVENTH, TWELFTH and CBOE Holdings Bylaws, Section 10.2 *with* BGM Charter, Art. FOURTEENTH and BGM Bylaws, Article XI.

[31] *See* Securities Exchange Act Release No. 71449 (January 30, 2014), 79 FR 6961 (February 5, 2014) (SR–EDGA–2013–34; SR–EDGX–2013–43).

[32] 15 U.S.C. 78f(b).

[33] 15 U.S.C. 78s(g).

[34] Delaware Limited Liability Company Act § 18–201.

[35] CBOE V Operating Agreement, Section 1.1.

[36] CBOE V Operating Agreement, Section 5.1.

to carry out its responsibilities under the Act.[37]

The CBOE V Operating Agreement also would require that CBOE V comply with the U.S. federal securities laws and rules and regulations thereunder and cooperate with the Commission and each Exchange Subsidiary, as applicable, pursuant to and to the extent of their respective regulatory authority.[38] Further, CBOE V's officers, directors, employees and agents shall be deemed to agree to (i) comply with the U.S. federal securities laws and the rules and regulations thereunder; and (ii) cooperate with the Commission and each Exchange Subsidiary in respect of the Commission's oversight responsibilities regarding such Exchange Subsidiary and the self-regulatory functions and responsibilities of the Exchange Subsidiaries, and CBOE V will take reasonable steps to cause its officers, employees and agents to so cooperate.[39]

Furthermore, to the fullest extent permitted by law, CBOE V and its officers, directors, employees and agents will be deemed to irrevocably submit to the jurisdiction of the U.S. federal courts, the Commission, and each Exchange Subsidiary, as applicable, for purposes of any suit, action, or proceeding pursuant to the U.S. federal securities laws or the rules or regulations thereunder arising out of, or relating to, the activities of such Exchange Subsidiary.[40]

The proposed CBOE V Operating Agreement also contains a number of provisions designed to ensure that the Exchange will have sufficient access to the books and records of CBOE V as they relate to any Exchange Subsidiary. Pursuant to the CBOE V Operating Agreement, to the extent they are related to the operation or administration of an Exchange Subsidiary, the books, records, premises, officers, agents, and employees of CBOE V are deemed to be the books, records, premises, officers, agents and employees of such Exchange Subsidiary for the purposes of, and subject to oversight pursuant to, the Act.[41] In addition, for as long as CBOE V controls, directly or indirectly, an Exchange Subsidiary, CBOE V's books and records shall be subject at all times to inspection and copying by the Commission and the applicable Exchange Subsidiary, provided that such books and records are related to the operation or administration of an Exchange Subsidiary.[42]

The proposed CBOE V Operating Agreement also provides that, to the fullest extent permitted by law, all books and records of any Exchange Subsidiary reflecting confidential information pertaining to the self-regulatory function of such Exchange Subsidiary (including disciplinary matters, trading data, trading practices and audit information) that comes into the possession of CBOE V, shall be retained in confidence by CBOE V, CBOE V's officers, employees and agents and CBOE Holdings, and not used for any non-regulatory purposes.[43] The proposed CBOE V Operating Agreement provides, however, that the foregoing shall not limit or impede the rights of the Commission or an Exchange Subsidiary to access and examine such confidential information pursuant to the U.S. federal securities laws and the rules and regulations thereunder, or limit or impede the ability of CBOE Holdings or any of CBOE V's officers, employees or agents to disclose such confidential information to the Commission or an Exchange Subsidiary.[44]

In addition, the CBOE V Operating Agreement provides that for so long as CBOE V controls, directly or indirectly, any Exchange Subsidiary, before any amendment to or repeal of any provision of the CBOE V Operating Agreement will be effective, those changes must be submitted to the board of directors of each Exchange Subsidiary, and if the same must be filed with, or filed with and approved by, the Commission before the changes may be effective under Section 19 of the Act[45] and the rules promulgated thereunder, then the proposed changes shall not be effective until filed with, or filed with and approved by, the Commission, as the case may be.[46]

7. Direct Edge Operating Agreement

The Direct Edge Operating Agreement currently provides that the sole member of Direct Edge is BGM. However, as a result of the Transaction, CBOE V will become the sole member of Direct Edge. The Exchange proposes to amend the Direct Edge Operating Agreement to reflect this change, as set forth in Exhibit 5F.

8. Bylaws of the Exchange

In connection with the Transaction, the Exchange proposes to amend and restate its Fifth Amended and Restated Bylaws and adopt the amended Exchange Bylaws as its Sixth Amended and Restated Bylaws, attached as Exhibit 5G. Specifically, the Exchange proposes to (i) expand the prohibition contained in Section 2 of Article XI of the Exchange Bylaws and (ii) add a definition of ''Trading Permit Holder'' to Article I.

Currently, Section 2 of Article XI of the Exchange Bylaws prohibits directors of BGM or Direct Edge who are not also directors, officers, staff, counsel or advisors of the Exchange from participating in any meetings of the Exchange's board of directors (or any committee thereof) pertaining to the self-regulatory function of the Exchange (including disciplinary matters). This provision refers to BGM and Direct Edge because they are currently the only direct and indirect owners of the Exchange. However, following the Transaction, the Exchange will be owned indirectly by CBOE V and CBOE Holdings (in addition to its direct ownership by Direct Edge). Therefore, the Exchange is proposing to remove the reference to BGM and insert references to CBOE V and CBOE Holdings, so that CBOE V and CBOE Holdings will both be covered by this prohibition. The Exchange believes that this amendment will protect the independence of the Exchange's self-regulatory activities.

In addition, as noted above, the CBOE Holdings Charter currently prohibits certain persons from owning or exercising voting rights over certain percentages of ownership of CBOE Holdings. The CBOE Holdings Charter permits the board of directors of CBOE Holdings to waive the limitation on the exercise of voting rights in excess of 20 percent of the then outstanding votes entitled to be cast on such matter only if, among other things, ''for so long as [CBOE Holdings] directly or indirectly controls any Regulated Securities Exchange Subsidiary, neither such Person nor any of its Related Persons is a 'Trading Permit Holder' (as defined in the Bylaws of any Regulated Securities Exchange Subsidiary as they may be amended from time to time).''[47]

The Exchange does not issue ''trading permits,'' but admits members. The Exchange believes the provisions of the CBOE Holdings Charter that refer to Trading Permit Holders of its Regulated Securities Exchange Subsidiaries should apply equally to members of the

[37] *See* CBOE V Operating Agreement, Section 10.1(a).

[38] *See* CBOE V Operating Agreement, Section 10.2(a).

[39] *Id.*

[40] *See* CBOE V Operating Agreement, Section 10.3(a).

[41] *See* CBOE V Operating Agreement, Section 8.4(b).

[42] *Id.*

[43] *See* CBOE V Operating Agreement, Section 8.4(a).

[44] *Id.*

[45] 15 U.S.C. 78s.

[46] *See* CBOE V Operating Agreement, Section 11.2.

[47] *See* CBOE Holdings Charter, Art. SIXTH, para. (a)(ii)(C).

Exchange once it becomes a Regulated Securities Exchange Subsidiary of CBOE Holdings. As a result, the Exchange proposes to add clause (ff) to Article I of the Exchange Bylaws, providing that ''Trading Permit Holder' shall have the same meaning as Exchange Member.'' This will ensure that the Exchange's members will be considered Trading Permit Holders of a Regulated Securities Exchange Subsidiary for purposes of the CBOE Holdings Charter.

9. Exchange Rules

a. Exchange Rule 2.3—Member Eligibility

Pursuant to Exchange Rule 2.3, in order to be eligible for membership in the Exchange, a registered broker or dealer is currently required to be a member of at least one other national securities association or national securities exchange. However, membership in the Exchange's affiliated national securities exchanges, BZX, BYX or EDGX, is not sufficient for purposes of eligibility for Exchange membership. The Exchange adopted this because the Bats Exchanges have historically not functioned as the designated examining authority for any of its members, and the Exchange wanted to be sure that any member would be appropriately supervised by another national securities association or national securities exchange that has the capacity to function as the member's designated examining authority.

As a result of the Transaction, the Exchange will additionally become affiliated with the CBOE Exchanges. As with the Bats Exchanges, C2 does not currently serve as the designated examination authority for any of its members. CBOE, however, does act as the designated examining authority for certain of its members. Therefore, the Exchange proposes to amend Exchange Rule 2.3 to specify that a registered broker or dealer will be eligible for membership only if it is a member of a national securities association or national securities exchange other than or in addition to the following affiliates of the Exchange: BZX, BYX, EDGX and C2.

In addition, to ensure there is no confusion with respect to the possibility that a broker or dealer could qualify for membership in the Exchange based solely on membership in CBOE Futures or any other national securities exchange notice-registered with the Commission pursuant to Section 6(g) of the Act [48] that lists or trades security-futures products, the Exchange proposes to also specify that eligibility for membership requires membership in a national securities association registered pursuant to Section 15A of the Act or a national securities exchange registered with the Commission pursuant to Section 6(a) of the Act, so as to exclude a national securities exchange registered solely under Section 6(g) of the Act. The proposed amendments to Exchange Rule 2.3 are set forth in Exhibit 5H.

b. Exchange Rule 2.10—Affiliation Between Exchange and a Member

Exchange Rule 2.10 provides that, without prior approval of the Commission, neither the Exchange, nor any of its affiliates, shall directly or indirectly acquire or maintain an ownership interest in a member of the Exchange. This restriction is intended to address potential conflicts of interest that could result from affiliation between the Exchange and a member. Notwithstanding this general restriction, Exchange Rule 2.10 provides that it does not prohibit a member or its affiliate from acquiring or holding an equity interest in BGM that is permitted by the ownership and voting limitations contained in the BGM Charter and the BGM Bylaws. In addition, Exchange Rule 2.10 states that it does not prohibit a member from being or becoming an affiliate of the Exchange, or an affiliate of any affiliate of the Exchange, solely by reason of such member or any officer, director, manager, managing member, partner or affiliate of such member being or becoming either (a) a director of the Exchange pursuant to the Bylaws of the Exchange, or (b) a director of the Exchange serving on the board of directors of BGM. The Exchange proposes to replace the references to BGM in Rule 2.10 with references to CBOE Holdings to reflect the fact that following the Transaction, CBOE Holdings will replace BGM as the ultimate parent holding company of the Exchange.

Exchange Rule 2.10 also clarifies that it does not prohibit the Exchange from being an affiliate of its routing broker-dealer Direct Edge ECN LLC d/b/a DE Route (''DE Route'') or of EDGX, BZX, BYX, or Bats Trading, each of which are affiliated with the Exchange. The Exchange proposes to remove the reference to DE Route to reflect the fact that Bats Trading previously replaced DE Route as the Exchange's routing broker-dealer.[49] The Exchange also proposes to add references to the CBOE Exchanges, as the CBOE Exchanges will become new affiliated exchanges following the Transaction. The proposed amendments to Exchange Rule 2.10 are set forth in Exhibit 5H.

c. Exchange Rule 2.12—Bats Trading, Inc. as Inbound Router

Exchange Rule 2.12 provides that the Exchange, on behalf of BGM, shall establish and maintain procedures and internal controls reasonably designed to ensure that Bats Trading does not develop or implement changes to its systems on the basis of nonpublic information obtained as a result of its affiliation with the Exchange until such information is available generally to similarly situated members of the Exchange in connection with the provision of inbound order routing to the Exchange. The Exchange proposes to replace the reference to BGM with a reference to ''the holding company indirectly owning the Exchange and Bats Trading.'' This change would reflect the fact that BGM would no longer be the ultimate holding company of the Exchange following the Transaction and would also make this language consistent with the language used in Rule 2.12 of the BZX and BYX rulebooks. The proposed amendments to Exchange Rule 2.12 are set forth in Exhibit 5H.

2. Statutory Basis

The Exchange believes that the Proposed Rule Change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[50] In particular, the proposal is consistent with Section 6(b)(1) of the Act [51] in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the Rules of the Exchange.

The Proposed Rule Change is designed to enable the Exchange to continue to have the authority and ability to effectively fulfill its self-regulatory duties pursuant to the Act and the rules promulgated thereunder. In particular, the Proposed Rule Change includes in the CBOE Holdings Charter and CBOE Holdings Bylaws, like the BGM Charter and BGM Bylaws, various provisions intended to protect and maintain the integrity of the self-

[48] 15 U.S.C. 78f(g).

[49] *See* Securities Exchange Act Release No. 71449 (January 30, 2014), 79 FR 6961 (February 5, 2014) (SR–EDGA–2013–34; SR–EDGX–2013–43).

[50] 15 U.S.C. 78f(b).

[51] 15 U.S.C. 78f(b)(1).

regulatory functions of the Exchange upon Closing. For example, the CBOE Holdings Charter, as described above, is drafted to preserve the independence of the Exchange's self-regulatory function and carry out its regulatory responsibilities under the Act. In addition, the CBOE Holdings Charter imposes limitations similar to the BGM Ownership Limitation and BGM Voting Limitation to preclude undue influence over or interference with the Exchange's self-regulatory functions and fulfillment of its regulatory duties under the Act.

Moreover, notwithstanding the Proposed Rule Change, including the change to the indirect ownership of the Exchange, the Commission will continue to have regulatory authority over the Exchange, as is currently the case, as well as jurisdiction over the Exchange's direct and indirect parent companies with respect to activities related to the Exchange.[52] As a result, the Proposed Rule Change will facilitate an ownership structure that will provide the Commission with appropriate oversight tools to ensure that the Commission will have the ability to enforce the Act with respect to the Exchange, its direct and indirect parent companies and their directors, officers, employees and agents to the extent they are involved in the activities of the Exchange.

The Exchange also believes that the Proposed Rule Change furthers the objectives of Section 6(b)(5) of the Act[53] because the Proposed Rule Change would be consistent with and facilitate a governance and regulatory structure that is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

In addition, as discussed further in the Exchange's Statement on Burden on Competition below, the Exchange expects that the Transaction will foster further innovation while facilitating efficient, transparent and well-regulated markets for issuers and investors, removing impediments to, and perfecting the mechanism of a free and open market and a national market system. The Transaction will benefit investors and the securities market as a whole by, among other things, enhancing competition among securities venues and reducing costs.

Furthermore, the Exchange is not proposing any significant changes to its existing operational and trading structure in connection with the change in ownership; the Exchange will operate in essentially the same manner upon Closing as it operates today. Therefore, the Exchange believes that it will continue to satisfy the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange. The changes that the Exchange is proposing to the Exchange Rules are designed to reflect the prospective affiliation with CBOE Holdings and the CBOE Exchanges. The Exchange believes that the proposed change to its Rules is consistent with the requirements of the Act and the rules and regulations thereunder.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the Proposed Rule Change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Indeed, the Exchange believes that the Proposed Rule Change will enhance competition among trading venues, as the Exchange believes that the Transaction will result in various synergies and efficiencies. For example, the Transaction will allow the Bats Exchanges and the CBOE Exchanges to utilize a single technology platform, which the Exchange expects will reduce Bats Exchanges' and the CBOE Exchanges' combined costs, creating the opportunity to further reduce costs to their respective members and other constituents. The potential use of a single technology platform may also reduce investors' costs of connecting to and using the Bats Exchanges and the CBOE Exchanges, including through the combination of data centers and market data services. Combining the expertise of the CBOE Exchanges' personnel with the expertise of the Bats Exchanges' personnel will also facilitate ongoing innovation, including through new product creation and platform improvements.

The Exchange notes that the Bats Exchanges and the CBOE Exchanges generally operate with different business models, target different customer bases and primarily focus on different asset classes, limiting any concern that the Transaction could burden competition. Therefore, the Exchange expects that the Transaction will benefit investors, issuers, shareholders and the market as a whole. The Exchange will continue to conduct regulated activities (including operating and regulating its market and members) of the type it currently conducts, but will be able to do so in a more efficient manner to the benefit of its members. These efficiencies will pass through to the benefit of investors and issuers, promoting further efficiencies, competition and capital formation, placing no burden on competition not necessary or appropriate in furtherance of the Act.

Furthermore, the Exchange's conclusion that the Proposed Rule Change would not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act is consistent with the Commission's prior conclusions about similar combinations involving multiple exchanges in a single corporate family.[54]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited or received written comments on the Proposed Rule Change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will: (a) by order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[52] *See, e.g.,* CBOE Holdings Charter, Art. FOURTEENTH; CBOE V Operating Agreement, Section 10.3; Direct Edge Operating Agreement, Section 10.3.

[53] 15 U.S.C. 78f(b)(5).

[54] *See, e.g.,* Securities Exchange Act Release Nos. 71375 (January 23, 2014), 79 FR 4771 (January 29, 2014) (SR–BATS–2013–059; SR–BYX–2013–039); 66071 (December 29, 2011), 77 FR 521 (January 5, 2012) (SR–CBOE–2011–107 and SR–NSX–2011–14); 58324 (August 7, 2008), 73 FR 46936 (August 12, 2008) (SR–BSE–2008–02; SR–BSE–2008–23; SR–BSE–2008–25; SR–BSECC–2008–01); 53382 (February 27, 2006), 71 FR 11251 (March 6, 2006) (SR–NYSE–2005–77).

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–BatsEDGA–2016–24 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–BatsEDGA–2016–24. 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 the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsEDGA–2016–24, and should be submitted on or before December 6, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[55]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27370 Filed 11–14–16; 8:45 am]

BILLING CODE 8011–01–P

[55] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79263; File No. SR–NASDAQ–2016–151]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Commentary .14 to Rule 4770 (Compliance With Regulation NMS Plan To Implement a Tick Size Pilot)

November 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 31, 2016, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Commentary .14 to Rule 4770 (Compliance with Regulation NMS Plan to Implement a Tick Size Pilot) to provide the SEC with notice of its efforts to re-program its systems to eliminate a re-pricing functionality for certain orders in Test Group Three securities in connection with the Regulation NMS Plan to Implement a Tick Size Pilot Program (''Plan'' or ''Pilot'').[3]

The text of the proposed rule change is set forth below. Proposed new language is underlined; deleted text is in brackets.

* * * * *

The NASDAQ Stock Market Rules

* * * * *

4770. Compliance With Regulation NMS Plan To Implement a Tick Size Pilot

(a) through (d) No Change.

Commentary

.01–.13 No change.

.14 Until [October 31, 2016]*November 14, 2016,* the treatment of Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols in Test Group Three securities shall be as follows:

Following entry, and if market conditions allow, a Price to Comply Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Comply Order is able to be ranked and displayed at its original entered limit price.

Following entry, and if market conditions allow, a Price to Display Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Display Order is able to be ranked and displayed at its original entered limit price.

Following entry, and if market conditions allow, a Non-Displayed Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO up (down) to the Order's limit price.

Following entry, and if market conditions allow, the Post-Only Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO or the best price on the Nasdaq Book, as applicable until such time as the Post-Only Order is able to be ranked and displayed at its original entered limit price.

* * * * *

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

On September 7, 2016, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change (''Proposal'') to adopt paragraph (d) and Commentary .12 to Exchange Rule 4770 to describe changes to system

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) (''Approval Order'').

functionality necessary to implement the Plan. The Exchange also proposed amendments to Rule 4770(a) and (c) to clarify how the Trade-at exception may be satisfied. The SEC published the Proposal in the **Federal Register** for notice and comment on September 20, 2016.[4] Nasdaq subsequently filed three Partial Amendments to clarify aspects of the Proposal. The Commission approved the Proposal, as amended, on October 7, 2016.[5]

In SR–NASDAQ–2016–126, Nasdaq had initially proposed a re-pricing functionality for Price to Comply Orders, Non-Displayed Orders, and Post-Only Orders entered through the OUCH and FLITE protocols in Group Three securities.[6] Nasdaq subsequently determined that it would not offer this re-pricing functionality for Price to Comply Orders, Non-Displayed Orders, and Post-Only Orders entered through the OUCH and FLITE protocols in Group Three securities. As part of Partial Amendment No. 2 to SR–NASDAQ–2016–126, Nasdaq proposed to delete the relevant language from Rule 4770 related to this re-pricing functionality.

In that amendment, Nasdaq noted that this change would only impact the treatment of Price to Comply Orders, Non-Displayed Orders, and Post-Only orders that are submitted through the OUCH and FLITE protocols in Test Group Three Pilot Securities, as these types of Orders that are currently submitted to Nasdaq through the RASH, QIX or FIX protocols are already subject to this re-pricing functionality and will remain subject to this functionality under the Pilot.

In the Amendment, Nasdaq further noted that its systems are currently programmed so that Price to Comply Orders, Non-Displayed Orders and Post-Only Orders entered through the OUCH and FLITE protocols in Test Group Three Securities may be adjusted repeatedly to reflect changes to the NBBO and/or the best price on the Nasdaq book. Nasdaq stated that it is re-programming its systems to remove this functionality for Price to Comply Orders, Non-Displayed Orders and Post-Only Orders entered through the OUCH and FLITE protocols in Test Group Three Securities. In the Amendment, Nasdaq stated that it anticipated that this re-programming shall be completed no later than November 30, 2016. If it appeared that this functionality would remain operational by October 17, 2016, Nasdaq indicated that it would file a proposed rule change with the SEC and will provide notice to market participants sufficiently in advance of that date to provide effective notice. The rule change and the notice to market participants would describe the current operation of the Nasdaq systems in this regard, and the timing related to the re-programming.

On October 17, 2016, Nasdaq filed a proposal to extend the date by which it would complete the re-programing of its systems to eliminate the re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols.[7] In that proposal, Nasdaq stated that it anticipated that this re-programming shall be complete on or before October 31, 2016.[8]

At this time, Nasdaq is still determining how to modify its systems to eliminate the current re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols. Nasdaq is therefore submitting this proposal to extend the date by which the current re-pricing functionality will be eliminated. Nasdaq anticipates that the re-programming to eliminate the current re-pricing functionality shall be completed on or before November 14, 2016.

Therefore, the current treatment of Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols in Test Group Three securities shall be as follows:

Following entry, and if market conditions allow, a Price to Comply Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Comply Order is able to be ranked and displayed at its original entered limit price.

Following entry, and if market conditions allow, a Price to Display Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Display Order is able to be ranked and displayed at its original entered limit price.

Following entry, and if market conditions allow, a Non-Displayed Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO up (down) to the Order's limit price.

Following entry, and if market conditions allow, a Post-Only Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO or the best price on the Nasdaq Book, as applicable until such time as the Post-Only Order is able to be ranked and displayed at its original entered limit price.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The purpose of this filing is to inform the SEC and market participants of the status of Nasdaq's attempts to re-program its systems to remove the re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols, and the current treatment of such orders pending the removal of this functionality. This proposal is consistent with the Act because it provides the SEC and market participants with notice of Nasdaq's efforts in this regard, and is being submitted in connection with the statements made by Nasdaq in SR–NASDAQ–2016–126 and SR–NASDAQ–

[4] *See* Securities Exchange Act Release No. 78837 (September 14, 2016), 81 FR 64544 (September 20, 2016) (SR–NASDAQ–2016–126).

[5] *See* Securities Exchange Act Release No. 79075 (October 7, 2016) (SR–NASDAQ–2016–126).

[6] As originally proposed, Rule 4770(d)(2) stated that Price to Comply Orders in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO until such time as the Price to Comply Order is able to be ranked and displayed at its original entered limit price. Rule 4770(d)(3) stated that, if market conditions allow, a Non-Displayed Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO up (down) to the Order's limit price. Rule 4770(d)(4) stated that, if market conditions allow, the Post-Only Order in a Test Group Three Pilot Security will be adjusted repeatedly in accordance with changes to the NBBO or the best price on the Nasdaq Book, as applicable until such time as the Post-Only Order is able to be ranked and displayed at its original entered limit price.

[7] *See* Securities Exchange Act Release No. 79155 (October 25, 2016) (SR–NASDAQ–2016–143).

Subsequent to the approval of SR–NASDAQ–2016–126, Nasdaq become aware that this re-pricing functionality also applies to Price to Display Orders that are entered through the OUCH and FLITE protocols in Test Group Three Securities, and included those Orders as part of SR–NASDAQ–2016–143 accordingly. Price to Display Orders will be treated in the same manner as Price to Comply Orders under the re-pricing functionality.

[8] *Id.*

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

2016–143 in proposing the removal of this functionality.

Nasdaq also believes that the proposal is consistent with the Act because the re-pricing functionality will not significantly impact the data gathered pursuant to the Pilot. Nasdaq notes that this re-pricing functionality only affects Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols for Test Group Three securities until the re-pricing functionality is eliminated, and only becomes relevant when an Order in a Test Group Three security would cross a Protected Quotation of another market center. Nasdaq has analyzed data relating to the frequency with which Orders in Test Group Three securities are entered with a limit price that would cross a Protected Quotation of another market center, and believes that the re-pricing functionality will be triggered infrequently once Test Group Three becomes fully operational.[11] The Exchange also notes that it is diligently working to eliminate the current re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols, and that it anticipates this re-programming to be complete on or before November 14, 2016.

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 purpose of this proposal is to provide the SEC and market participants with notice of Nasdaq's efforts to remove its re-pricing functionality in Test Group Three securities for Price to Comply Orders, Price to Display Orders, Non-Displayed Orders, and Post-Only Orders that are entered through the OUCH or FLITE protocols, consistent with its statements in SR–NASDAQ–2016–126 and SR–NASDAQ–2016–143.

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.

[11] For example, on October 31, 2016, in the one hundred Test Group Three securities that are currently live, 0.06% of orders that were entered on Nasdaq in those securities were entered at a price that crossed the NBBO.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[12] and subparagraph (f)(6) of Rule 19–4 thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing. Rule 19b–4(f)(6)(iii), however, permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay contained in Rule 19b–4(f)(6)(iii) so that this proposed change will be in operative as of October 31, 2016, the date that Test Group Three securities are fully implemented and are subject to the quoting and trading restrictions of the Plan and, therefore, the relevant language in Rule 4770.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to implement the proposed rules immediately thereby preventing delays in the implementation of the Plan. The Commission notes that the Pilot started implementation on October 3, 2016, Test Group Three securities were fully phased into the Pilot on October 31, 2016, and waiving the 30-day operative delay would ensure that the rules of the Exchange would be in place during implementation. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2016–151 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–NASDAQ–2016–151. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2016–151, and should be

submitted on or before December 6, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27368 Filed 11–14–16; 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 20549–2736.

Extension:

Rule 602, SEC File No. 270–404, OMB Control No. 3235–0461.

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'') 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 602 of Regulation NMS (17 CFR 240.602), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 602 of Regulation NMS, Dissemination of Quotations in NMS securities, contains two related collections. The first collection of information is found in Rule 602(a).[1] This third-party disclosure requirement obligates each national securities exchange and national securities association to make available to quotation vendors for dissemination to the public the best bid, best offer, and aggregate quotation size for each ''subject security,'' as defined under the Rule. The second collection of information is found in Rule 602(b).[2] This disclosure requirement obligates any exchange member and over-the-counter (''OTC'') market maker that is a ''responsible broker or dealer,'' as defined under the Rule, to communicate to an exchange or association their best bids, best offers, and quotation sizes for subject securities.[3]

It is anticipated that twenty respondents, consisting of nineteen national securities exchanges and one national securities association, will collectively respond approximately 2,184,303,485,488 times per year pursuant to Rule 602(a) at 18.22 microseconds per response, resulting in a total annual burden of approximately 11,640 hours. It is anticipated that no respondents will have a reporting burden pursuant to Rule 602(b).[4]

Thus, the aggregate third-party disclosure burden under Rule 602 is 11,640 hours annually which is comprised of 11,640 hours relating to Rule 602(a) and 0 hours relating to Rule 602(b).

Compliance with Rule 602 of Regulation NMS is mandatory and the information collected is made available to the public.

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.

The public may view 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) Pamela C. Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: November 8, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–27377 Filed 11–14–16; 8:45 am]

BILLING CODE 8011–01–P

[15] 17 CFR 200.30–3(a)(12).

[1] 17 CFR 242.602(a).

[2] 17 CFR 242.602(b).

[3] Under Rule 602(b)(5), electronic communications networks (''ECNs'') have the option of reporting to an exchange or association for public dissemination, on behalf of customers that are OTC market makers or exchange market makers, the best-priced orders and the full size for such orders entered by market makers on the ECN, to satisfy such market makers' reporting obligation under Rule 602(b). Since this reporting requirement is an alternative method of meeting the market makers' reporting obligation, and because it is directed to nine or fewer persons (ECNs), this collection of information is not subject to OMB review under the Paperwork Reduction Act (''PRA'').

[4] For the reporting obligation under Rule 602(b), the respondents are exchange members and OTC market makers. The Commission believes that communication of quotations through an exchange's electronic trading system effectively means that exchange members currently have no reporting burden under Rule 602(b) for these quotations. The Commission also believes that there are presently no OTC market makers that quote other than on an exchange.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79268; File No. SR–CBOE–2016–076]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of a Proposed Rule Change in Connection With a Proposed Corporate Transaction Involving CBOE Holdings, Inc. and Bats Global Markets, Inc.

November 8, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1], and Rule 19b–4 thereunder,[2] notice is hereby given that on November 4, 2016, Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange submits this rule filing in connection with a proposed corporate transaction (the ''Transaction'') involving its ultimate parent company, CBOE Holdings, Inc. (''CBOE Holdings''), two wholly owned subsidiaries of CBOE Holdings, CBOE Corporation and CBOE V, LLC (''CBOE V''), and Bats Global Markets, Inc. (''BGM''). BGM is the ultimate parent company of Bats BZX Exchange, Inc. (''Bats BZX''), Bats BYX Exchange, Inc. (''Bats BYX''), Bats EDGX Exchange, Inc. (''Bats EDGX''), and Bats EDGA Exchange, Inc. (''Bats EDGA'' and, together with Bats BZX, Bats BYX, and Bats EDGX, the ''Bats Exchanges''). Upon completion of the Transaction (the ''Closing''), CBOE Holdings will become the ultimate parent of the Bats Exchanges.

On September 25, 2016, CBOE Holdings, CBOE Corporation, CBOE V, and BGM entered into an Agreement and Plan of Merger, as it may be amended from time to time (the ''Merger Agreement''). In connection with the Transaction, the Exchange seeks the Commission's approval of a provision in the Merger Agreement regarding the composition of the CBOE Holdings Board of Directors (''CBOE Holdings Board'') upon the Closing. There are no

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

proposed changes to Exchange rules or governing documents of CBOE Holdings or the Exchange.

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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange submits this filing for Commission approval of a provision in the Merger Agreement regarding the composition of the CBOE Holdings Board upon Closing. Other than as described herein, the Exchange will continue to conduct its regulated activities (including operating and regulating its market and Trading Permit Holders) in essentially the same manner it conducts them today, and will not make any changes to its regulated activities in connection with the Transaction. The Exchange is not proposing any amendments to its trading and regulatory rules or organizational and governance documents at this time. If the Exchange determines to make any such changes, it will submit rule filings to the Commission proposing such changes to the extent required by the Act and the rules and regulations thereunder.

Current Corporate Structures

Each of CBOE and C2 Options Exchange, Incorporated (''C2'' and, together with the Exchange, the ''CBOE Exchanges'') is a Delaware corporation that is a national securities exchange registered with the Commission pursuant to Section 6(a) of the Act.[3] Each CBOE Exchange is a direct, wholly owned subsidiary of CBOE Holdings, a publicly traded Delaware corporation. CBOE V is a Delaware limited liability company and direct, wholly owned subsidiary of CBOE Holdings, which currently has no material assets and conducts no operations.

Each Bats Exchange is a Delaware corporation that is a national securities exchange registered with the Commission pursuant to Section 6(a) of the Act.[4] BGM is a publicly traded Delaware corporation and the ultimate parent of the Bats Exchanges.

The Transaction

Pursuant to and subject to the terms of the Merger Agreement, at the Closing, among other things, each share of BGM common stock (whether voting or non-voting) issued and outstanding (other than shares owned by CBOE Holdings, BGM or any of their respective subsidiaries, and certain shares held by BGM stockholders that are entitled to and properly demand appraisal rights) will be converted into the right to receive a particular number of shares of CBOE Holdings common stock, an amount of cash, or a combination of both, at the election of the holder of such share of BGM common stock. BGM will ultimately merge with and into CBOE Holdings' wholly owned subsidiary CBOE V, at which time the separate existence of BGM will cease and CBOE V will be the surviving company.

Post-Closing Corporate Structure

As a result of the Transaction, CBOE Holdings will be the ultimate parent of the Bats Exchanges, each of which will continue to operate separately. CBOE Holdings will continue to be a publicly owned company and the ultimate parent of the CBOE Exchanges, each of which will continue to operate separately.

Post-Closing CBOE Holdings Board

In connection with the Transaction, CBOE Holdings agreed in the Merger Agreement to take all requisite actions so, as of the Closing, the CBOE Holdings Board will include three individuals designated by BGM who (1) are serving as BGM directors immediately prior to the Closing and (2) comply with the policies (including clarifications of the policies provided to BGM) of the Nominating and Governance Committee of the CBOE Holdings Board as in effect on the date of the Merger Agreement and previously provided to BGM (each of whom will be appointed to the CBOE Holdings Board as of the Closing). The CBOE Holdings Board currently consists of 14 directors.[5] The Exchange expects three current CBOE Holdings directors to resign effective prior to the Closing and the remaining CBOE Holdings directors to fill the vacancies created by those resignations with the three BGM directors designated by BGM.[6]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[7] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] because it would be consistent with and facilitate a governance and regulatory structure designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange also believes the proposed rule change is consistent with Section 6(b)(1) of the Act,[9] which provides the Exchange be organized and have the capacity to be able to carry out the purposes of the Act and to enforce compliance by the Exchange's Trading Permit Holders and persons associated with its Trading Permit Holders with the Act, the rules and regulations thereunder, and the rules of the Exchange.

The proposed rule change is consistent with CBOE Holdings' organizational and governing documents previously filed with the Commission.[10] The Exchange will continue to have the authority and ability to effectively fulfill its self-regulatory duties pursuant to the Act and the rules promulgated thereunder. CBOE Holdings' governing documents will not change at the Closing and,

[3] 15 U.S.C. 78f(a).

[4] 15 U.S.C. 78f(a).

[5] Pursuant to the Second Amended and Restated Certificate of Incorporation of CBOE Holdings (''CBOE Holdings Certificate'') and the Third Amended and Restated Bylaws of CBOE Holdings (''CBOE Holdings Bylaws''), the CBOE Holdings Board will consist of no less than 11 and no more than 23 directors, the exact number to be fixed by the CBOE Holdings Board from time to time pursuant to resolution adopted by the Board. *See* CBOE Holdings Certificate Article Seventh (b) and CBOE Holdings Bylaws Section 3.2.

[6] *See* Sections 3.4 and 3.5 of the CBOE Holdings Bylaws.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(1).

[10] *See, e.g.,* Securities Exchange Act Release Nos. 34–76282 (October 27, 2015), 80 FR 67464 (November 2, 2015) (SR–CBOE–2015–092); and 34–76281 (October 27, 2015), 80 FR 67461 (November 2, 2015) (SR–C2–2015–022) (notices of filing and immediate effectiveness of recent proposed rule changes to amend the CBOE Holdings Certificate and Bylaws); *see also supra* notes 5 and 6.

therefore, will continue to include various provisions intended to protect and maintain the integrity of the self-regulatory functions of the Exchange. Additionally, the Commission will continue to have regulatory authority over the Exchange, as is currently the case, as well as jurisdiction over CBOE Holdings with respect to activities related to the Exchange.[11]

The Exchange is proposing no changes to its existing operational and trading structure in connection with the Transaction. Upon Closing, the Exchange will operate in essentially the same manner as it operates today. Therefore, the Exchange believes it will continue to satisfy the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change relates to the corporate governance of CBOE Holdings—specifically a change in composition of the CBOE Holdings Board in connection with a corporate transaction—and not the operations of the Exchange. This is not a competitive filing and, therefore, imposes no burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. by order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2016–076 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–CBOE–2016–076. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2016–076, and should be submitted on or before December 6, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Brent J. Fields,

Secretary.

[FR Doc. 2016–27373 Filed 11–14–16; 8:45 am]

BILLING CODE 8011–01–P

[11] *See, e.g.,* CBOE Holdings Certificate Article Fourteenth.

[12] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2016–0055]

Agency Information Collection Activities: Proposed Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, *Fax:* 202–395–6974, *Email address: OIRA_Submission@omb.eop.gov.*

(SSA), Social Security Administration, OLCA, *Attn:* Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, *Fax:* 410–966–2830, *Email address: OR.Reports.Clearance@ssa.gov.*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2016–0055].

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than January 17, 2017. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Agreement to Sell Property—20 CFR 416.1240–416.1245—0960–0127. Individuals or couples who are otherwise eligible for Supplemental Security Income (SSI) payments, but whose resources exceed the allowable limit may receive conditional payments if they agree to dispose of the excess non-liquid resources and make repayments. SSA uses Form SSA–8060–U3 to document this agreement, and to ensure the individuals understand their obligations. Respondents are applicants for and recipients of SSI payments who will be disposing of excess non-liquid resources.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of responses	Frequency of response	Average burden per response (minutes)	Total estimated total annual burden (hours)
SSA–8060–U3	20,000	1	10	3,333

2. Development of Participation in a Vocational Rehabilitation or Similar Program—20 CFR 404.316(c), 404.337(c), 404.352(d), 404.1586(g), 404.1596, 404.1597(a), 404.327, 404.328, 416.1321(d), 416.1331(a)–(b), and 416.1338, 416.1402—0960–0282. State Disability Determination Services (DDS) must determine if Social Security disability payment recipients whose disability ceased and who participate in vocational rehabilitation programs may continue to receive disability payments. To do this, DDSs need information about the recipients; the types of program participation; and the services they receive under the rehabilitation program. SSA uses Form SSA–4290 to collect this information. The respondents are State employment networks; vocational rehabilitation agencies; or other providers of educational or job training services.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of responses	Frequency of Response	Average burden per response (minutes)	Total estimated total annual burden (hours)
SSA–4290	3,000	1	15	750

3. Appointment of Representative—20 CFR 404.1707, 404.1720, 408.1101, 416.1507, and 416.1520—0960–0527. Individuals claiming rights or benefits under the Social Security Act (Act) must notify SSA in writing when they appoint an individual to represent them in dealing with SSA. SSA collects the information on Form SSA–1696–U4 to verify the appointment of such representatives. The SSA–1696–U4 allows SSA to inform representatives of items that affect the recipient's claim, and allows claimants to give permission to their appointed representatives to designate a person to receive their claims files. Respondents are applicants for or recipients of Social Security disability benefits (SSDI) or SSI payments who are notifying SSA they have appointed a person to represent them in their dealings with SSA.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of responses	Frequency of response	Average burden per response (minutes)	Total estimated total annual burden (hours)
SSA–1696–U4	800,000	1	10	133,333

4. Work Activity Report (Self-Employment)—20 CFR 404.1520(b), 20 CFR 404.1571–404.1576, 20 CFR 404.1584–404.1593, and 20 CFR 416.971–416.976—0960–0598. SSA uses Form SSA–820–U4 to determine initial or continuing eligibility for (1) Title II SSDI or (2) Title XVI SSI payments. Under Titles II and XVI of the Act, recipients receive disability benefits and SSI payments based on their inability to engage in substantial gainful activity (SGA) due to a physical or mental condition. Therefore, when the recipients resume work, they must report their work so SSA can evaluate and determine by law whether they continue to meet the disability requirements. SSA uses Form SSA–820–U4 to obtain information on self-employment activities of Social Security Title II and XVI disability applicants and recipients. We use the data we obtain to evaluate disability claims, and to help us determine if the claimant meets current disability provisions under Titles II and XVI. Since applicants for disability benefits or payments must prove an inability to perform any kind of SGA generally available in the national economy for which we expect them to qualify based on age, education, and work experience, any work an applicant performed until, or subsequent to, the date the disability allegedly began, affects our disability determination. The respondents are applicants and claimants for SSI payments or SSDI benefits.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minute)	Estimated annual burden (hours)
SSA–820–BK	100,000	1	30	50,000

Dated: November 9, 2016.

Naomi R. Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2016–27435 Filed 11–14–16; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Nineteenth RTCA SC–227 Standards of Navigation Performance Navigation Information on Electronic Maps

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

ACTION: Nineteenth RTCA SC–227 Standards of Navigation Performance Navigation Information on Electronic Maps.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Nineteenth RTCA SC–227 Standards of Navigation Performance Navigation Information on Electronic Maps.

DATES: The meeting will be held Monday through Thursday, December 05–08, 2016 09:00 a.m.–05:00 p.m.

ADDRESSES: The meeting will be held at: RTCA Headquarters, 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Claudia Chaudhari at *cchaudhari@rtca.org* or 202–330–0662, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Nineteenth RTCA SC–227 Standards of Navigation Performance Navigation Information on Electronic Maps. The agenda will include the following:

Plenary—Monday, December 5, 2016, 09:00 a.m.–10:00 a.m.

1. Welcome and Administrative Remarks
2. Introduction
3. Review of Minutes from Meeting 18.
4. Agenda Overview
   a. Schedule
   b. New Business
5. Review and discussion of MOPS issues and change proposals.

Closing Plenary—Thursday, December 8, 2016, 3:30 p.m.–4:30 p.m.

1. Working Group 3 Progress Report/Summary
2. Other Business
3. Date of Next Meeting
4. Adjourn

All other times will be designated for Working Groups.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 9, 2016.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2016–27390 Filed 11–14–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Second RTCA SC–236 Joint Plenary With EUROCAE WG–96

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

ACTION: Second RTCA SC–236 Joint Plenary with EUROCAE WG–96.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Second RTCA SC–236 Joint Plenary with EUROCAE WG–96.

DATES: The meeting will be held December 5–7, 2016, 9:00 a.m.–5:00 p.m.

ADDRESSES: The meeting will be held at: Texas A&M University, College Station, Texas.

FOR FURTHER INFORMATION CONTACT: Rebecca Morrison at *rmorrison@rtca.org* or 202–330–0654, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Second RTCA SC–236 Joint Plenary with EUROCAE WG–96. The agenda will include the following:

Monday Through Wednesday, December 5–7, 2016, 9:00 a.m.–5:00 p.m.

1. Welcome/Administrative Duties
2. IPR/Membership Call-Out and Introductions
3. Acceptance of Meeting Minutes for the First Joint Plenary of SC–236/WG–96
4. Recap of Sub-working Group Structure and Scope Statements
5. Review of Schedule for Sub-working groups
6. Break-out into Initial Working Groups
7. Reports of the Plans for the Working Groups
8. New Business Discussions
9. Review of Action Items
10. Plan for next meeting
11. Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 9, 2016.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2016–27391 Filed 11–14–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–1998–3637; FMCSA–2000–7006; FMCSA–2000–7165; FMCSA–2000–8203; FMCSA–2001–10578; FMCSA–2002–12294; FMCSA–2004–18885; FMCSA–2008–0106; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2010–0082; FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0201; FMCSA–2011–0324; FMCSA–2012–0105; FMCSA–2012–0215; FMCSA–2014–0005; FMCSA–2014–0006; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2014–0297]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from

the vision requirement in the Federal Motor Carrier Safety Regulations for 38 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: Each group of renewed exemptions are effective from the dates stated in the discussions below. Comments must be received on or before December 15, 2016.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: [Docket No. FMCSA–1998–3637; FMCSA–2000–7006; FMCSA–2000–7165; FMCSA–2000–8203; FMCSA–2001–10578; FMCSA–2002–12294; FMCSA–2004–18885; FMCSA–2008–0106; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2010–0082; FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0201; FMCSA–2011–0324; FMCSA–2012–0105; FMCSA–2012–0215; FMCSA–2014–0005; FMCSA–2014–0006; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2014–0297], using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on January 17, 2008 (73 FR 3316).

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

Exemption Decision

This notice addresses 38 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 38 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. Each individual is identified according to the renewal date.

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. The following group(s) of drivers will receive renewed exemptions effective in the month of November and are discussed below.

As of November 9, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 36 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (63 FR 196; 63 FR 30285; 65 FR 20245; 65 FR 33406; 65 FR 57230; 65 FR 57234; 65 FR 66293; 66 FR 53826; 66 FR 66966; 67 FR 46016; 67 FR 57266; 67 FR 57267; 67 FR 67234; 68 FR 69434; 69 FR 51346; 69 FR 52741; 69 FR 53493; 69 FR 62741; 69 FR 62742; 70 FR 74102; 71 FR 50970; 71 FR 53489; 71 FR 62147; 71 FR 62148; 73 FR 35196; 73 FR 36955; 73 FR 46973; 73 FR 48270; 73 FR 48275; 73 FR 51336; 73 FR 51689; 73 FR 54888; 73 FR 61925; 73 FR 63047; 73 FR 74565; 75 FR 25919; 75 FR 36779; 75 FR 39725; 75 FR 39729; 75 FR 44051; 75 FR 47883; 75 FR 50799; 75 FR 52061; 75 FR 52062; 75 FR 52063; 75 FR 54958; 75 FR 59327; 75 FR 61833; 75 FR 63257; 75 FR 64396; 75 FR 66423; 75 FR 70078; 77 FR 7657; 77 FR 22059; 77 FR 27852; 77 FR 38384; 77 FR 39379; 77 FR 40946; 77 FR 46153; 77 FR 48590; 77 FR 52381; 77 FR 52388; 77 FR 52389; 77 FR 60010; 77 FR 64582; 77 FR 64583; 77 FR 64841; 77 FR 68199; 77 FR 68200; 79 FR 27681; 79 FR

35212; 79 FR 35218; 79 FR 38649; 79 FR 38659; 79 FR 45868; 79 FR 46153; 79 FR 46300; 79 FR 47175; 79 FR 51643; 79 FR 53514; 79 FR 56097; 79 FR 56099; 79 FR 56104; 79 FR 56117; 79 FR 58856; 79 FR 59348; 79 FR 59357; 79 FR 64001; 79 FR 68199; 79 FR 70928; 79 FR 72754:

Charles S. Amyx, Jr. (LA)
John W. Arnold (KY)
Derric D. Burrell (AL)
Kenneth C. Caldwell (NY)
John P. Catalano (NJ)
Lee A. Clason (NE)
Edward Cunningham (MI)
Eric P. Demers (NH)
Louis A. DiPasqua, Jr. (NY)
Roderick L. Duvall (PA)
Kelvin Frandin Bombu (KY)
Tyron O. Friese (MN)
James O. Hancock (IN)
John H. Holmberg (WI)
Stetson W. King (FL)
Donald L. McCraw, Jr. (VA)
Elijah Mitchell (TX)
Charles J. Morman (FL)
Benny R. Morris (WV)
Timothy L. Morton (NC)
Dennis E. Palmer, Jr. (CT)
Jesus Penuelas (AZ)
Larry A. Priewe (ND)
John C. Rodriguez (PA)
Sabahudin Sabic (IA)
Antonio Sanchez (NJ)
Garry R. Setters (KY)
Jimmy E. Settle (MO)
Lawrence Siegler (MN)
Lee F. Taylor (NJ)
Richard T. Traigle (LA)
Wilbert Walden (NC)
Donald Wallace (IL)
Carl V. Wheeler (NC)
Earl L. White, Jr. (NH)
Hubert Whittenburg (MO)

The drivers were included in one of the following dockets: Docket Nos. FMCSA–1998–3637; FMCSA–2000–7006; FMCSA–2000–7165; FMCSA–2000–8203; FMCSA–2001–10578; FMCSA–2002–12294; FMCSA–2004–18885; FMCSA–2008–0106; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2010–0082; FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0201; FMCSA–2011–0324; FMCSA–2012–0105; FMCSA–2012–0215; FMCSA–2014–0005; FMCSA–2014–0006; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296. Their exemptions are effective as of November 9, 2016, and will expire on November 9, 2018.

As of November 22, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 2 individuals have satisfied the conditions for obtaining a renewed exemption from the vision requirements (79 FR 63211; 80 FR 2471):

Dewey P. Huffman (OR)
Michael J. Monroe (IA)

The drivers were included in one of the following dockets: Docket No. FMCSA–2014–0297. Their exemptions are effective as of November 22, 2016, and will expire on November 22, 2018.

Each of the 38 applicants listed in the groups above has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by December 15, 2016.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 38 individuals from the vision requirement in 49 CFR 391.41(b)(10). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the qualifications, experience, and medical condition of each applicant for an exemption from the vision requirements. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket numbers FMCSA–1998–3637; FMCSA–2000–7006; FMCSA–2000–7165; FMCSA–2000–8203; FMCSA–2001–10578; FMCSA–2002–12294; FMCSA–2004–18885; FMCSA–2008–0106; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2010–0082; FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0201; FMCSA–2011–0324; FMCSA–2012–0105; FMCSA–2012–0215; FMCSA–2014–0005; FMCSA–2014–0006; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2014–0297 and click the search button. When the new screen appears, click on the blue ''Comment Now!'' button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period. FMCSA may issue a final rule at any time after the close of the comment period.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–1998–3637; FMCSA–2000–7006; FMCSA–2000–7165; FMCSA–2000–8203; FMCSA–2001–10578; FMCSA–2002–12294; FMCSA–2004–18885; FMCSA–2008–0106; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2010–0082; FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0201; FMCSA–2011–0324; FMCSA–2012–0105; FMCSA–2012–0215; FMCSA–2014–0005; FMCSA–2014–0006; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2014–0297 and click ''Search.'' Next, click ''Open Docket Folder'' and you will find all documents and comments related to this notice.

Issued on: November 1, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–27397 Filed 11–14–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2010–0247; FMCSA–2012–0128; FMCSA–2012–0217; FMCSA–2012–0219; FMCSA–2014–0021]

Qualification of Drivers; Exemption Applications; Diabetes

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions of 117 individuals from its rule prohibiting persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. FMCSA has statutory authority to exempt individuals from this rule if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: Each group of renewed exemptions are effective from the dates stated in the discussions below. Comments must be received on or before December 15, 2016.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. FMCSA–2010–0247; FMCSA–2012–0128; FMCSA–2012–0217; FMCSA–2012–0219; FMCSA–2014–0021, using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on January 17, 2008 (73 FR 3316).

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–113, Washington, DC 20590–0001. Office hours are from 8 a.m. to 5:30 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the Federal Motor Carrier Safety Regulations 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 117 individuals listed in this notice have recently become eligible for a renewed exemption from the diabetes prohibition in 49 CFR 391.41(b)(3), which applies to drivers of CMVs in interstate commerce. The drivers remain in good standing with the Agency, have maintained their required medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period.

Exemption Decision

This notice addresses 117 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. These 117 drivers remain in good standing with the Agency, have maintained their required medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period. Therefore, FMCSA has decided to extend each exemption for a renewable two-year period. Each individual is identified according to the renewal date.

The exemptions are renewed subject to the following conditions: (1) That each individual submit a quarterly monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) that each individual reports within 2 business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) that each individual submit an annual ophthalmologist's or optometrist's report; and (4) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's

qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. The following groups of drivers received renewed exemptions in the month of October and are discussed below.

As of October 8, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual, Gary B. Bland (GA), has satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (75 FR 52813; 75 FR 64394). The driver was included in Docket No. FMCSA–2010–0247. The exemption is effective as of October 8, 2016, and will expire on October 8, 2018.

As of October 10, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 8 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (77 FR 48587; 77 FR 61655).

Dominick Bravata (IL)
Barry J. Drews (MI)
Mason L. Hall (SD)
Chad E. Hasler (MT)
Norman A. Latondresse (RI)
Robert C. Lister, Jr. (OH)
Robert E. Smith (GA)
Steven A. Wilson (FL)

The drivers were included in Docket No. FMCSA–2012–0217. Their exemptions are effective as of October 10, 2016, and will expire on October 10, 2018.

As of October 19, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 14 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (75 FR 52813; 75 FR 64394).

Eric A. Anderson (ND)
Juan E. Boyd (NC)
Bradley R. Burns (OH)
Leo G. Dinero (GA)
Terry W. Ferguson (GA)
Thomas G. Flanagan (IN)
Donald K. Fraase (ND)
Jason W. Geier (MT)
Scott R. Grange (CA)
John A. Hayes (NY)
Bradley D. Heagel (IA)
Harold A. Meeker, Jr. (MA)
Ronald D. Olson (WI)
Daniel E. Velasco (MD)

The drivers were included in Docket No. FMCSA–2010–0247. Their exemptions are effective as of October 19, 2016, and will expire on October 19, 2018.

As of October 21, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 71 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (79 FR 56107; 79 FR 73946):

Michael L. Agnitsch (NE)
Earl W. Avery (TN)
Michael A. Baker (CT)
Pablo H. Bilbao La Vieja Pozo (RI)
Todd D. Bloomfield (WA)
Charles K. Bond (PA)
Christopher R. Cook (NY)
Wygila M. Corliss (NM)
Timothy J. Cornish (OH)
Evan R. Dieken (MN)
Greg B. Duck (TX)
Richard A. Durr (IL)
George B. Ferris, Jr. (NY)
John B. Flood (MO)
Brian K. Forrest (PA)
David S. Fortune (VA)
John Galione (NJ)
Peter E. Ganss (KS)
David E. Gates (MA)
Michael Hawkins (SC)
Rodney J. Hendricks (ID)
Timothy U. Herring (NC)
Richard L. Hines (NC)
David M. Hughes (UT)
Jammie L. Hughes (OH)
Andy L. Hughes (IL)
Rodney L. Johnson (OR)
Paul D. Kimmel (IA)
Scott M. Klain (OR)
Jeffrey P. Kloeckl (SD)
John J. Kress (AZ)
Gregory L. Kuharski (MN)
Robert B. Langston, III (MS)
Mark W. Lavorini (PA)
Alan S. Lewis (NM)
William M. Linskey (MA)
Jason D. Lowder (OH)
Arnold V. Magaoay (HI)
Norman C. Mallett (AR)
Justin T. Mattice (AZ)
Leldon W. McCutcheon (AL)
William F. McQueen Jr. (MO)
Kenneth M. Miller (ID)
William F. Mitchell (CT)
Richard E. Moore (NY)
Matthew K. Morrison (UT)
Gary R. Nelson (MN)
Edward L. Norfleet (AL)
Mark P. Norwood (NV)
Kyle R. Perry (PA)
Michael L. Plinski (WA)
Christopher M. Provance (NE)
James A. Rambo (VA)
Michael E. Reck (OH)
Warren A. Richter (MN)
Richard D. Sandison (ND)
James E. Seymour (PA)
Calvin R. Smith (IL)
Wesley J. Summerville (PA)
William R. Thome (IA)
Stephen M. Thompson (GA)
Randy L. Triplett (OH)
John E. Trygstad (SD)
Steven R. Weir (MA)
Richard T. Whitney (MN)
Donald D. Willard (IA)
Gary W. Wozniak (NE)
Steven L. Yokom (ID)
Allan M. Younglas (PA)
Daniel R. Zuriff (MN)

The drivers were included in Docket No. FMCSA–2014–0021. Their exemptions are effective as of October 21, 2016, and will expire on October 21, 2018.

As of October 22, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 16 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (77 FR 52384; 77 FR 64585).

Richard T. Ewell (IL)
Patrick D. Fortier (MN)
Daniel J. Gladen (MN)
Walter V. Gruba (VA)
Marshall D. Howell (MI)
Roger P. LaFever (WI)
William R. Lawrence (MT)
Duane J. Mullins (WI)
Louis R. Noellsch (WA)
Darrin W. Pettis (WA)
Michael J. Raposa (MA)
Anthony E. Reed (MO)
Earl L. Slater (NY)
Keith J. Tavares (MA)
Phillip L. Truitt (MD)
David A. Weinbroer (KY)

The drivers were included in Docket No. FMCSA–2012–0128. Their exemptions are effective as of October 22, 2016, and will expire on October 22, 2018.

As of October 31, 2016, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 7 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (77 FR 56258; 77 FR 65929).

Edward K. Belcher (KY)
Philip C. Brooks, Jr. (VA)
Michael R. Conley (MN)
Patrick J. Connors (MA)
John C. Halabura (PA)
Paul L. Harrison III (NY)
Robert D. Marshall (PA)

The drivers were included in Docket No. FMCSA–2012–0219. Their

exemptions are effective as of October 31, 2016, and will expire on October 31, 2018.

Each of the 117 drivers in the aforementioned groups qualifies for a renewal of the exemption. They have maintained their required medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each of the 117 drivers for a period of two years is likely to achieve a level of safety equal to that existing without the exemption. The drivers were included in docket numbers FMCSA–2010–0247; FMCSA–2012–0128; FMCSA–2012–0217; FMCSA–2012–0219; FMCSA–2014–0021.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by December 15, 2016.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 117 individuals from rule prohibiting persons with ITDM from operating CMVs in interstate commerce in 49 CFR 391.41(b)(3). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the medical condition of each applicant for an exemption from rule prohibiting persons with ITDM from operating CMVs in interstate commerce. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket numbers FMCSA–2010–0247; FMCSA–2012–0128; FMCSA–2012–0217; FMCSA–2012–0219; FMCSA–2014–0021 and click the search button. When the new screen appears, click on the blue ''Comment Now!'' button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period. FMCSA may issue a final determination at any time after the close of the comment period.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2010–0247; FMCSA–2012–0128; FMCSA–2012–0217; FMCSA–2012–0219; FMCSA–2014–0021 and click ''Search.'' Next, click ''Open Docket Folder'' and you will find all documents and comments related to this notice.

Issued on: November 1, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–27396 Filed 11–14–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF VETERANS AFFAIRS

Tribal Health Programs—Community Care Consolidation

AGENCY: Department of Veterans Affairs.

ACTION: Notice of tribal consultation.

SUMMARY: The Department of Veterans Affairs (VA), Veterans Health Administration (VHA) will facilitate a Tribal Consultation on VHA's effort to improve continuity of care and health care access for Veterans by consolidating multiple community care programs, previously known as non-VA care, into one standard program with standard rates. In October 2015, VA submitted to Congress the *Plan to Consolidate Programs of Department of Veterans Affairs to Improve Access to Care, http://www.va.gov/opa/publications/VA_Community_Care_Report_11_03_2015.pdf,* which lays out the vision for a consolidated community care program that is easy to understand, simple to administer, and meets the needs of Veterans, community providers, and VA staff. As VA continues to move forward with implementing the vision of the *Plan,* we again seek tribal input to assist VA in developing the network of providers in a manner that would build on VA's existing relationships with tribal health programs and facilitate future collaboration to improve health care services provided to all eligible, VA-enrolled Veterans, regardless of whether they are eligible for Indian Health Service-funded health care or not. We are seeking tribal consultation regarding the tribal health programs' participation in the core provider network, as outlined in the *Plan,* and potentially transitioning from the current reimbursement agreement structure to a model under which tribal health programs deliver care to all eligible, VA enrolled Veterans, using a standard reimbursement rate based on Medicare rates.

DATES: Comments must be received by VA on or before November 30, 2016.

ADDRESSES: Written comments should be submitted by email at *Tribalgovernmentconsultation@va.gov,* by fax at 202–273–5716, or by mail at U.S. Department of Veterans Affairs, Suite 915L, 810 Vermont Avenue NW., Washington, DC 20420.

FOR FURTHER INFORMATION CONTACT: Majed Ibrahim, VA Office of Community Care, VHA at (562) 400–3134 (this is not a toll-free number), or by email at *majed.ibrahim@va.gov.*

SUPPLEMENTARY INFORMATION: VA is seeking consultation and comments on the following questions:

(1) What would be the impact of transitioning from the existing reimbursement agreement structure, which requires each tribe to enter into an individual reimbursement agreement with VA, to a standard arrangement for reimbursement of direct care services provided to eligible Veterans managed by a third party administrator for VA?

(2) Would tribal health programs be interested in expanding direct care services under this new structure to include reimbursements for care provided to all Veterans enrolled in VA health care, regardless of whether they are eligible for health care funded by Indian Health Service (IHS) or not?

(3) Would tribal health programs be interested in receiving standard reimbursement rates based on Medicare rates plus a feasible percentage of those rates to minimize improper payments and comply with industry standards?

(4) Would tribal health programs be interested in extending existing reimbursement agreements between VA and tribal health programs through December 2018 and ensuring any new reimbursement agreements between VA and tribal health programs extend through December 2018, as VA works in collaboration with tribes and other VA stakeholders on implementing a consolidated community care program?

Tribal leaders and/or their designated representatives and other interested parties are invited to attend and provide comments during the in-person consultation and/or submit written comments.

Dated: November 9, 2016.

Jeffrey Martin,

Office Program Manager, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2016–27436 Filed 11–14–16; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, et al.

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 417, 422, 423, 424, 425, and 460

[CMS–1654–F]

RIN 0938–AS81

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This major final rule addresses changes to the physician fee schedule and other Medicare Part B payment policies, such as changes to the Value Modifier, 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. This final rule also includes changes related to the Medicare Shared Savings Program, requirements for Medicare Advantage Provider Networks, and provides for the release of certain pricing data from Medicare Advantage bids and of data from medical loss ratio reports submitted by Medicare health and drug plans. In addition, this final rule expands the Medicare Diabetes Prevention Program model.

DATES: These regulations are effective on January 1, 2017.

FOR FURTHER INFORMATION CONTACT:

Jessica Bruton, (410) 786–5991, for issues related to identification of potentially misvalued services and any physician payment issues not identified below.

Gail Addis, (410) 786–4522, for issues related to diabetes self-management training.

Jaime Hermansen, (410) 786–2064, for issues related to moderate sedation coding and anesthesia services.

Roberta Epps, (410) 786–4503, for issues related to PAMA section 218(a) policy and the transition from traditional x-ray imaging to digital radiography.

Ann Marshall, (410) 786–3059, for primary care issues related to chronic care management (CCM), burden reduction, telehealth services and evaluation and management services.

Emily Yoder, (410) 786–1804, for issues related to resource intensive services, telehealth services and other primary care issues.

Lindsey Baldwin, (410) 786–1694, for primary care issues related to behavioral health integration services.

Geri Mondowney, (410) 786–4584, and Donta Henson, (410) 786–1947, for issues related to geographic practice cost indices.

Michael Soracoe, (410) 786–6312, for issues related to the target and phase-in provisions, the practice expense methodology, impacts, conversion factor, and the valuation of pathology and surgical procedures.

Pamela West, (410) 786–2302, for issues related to therapy.

Patrick Sartini, (410) 786–9252, for issues related to malpractice RVUs, radiation treatment, mammography and other imaging services.

Kathy Bryant, (410) 786–3448, for issues related to collecting data on resources used in furnishing global services.

Donta Henson, (410) 786–1947, for issues related to ophthalmology services.

Corinne Axelrod, (410) 786–5620, for issues related to rural health clinics or federally qualified health centers.

Simone Dennis, (410) 786–8409, for issues related to FQHC-specific market basket.

JoAnna Baldwin, (410) 786–7205, or Sarah Fulton, (410) 786–2749, for issues related to appropriate use criteria for advanced diagnostic imaging services.

Robin Usi, (410) 786–0364, for issues related to open payments.

Sean O'Grady, (410) 786–2259, or Julie Uebersax, (410) 786–9284, for issues related to release of pricing data from Medicare Advantage bids and release of medical loss ratio data submitted by Medicare Advantage organizations and Part D sponsors.

Sara Vitolo, (410) 786–5714, for issues related to prohibition on billing qualified Medicare beneficiary individuals for Medicare cost-sharing.

Michelle Peterman, (410) 786–2591, for issues related to Accountable Care Organization (ACO) participants who report PQRS quality measures separately.

Katie Mucklow, (410) 786–0537 or John Spiegel, (410) 786–1909, for issues related to Provider Enrollment Medicare Advantage Program.

Jen Zhu, (410) 786–3725, Carlye Burd, (410) 786–1972, or Nina Brown, (410) 786–6103, for issues related to Medicare Diabetes Prevention Program model expansion.

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.

Lisa Ohrin Wilson, (410) 786–8852, or Gabriel Scott, (410) 786–3928, for issues related to physician self-referral updates.

SUPPLEMENTARY INFORMATION:

Table of Contents

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) 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 final rule are available through the Internet on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* Click on the link on the left side of the screen titled,

''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2017 PFS Final Rule, refer to item CMS–1654–F. Readers who experience any problems accessing any of the Addenda or other documents referenced in this rule and posted on the CMS Web site identified above should contact Jessica Bruton at (410) 786–5991.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2015 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This major final rule revises payment polices under the Medicare Physician Fee Schedule (PFS) and makes other policy changes related to Medicare Part B payment. These changes will be applicable to services furnished in CY 2017. In addition, this final rule includes the following provisions: Payment policy changes for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs); expansion of the Medicare Diabetes Prevention Program model; policy changes related to the Medicare Shared Savings Program; and release of pricing data submitted to CMS by Medicare Advantage (MA) organizations; and medical loss ratio reports submitted by MA plans and Part D plans. These additional policies are addressed in section III. of this final rule.

2. 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 final rule, we establish RVUs for CY 2017 for the PFS, and other Medicare Part B payment policies, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. In addition, this final rule includes summaries of public comments and final policies regarding:

- Potentially Misvalued Codes.
- Telehealth Services.
- Establishing Values for New, Revised, and Misvalued Codes.
- Target for Relative Value Adjustments for Misvalued Services.
- Phase-in of Significant RVU Reductions.
- Chronic Care Management (CCM) and Transitional Care Management (TCM) Supervision Requirements in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).
- FQHC-Specific Market Basket.
- Appropriate Use Criteria for Advanced Diagnostic Imaging Services.
- Reports of Payments or Other Transfers of Value to Covered Recipients: Solicitation of Public Comments.
- Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D Medical Loss Ratio (MLR) Data.
- Prohibition on Billing Qualified Medicare Beneficiary Individuals for Medicare Cost-Sharing.
- Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number.
- Accountable Care Organization (ACO) Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately.
- Medicare Advantage Provider Enrollment.
- Expansion of the Diabetes Prevention Program (DPP) Model.
- Medicare Shared Savings Program.
- Value-Based Payment Modifier and the Physician Feedback Program.
- Physician Self-referral Updates.
- Designated Health Services.

3. Summary of Costs and Benefits

The statute requires that annual adjustments to PFS RVUs may not cause annual estimated expenditures to differ by more than $20 million from what they would have been had the adjustments not been made. If adjustments to RVUs would cause expenditures to change by more than $20 million, we must make adjustments to preserve budget neutrality. These adjustments can affect the distribution of Medicare expenditures across specialties. In addition, several changes in this final rule will affect the specialty distribution of Medicare expenditures. When considering the combined impact of work, PE, and MP RVU changes, the projected payment impacts would be small for most specialties; however, the impact would be larger for a few specialties.

We have determined that this major final rule is economically significant. For a detailed discussion of the economic impacts, see section VI. of this final rule.

B. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (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 final rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for services furnished to Medicare beneficiaries.

1. Development of the Relative Values

a. Work RVUs

The work RVUs established for the initial fee schedule, which was implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion

of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations. 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 HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those facility resources is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, enacted on November 29, 1999) (BBRA) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' malpractice insurance premium data from all the states, the District of Columbia, and Puerto Rico. For more information on MP RVUs, see section II.B.2. of this final rule.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed five-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In addition to the five-year reviews, beginning for CY 2009, CMS and the RUC have identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, 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 final 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 did not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each component.

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The formula for calculating the Medicare fee schedule payment amount for a given service and fee schedule area can be expressed as:

Payment = [(RVU work × GPCI work) + (RVU PE × GPCI PE) + (RVU MP × GPCI MP)] × CF.

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia conversion factor, in a manner to 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.

4. Most Recent Changes to the Fee Schedule

Section 220(d) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93, enacted on April 1, 2014) (PAMA) added a new subparagraph (O) to section 1848(c)(2) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. If the estimated net reduction in expenditures for a year is equal to or greater than the target for that year, the provision specifies that reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS. The provision specifies that the amount by which such reduced expenditures exceed the target for a given year shall be treated as a reduction in expenditures for the subsequent year for purposes of determining whether the target for the subsequent year has been met. The provision also specifies that an amount equal to the difference between the target and the estimated net reduction in expenditures, called the target recapture amount, shall not be taken into account when applying the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. The PAMA amendments originally made the target provisions applicable for CYs 2017 through 2020 and set the target for reduced expenditures at 0.5 percent of estimated expenditures under the PFS for each of those 4 years.

Subsequently, section 202 of the Achieving a Better Life Experience Act of 2014 (Division B of Pub. L. 113–295, enacted December 19, 2014) (ABLE) accelerated the application of the target, amending section 1848(c)(2)(O) of the Act to specify that target provisions apply for CYs 2016, 2017, and 2018; and setting a 1 percent target for reduced expenditures for CY 2016 and a 0.5 percent target for CYs 2017 and 2018. The implementation of the target legislation was finalized in the CY 2016 PFS final rule with comment period, and revisions are discussed in section II.G. of this final rule.

Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specified that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. Section 220(e) of the PAMA required the phase-in of RVU reductions of 20 percent or more to begin for 2017. Section 1848(c)(7) of the Act was later amended by section 202 of the ABLE Act to require instead that the phase-in must begin in CY 2016. The implementation of the phase-in legislation was finalized in the CY 2016 PFS final rule with comment period and revisions in this year's rulemaking are discussed in section II.H. of this final rule.

II. Provisions of the Final Rule for PFS

A. Determination of Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the Five-Year Review of Work Relative Value Units under the PFS and Proposed Changes to the Practice Expense Methodology proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the practice expense per hour (PE/HR) by specialty that was obtained from the AMA's Socioeconomic Monitoring Surveys (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and nonphysician practitioners (NPPs) paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the 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 continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010, we changed the PE/HR crosswalk for portable X-ray suppliers from radiology to IDTF, a more appropriate crosswalk because these specialties are more similar to each other for work time.

For registered dietician services, the resource-based PE RVUs have been calculated in accordance with the final policy that crosswalks the specialty to the ''All Physicians'' PE/HR data, as adopted in the CY 2010 PFS final rule with comment period (74 FR 61752) and discussed in more detail in the CY 2011 PFS final rule with comment period (75 FR 73183). We have incorporated the available utilization data for interventional cardiology, which became a recognized Medicare specialty during 2014. We finalized the use of a proxy PE/HR value for interventional cardiology in the CY 2016 final rule with comment period (80 FR 70892), as there are no PPIS data for this specialty, by crosswalking the PE/HR from Cardiology, since the specialties furnish similar services in the Medicare claims data.

Comment: A commenter questioned the validity of the PPIS survey data since it is nearly 10 years old. Several other commenters stated that CMS' estimated per-minute labor cost inputs are lower than actual labor costs.

Response: We have previously identified several concerns regarding the underlying data used in determining PE RVUs in the CY 2014 PFS final rule (78 FR 74246–74247). Even when we first incorporated the survey data into the PE methodology, many in the community expressed serious concerns over the accuracy of this or other PE surveys as a way of gathering data on PE inputs from the diversity of providers paid under the PFS. However, we currently lack another source of comprehensive data regarding PE costs, and as a result, we continue to believe that the PPIS survey data is the best data currently available. We continue to seek the best broad-based, auditable, routinely-updated source of information regarding PE costs.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

Section II.A.2.b. of this final rule describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocated the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporated the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we used the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is

calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represented 25 percent of total costs for the specialties that furnished the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).

- Next, we added the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had 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 (TCs) and Professional Components (PCs)

Diagnostic services are generally comprised of two components: A professional component (PC) and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a ''global'' service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(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 2017 PFS final 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 below 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 factor to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling factor to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs, as long as the same CF is used in Step 4 and Step 5. Different CFs will result in different direct PE scaling factors, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling factors offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. As we stated in the CY 2016 final rule with comment period (80 FR 70894), we believe that the 3-year average will mitigate the need to use dominant or expected specialty instead of the 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 provide a first opportunity to determine whether service-level overrides of claims data are necessary. Currently, in the development of PE RVUs we apply only the overrides that also apply to the MP RVU calculation. Since the proposed PE RVUs include a new year of claims into the 3-year average for the first time, we solicited comment on the proposed CY 2017 PFS rates and whether or not the incorporation of a new year of utilization data into a 3-year average mitigates the need for alternative service-level overrides such as a claims-based approach (dominant specialty) or stakeholder-recommended approach

(expected specialty) in the development of PE (and MP) RVUs for low-volume codes. Prior year RVUs are available at several locations on the PFS Web site located at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

Comment: Several commenters contended that even a multi-year average of claims data to determine the mix of specialties that furnish the services creates distortions and wide variability for low volume services, particularly those services with fewer than 100 annual Medicare claims. Commenters stated that low volume codes that use a specialty override appear to have stable PE and MP RVUs, while other low volume codes without overrides continue to shift from year to year. Given these fluctuations, commenters suggested that CMS implement service-level overrides to determine the specialty mix for these low volume procedures. These commenters provided a list of nearly 2000 codes and suggested specialty overrides.

Response: We appreciate commenters' interest in relatively stable PE and MP RVUs and for continuing to highlight the challenges faced when determining the specialty allocation for low volume services. Since we did not make a proposal regarding specialty overrides for low volume services, we do not believe that it would be appropriate to establish overrides for several thousand codes at this time. However, given the continued concerns, we will consider the issue, including these specific recommendations, for future rulemaking.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: Indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: Indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(**Note:** For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in 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 of 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 section.)

(e) Setup File Information

- *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain 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.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION—Continued

Specialty code	Specialty description
56	Individual certified prosthetist.
57	Individual certified prosthetist-orthotist.
58	Medical supply company with registered pharmacist.
59	Ambulance service supplier, *e.g.,* private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (*e.g.,* drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION—Continued

Specialty code	Specialty description
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 final 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 below.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion below.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

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 (62 FR 33164).

We continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

Comment: One commenter stated that the cost of maintaining imaging equipment exceeds the cost of general medical equipment, and that for imaging modalities the median maintenance cost is approximately 10 percent of the equipment purchase price. The commenter stated that the current 5 percent equipment maintenance rate continues to be an inadequate and outdated reflection of actual maintenance costs. The commenter also stated that information on maintenance costs is readily available to CMS through both public and private sources. The commenter did not identify these sources.

Response: As we previously stated in the CY 2016 final rule with comment period (80 FR 70897), we agree with the commenter that we do not believe the annual maintenance factor for all equipment is exactly 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining maintenance factor, we do not believe that we have sufficient information at present to adopt a variable maintenance factor for equipment cost per minute pricing. 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. The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed in Table 3. (See 77 FR 68902 for a thorough discussion of this issue.) We did not propose any changes to these interest rates for CY 2017.

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

d. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2017 direct PE input database, which is available on our Web site under downloads for the CY 2017 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

(1) PE Inputs for Digital Imaging Services

Prior to the CY 2015 PFS rulemaking cycle, the RUC provided a recommendation regarding the PE inputs for digital imaging services. Specifically, the RUC recommended that we remove supply and equipment items associated with film technology from a previously specified list of codes since these items were no longer typical resource inputs. The RUC also recommended that the Picture Archiving and Communication System (PACS) equipment be included for these imaging services since these items are typically used in furnishing imaging services. However, since we did not receive any invoices for the PACS system prior to that year's proposed rule, we were unable to determine the appropriate pricing to use for the inputs. For CY 2015, we finalized our proposal to remove the film supply and equipment items, and to create a new equipment item as a proxy for the PACS workstation as a direct expense (79 FR 67561–67563). We used the price associated with ED021 (computer, desktop, w-monitor) to price the new item, ED050 (PACS Workstation Proxy), pending receipt of invoices to facilitate pricing specific to the PACS workstation. Subsequent to establishing payment rates for CY 2015, we received information from several stakeholders regarding pricing for items related to the digital acquisition and storage of images. We received invoices from one stakeholder that facilitated a proposed price update for the PACS workstation in the CY 2016 PFS proposed rule, and we updated the price for the PACS workstation to $5,557 in the CY 2016 PFS final rule with comment period (80 FR 70899).

In addition to the workstation used by the clinical staff for acquiring the images and furnishing the technical component (TC) of the services, a stakeholder also submitted more detailed information regarding a workstation used by the practitioner interpreting the image in furnishing the professional component (PC) of many of these services.

As we stated in the CY 2015 PFS final rule with comment period (79 FR 67563), we generally believe that workstations used by these practitioners are more accurately considered indirect costs associated with the PC of the service. However, we understand that the professional workstations for interpretation of digital images are similar in principle to some of the previous film inputs incorporated into the global and technical components of the codes, such as the view box equipment. Given that the majority of these services are reported globally in the nonfacility setting, we believe it is appropriate to include these costs as direct inputs for the associated HCPCS codes. Based on our established

methodology in which single codes with professional and technical components are constructed by assigning work RVUs exclusively to the professional component and direct PE inputs exclusively to the technical components, these costs would be incorporated into the PE RVUs of the global and technical component of the HCPCS code.

We stated in the CY 2016 PFS final rule with comment period that the costs of the professional workstation may be analogous to costs related to the use of film previously incorporated as direct PE inputs for these services. We also solicited comments on whether including the professional workstation as a direct PE input for these codes would be appropriate, given that the resulting PE RVUs would be assigned to the global and technical components of the codes. Commenters responded by indicating their approval of the concept of a professional PACS workstation used for interpretation of digital images. We received invoices for the pricing of a professional PACS workstation, as well as additional invoices for the pricing of a mammography-specific version of the professional PACS workstation. The RUC also included these new equipment items in its recommendations for the CY 2017 PFS rulemaking cycle.

Based on our analysis of submitted invoices, we proposed to price the professional PACS workstation (ED053) at $14,616.93. We did not propose a change in price for the current technical PACS workstation (ED050), which will remain at a price of $5,557.00.

The price of the professional PACS workstation is based upon individual invoices submitted for the cost of a PC Tower ($1531.52), a pair of 3 MP monitors ($10,500.00 in total), a keyboard and mouse ($84.95), a UPS power backup devices for TNP ($1098.00), and a switch for PACS monitors/workstations ($1402.46).

We proposed to add the professional PACS workstation to many CPT codes in the 70000 series that use the current technical PACS workstation (ED050) and include professional work for which such a workstation would be used. We did not propose to add the equipment item to add-on codes since the base codes would include minutes for the item. We also did not propose to add the item to codes that are therapeutic in nature, as the professional PACS workstation is intended for use in diagnostic services. We therefore did not propose to add the item to codes in the Radiation Therapy section (77261 through 77799) or the Nuclear Medicine Cardiology section (78414–78499). We also did not propose to add the item to image guidance codes where the dominant provider is not a radiologist (77002, 77011, 77071, 77077, and 77081) according to the most recent year of claims data, since we believe a single workstation would be more typical in those cases. We identified approximately 426 codes to which we proposed to add a professional PACS workstation. Please see Table 4 for the full list of affected codes.

For the professional PACS workstation, we proposed to assign equipment time equal to the intraservice work time plus half of the preservice work time associated with the codes, since the work time generally reflects the time associated with the professional interpretation. We proposed half of the preservice work time for the professional PACS workstation because we do not believe that the practitioner would typically spend all of the preservice work period using the equipment. For older codes that do not have a breakdown of physician work time by service period, and only have an overall physician work time, we proposed to use half the total work time as an approximation of the intraservice work time plus one half of the preservice work time. In our review of services that contained an existing PACS workstation and had a breakdown of physician work time, we found that half of the total time was a reasonable approximation for the value of intraservice work time plus one half of preservice work time where no such breakdown existed. We also considered using an equipment time formula of the physician intraservice time plus 1 minute (as a stand-in for the physician preservice work time). We solicited public comment on the most accurate equipment time formula for the professional PACS workstation.

We solicited public comment on the proposed list of codes that would incorporate the professional PACS workstation. We were interested in public comment on the codes for which a professional PACS workstation should be included, and whether one of these professional workstations should be included for codes outside the 70000 series. In cases within the 70000 series where radiologists are not the typical specialty reporting the code, such as CPT codes 77002 and 77011, we asked whether it would be appropriate to add one of the professional PACS workstations to these services.

The following is a summary of the comments we received on the proposed addition of the professional PACS workstation, the pricing of the workstation, the list of codes that would incorporate the professional PACS workstation, and the equipment minutes to assign to the workstation.

Comment: Commenters supported the general concept of the professional PACS workstation and its addition to the proposed list of codes. Commenters stated that the professional PACS workstation is an essential component of diagnostic imaging procedures due to the switch from film to digital technology, and the professional workstation would be an appropriate inclusion as a direct PE input for these services.

Response: We appreciate the support from the commenters for the addition of the professional PACS workstation.

Comment: Many commenters addressed the subject of the proper pricing of the professional PACS workstation. Several commenters requested that CMS increase the price of the workstation to include a third and fourth monitor (for speech recognition) priced at $1,715.98, an Admin Monitor (the extra working monitor) priced at $279.27, and a Powerscribe Microphone priced at $424.00. Commenters stated that speech recognition equipment is typical for a professional PACS workstation, and that physicians typically employed a monitor with greater resolution than what would be typically used for other purposes (such as for electronic health records). Related comments contended that the proposed pricing of the workstation remained significantly less than what the average imaging facility spends on PACS technology. Other commenters disagreed with these sentiments and supported the pricing of the professional PACS workstation at the proposed rate of $14,616.93.

Response: We appreciate the feedback from the commenters regarding the proper pricing of the professional PACS workstation. When proposing a price for the professional PACS workstation, we did not include the cost of the additional monitors and the Powerscribe microphone because these items represent indirect costs under the established PE methodology and the functionality would unlikely have been included in the previously existing film inputs the professional PACS workstation is replacing. Generally, we believe that monitors used to access electronic health records and microphones used for dictation are often used by practitioners who furnish a range a PFS services, are not allocable to particular services or patients, and therefore, are included in the administrative cost category of practice expense, and therefore, are allocated to

individual codes through indirect PE RVUs.

Comment: Many commenters stated that CMS should expand the list of codes with a professional PACS workstation. Commenters generally focused on three of the criteria proposed by CMS: The exclusion of the workstation from add-on services, the exclusion of therapeutic (as opposed to diagnostic) services, and the exclusion of codes outside the 70000 series. Commenters stated that add-on codes should be incorporated into the professional PACS workstation list, as they require additional time to perform, and therefore, more time with the technical PACS workstation for the technician, as well as additional time for the review and interpretation performed by the physician using the professional PACS workstation. Commenters also indicated that many therapeutic services would also require a professional PACS workstation, and disagreed with limiting the workstation to diagnostic services only. Finally, commenters supplied extensive lists of additional codes, both inside and outside of the 70000 series, where they stated that the inclusion of a professional PACS workstation was warranted.

Response: We appreciate the feedback from the commenters in helping to define the criteria for inclusion of the professional PACS workstation, along with more specific recommendations about which codes should include the workstation. After considering these comments, we will be adding the professional PACS workstation to additional suggested codes. We took the following into account in making these additions:

- 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 which 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 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 agree 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. We believe that in these specific cases, the use of the professional PACS workstation has been established to be typical for the code in question by the specialties furnishing the service, as a result of the evidence provided in the comments submitted in response to our proposal. We have added the workstation to many of the therapeutic codes requested by commenters, specifically codes listed outside the 70000 series, where use of the professional PACS station is typical.
- Within the 70000 series, we reviewed each of the codes submitted by commenters. Most of these codes did not fall within one of the categories where we proposed to add the professional PACS workstation in the proposed rule: They lacked a technical PACS workstation, they were add-on codes, or they were diagnostic procedures for which radiology is not the dominant specialty providing the service. We continue to believe that the professional PACS workstation should not be added to codes that do not fall into these categories, since we believe that the image must be captured in order to for it to be interpreted, that the use of the PACS workstation in the base code reported with add-on codes would accurately capture the associated resources used, and that the PACS professional workstation is only typically used by radiologists. Based on comments, we are adding the professional workstation to only one code in the 70000 series, CPT code 73562, as it includes a technical PACS workstation, is not an add-on code, and is typically furnished by radiologists.
- For codes in the 80000 and 90000 series, we are concerned about whether it is appropriate to include the technical PACS workstation into 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 are not removing the technical PACS workstation from these codes at this time, we do not believe that a professional PACS workstation should be added to these procedures. We will consider the inclusion of both PACS workstations for future rulemaking.

Comment: Several commenters addressed the topic of equipment time for the professional PACS workstation. Commenters requested that CMS allocate the entire preservice physician work time associated with the codes, as opposed to the proposed half of the preservice physician work time. Commenters stated that although certain physician work activities in the preservice period may not directly involve the professional workstation, even when the physician is engaged in these parallel work activities, the professional workstation is ''open'' to the patient at hand and cannot be used for other patients. Commenters also disagreed with the proposal to use half the total time for older codes in which there is no separation of preservice and intraservice period times. Commenters stated that using the entire physician work time would be the best option since there is no accurate way to estimate the service period times, and that it would avoid potential confusion in equipment formulas in the future.

Response: We continue to believe that the professional PACS workstation is more accurately assigned equipment time by using half of the preservice physician work time rather than the full preservice physician work time. As we stated in the proposed rule, we do not believe that the practitioner would typically spend all of the preservice work period using the equipment. Commenters agreed that the physician may not need the professional workstation for the full preservice period, but contended that the equipment would be ''open'' and unavailable for use by other physicians or for other patients. We disagree with this argument on clinical practice and methodological grounds. We do not agree that the professional PACS workstation would necessarily be unavailable for use by other physicians when the physician in question is not using the machine, Additionally, we note that the number of minutes assigned to the predecessor film inputs did not generally include the full number of pre-service minutes. Finally, our PE methodology is based on the resources typically used to furnish the procedure, and we typically assign time for equipment items based on when it cannot be used by another practitioner or for another patient due to its use in the given procedure. We continue to believe that half of the preservice physician work time (along with the full physician intraservice work time) is a good approximation of the time in the preservice period that the professional PACS workstation will typically be in use. As we stated in the proposed rule, we do not believe that the practitioner would typically spend all of the preservice time using the equipment, and would also spend preservice time on other activities, such as scrubbing and dressing, for example.

For older codes where there is no breakdown of work time values by service period, we do not agree with commenters that the professional PACS workstation should use the total work time. The comments do not provide a

persuasive rationale for using the total work time instead of our proposed alternative, developed for consistency with codes for which we do have work time breakdowns by service period. Therefore, in the absence of service period work time detail, we continue to believe that half of the total work time is a reasonable proxy for the small number of old codes affected by this issue. We are not concerned about the potential for confusion in the future with differing equipment time formulas, as the addition of the professional PACS workstation to these codes is a one-time inclusion that will not affect the future review of this equipment.

Finally, we believe that there is a difference in the pattern of equipment usage for the professional PACS workstation between diagnostic and therapeutic codes. Generally, the intraservice work for diagnostic imaging codes describes the review of images, while the intraservice work for therapeutic services describes a broader range of activities. Therefore, although we used an equipment formula of half the preservice physician work time and the full intraservice physician work time for the diagnostic procedures, we do not believe that this same time formula would be appropriate for therapeutic procedures since the professional PACS workstation would not be in use during the intraservice portion of these services. Therefore, we will use an equipment time formula of half the preservice physician work time and half the postservice physician work time for the therapeutic codes to which we are adding a professional PACS workstation, which we believe is more consistent with the descriptions of work for the codes in question. Consistent with our ongoing efforts to improve payment accuracy for these costs, we seek recommendations from the RUC and other stakeholders on a more precise allocation methodology for equipment minutes for these procedures.

After consideration of comments received, we are finalizing our proposal to add a professional PACS workstation (ED053) to the equipment database and price it at the proposed rate of $14,616.93. We are dividing the codes that will contain a professional PACS workstation into diagnostic and therapeutic categories. For diagnostic codes, we are assigning equipment minutes equal to half the preservice physician work time and the full intraservice physician work time. For the relatively smaller group of diagnostic codes with no service period time breakdown, we are assigning equipment time equal to half of the total physician work time. For therapeutic codes, we are assigning equipment minutes equal to half the preservice physician work time and half the postservice physician work time for the second group. There are no therapeutic codes on our current list which lack a service period time breakdown. The following table lists all of the codes that include a professional PACS workstation for CY 2017, along with the equipment minutes for the workstation.

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE DIRECT PE INPUT DATABASE

HCPCS	Procedure type	ED053 Minutes
10030	Therapeutic	23
10035	Therapeutic	15
19081	Therapeutic	19
19083	Therapeutic	17
19085	Therapeutic	19
19281	Therapeutic	18
19283	Therapeutic	19
19285	Therapeutic	18
19287	Therapeutic	19
22510	Therapeutic	32
22511	Therapeutic	32
22513	Therapeutic	32
22514	Therapeutic	32
32555	Therapeutic	19
32557	Therapeutic	19
36221	Therapeutic	34
36222	Therapeutic	34
36223	Therapeutic	34
36224	Therapeutic	34
36225	Therapeutic	34
36226	Therapeutic	34
36251	Therapeutic	31
36252	Therapeutic	31
36253	Therapeutic	31
36254	Therapeutic	31
36598	Therapeutic	13
37184	Therapeutic	30
37187	Therapeutic	25
37188	Therapeutic	23
37191	Therapeutic	22
37192	Therapeutic	23
37193	Therapeutic	23
37197	Therapeutic	26
37220	Therapeutic	34
37221	Therapeutic	34
37224	Therapeutic	34
37225	Therapeutic	34
37226	Therapeutic	34
37227	Therapeutic	34
37228	Therapeutic	34
37229	Therapeutic	34
37230	Therapeutic	34
37231	Therapeutic	34
37236	Therapeutic	31
37238	Therapeutic	31
37241	Therapeutic	26
37242	Therapeutic	31
37243	Therapeutic	38
37244	Therapeutic	38
47531	Therapeutic	20
47532	Therapeutic	22
47533	Therapeutic	26
47534	Therapeutic	26
47535	Therapeutic	19
47536	Therapeutic	16
47537	Therapeutic	19
47538	Therapeutic	22
47539	Therapeutic	26
47540	Therapeutic	26
47541	Therapeutic	26
49083	Therapeutic	18
49405	Therapeutic	28
49406	Therapeutic	28
49407	Therapeutic	28
49418	Therapeutic	27
49440	Therapeutic	29
49441	Therapeutic	29
49442	Therapeutic	29
49446	Therapeutic	22
49450	Therapeutic	20
49451	Therapeutic	20
49452	Therapeutic	20
49460	Therapeutic	20
49465	Therapeutic	13
50382	Therapeutic	28
50384	Therapeutic	24
50385	Therapeutic	27
50386	Therapeutic	25
50387	Therapeutic	22
50389	Therapeutic	15
50430	Therapeutic	23
50431	Therapeutic	20
50432	Therapeutic	25
50433	Therapeutic	25
50434	Therapeutic	23
50435	Therapeutic	18
50693	Therapeutic	25
50694	Therapeutic	25
50695	Therapeutic	25
58340	Therapeutic	7
62302	Therapeutic	17
62303	Therapeutic	17
62304	Therapeutic	17
62305	Therapeutic	18
70015	Diagnostic	12
70030	Diagnostic	3
70100	Diagnostic	3
70110	Diagnostic	4
70120	Diagnostic	3
70130	Diagnostic	4
70134	Diagnostic	4
70140	Diagnostic	3
70150	Diagnostic	4
70160	Diagnostic	3
70190	Diagnostic	3
70200	Diagnostic	4
70210	Diagnostic	3
70220	Diagnostic	4
70240	Diagnostic	3
70250	Diagnostic	4
70260	Diagnostic	7
70300	Diagnostic	2
70310	Diagnostic	3
70320	Diagnostic	3
70328	Diagnostic	3
70330	Diagnostic	22
70332	Diagnostic	6
70336	Diagnostic	20
70350	Diagnostic	3
70355	Diagnostic	5
70360	Diagnostic	3
70370	Diagnostic	4
70371	Diagnostic	9

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE DIRECT PE INPUT DATABASE—Continued

HCPCS	Procedure type	ED053 Minutes
70380	Diagnostic	3
70390	Diagnostic	5
70450	Diagnostic	12
70460	Diagnostic	15
70470	Diagnostic	18
70480	Diagnostic	13
70481	Diagnostic	13
70482	Diagnostic	14
70490	Diagnostic	13
70491	Diagnostic	13
70492	Diagnostic	14
70540	Diagnostic	14
70542	Diagnostic	19
70543	Diagnostic	19
70544	Diagnostic	13
70545	Diagnostic	18
70546	Diagnostic	18
70547	Diagnostic	13
70548	Diagnostic	20
70549	Diagnostic	25
70551	Diagnostic	21
70552	Diagnostic	23
70553	Diagnostic	28
70554	Diagnostic	43
71010	Diagnostic	4
71015	Diagnostic	3
71020	Diagnostic	4
71021	Diagnostic	4
71022	Diagnostic	4
71023	Diagnostic	5
71030	Diagnostic	4
71034	Diagnostic	5
71035	Diagnostic	3
71100	Diagnostic	5
71101	Diagnostic	4
71110	Diagnostic	4
71111	Diagnostic	5
71120	Diagnostic	3
71130	Diagnostic	3
71250	Diagnostic	18
71260	Diagnostic	17
71270	Diagnostic	13
71275	Diagnostic	28
71550	Diagnostic	15
71551	Diagnostic	30
71552	Diagnostic	28
71555	Diagnostic	33
72020	Diagnostic	3
72040	Diagnostic	4
72050	Diagnostic	6
72052	Diagnostic	6
72070	Diagnostic	4
72072	Diagnostic	3
72074	Diagnostic	3
72080	Diagnostic	3
72081	Diagnostic	6
72082	Diagnostic	7
72083	Diagnostic	8
72084	Diagnostic	9
72100	Diagnostic	4
72110	Diagnostic	6
72114	Diagnostic	6
72120	Diagnostic	4
72125	Diagnostic	18
72126	Diagnostic	12
72127	Diagnostic	12
72128	Diagnostic	18
72129	Diagnostic	12
72130	Diagnostic	12

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE DIRECT PE INPUT DATABASE—Continued

HCPCS	Procedure type	ED053 Minutes
72131	Diagnostic	18
72132	Diagnostic	12
72133	Diagnostic	12
72141	Diagnostic	23
72142	Diagnostic	26
72146	Diagnostic	23
72147	Diagnostic	26
72148	Diagnostic	23
72149	Diagnostic	26
72156	Diagnostic	28
72157	Diagnostic	28
72158	Diagnostic	28
72159	Diagnostic	31
72170	Diagnostic	5
72190	Diagnostic	3
72191	Diagnostic	28
72192	Diagnostic	12
72193	Diagnostic	12
72194	Diagnostic	12
72195	Diagnostic	30
72196	Diagnostic	26
72197	Diagnostic	30
72198	Diagnostic	28
72200	Diagnostic	3
72202	Diagnostic	3
72220	Diagnostic	3
72240	Diagnostic	19
72255	Diagnostic	18
72265	Diagnostic	18
72270	Diagnostic	23
72275	Diagnostic	36
72285	Diagnostic	9
72295	Diagnostic	9
73000	Diagnostic	3
73010	Diagnostic	3
73020	Diagnostic	3
73030	Diagnostic	5
73040	Diagnostic	6
73050	Diagnostic	3
73060	Diagnostic	4
73070	Diagnostic	3
73080	Diagnostic	4
73085	Diagnostic	6
73090	Diagnostic	3
73092	Diagnostic	3
73100	Diagnostic	4
73110	Diagnostic	4
73115	Diagnostic	6
73120	Diagnostic	4
73130	Diagnostic	4
73140	Diagnostic	3
73200	Diagnostic	18
73201	Diagnostic	11
73202	Diagnostic	12
73206	Diagnostic	35
73218	Diagnostic	25
73219	Diagnostic	25
73220	Diagnostic	30
73221	Diagnostic	23
73222	Diagnostic	23
73223	Diagnostic	35
73225	Diagnostic	31
73501	Diagnostic	4
73502	Diagnostic	5
73503	Diagnostic	6
73521	Diagnostic	5
73522	Diagnostic	6
73523	Diagnostic	7
73525	Diagnostic	6

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE DIRECT PE INPUT DATABASE—Continued

HCPCS	Procedure type	ED053 Minutes
73551	Diagnostic	4
73552	Diagnostic	5
73560	Diagnostic	4
73562	Diagnostic	5
73564	Diagnostic	6
73565	Diagnostic	4
73580	Diagnostic	6
73590	Diagnostic	4
73592	Diagnostic	3
73600	Diagnostic	4
73610	Diagnostic	4
73615	Diagnostic	6
73620	Diagnostic	4
73630	Diagnostic	4
73650	Diagnostic	3
73660	Diagnostic	3
73700	Diagnostic	18
73701	Diagnostic	11
73702	Diagnostic	12
73706	Diagnostic	35
73718	Diagnostic	20
73719	Diagnostic	25
73720	Diagnostic	30
73721	Diagnostic	23
73722	Diagnostic	24
73723	Diagnostic	32
73725	Diagnostic	33
74000	Diagnostic	4
74010	Diagnostic	3
74020	Diagnostic	4
74022	Diagnostic	4
74150	Diagnostic	14
74160	Diagnostic	17
74170	Diagnostic	21
74174	Diagnostic	33
74175	Diagnostic	28
74176	Diagnostic	25
74177	Diagnostic	28
74178	Diagnostic	33
74181	Diagnostic	15
74182	Diagnostic	28
74183	Diagnostic	35
74185	Diagnostic	33
74210	Diagnostic	5
74220	Diagnostic	5
74230	Diagnostic	12
74240	Diagnostic	7
74241	Diagnostic	7
74245	Diagnostic	9
74246	Diagnostic	7
74247	Diagnostic	18
74249	Diagnostic	9
74250	Diagnostic	5
74251	Diagnostic	33
74260	Diagnostic	6
74261	Diagnostic	43
74262	Diagnostic	48
74263	Diagnostic	42
74270	Diagnostic	7
74280	Diagnostic	23
74283	Diagnostic	19
74290	Diagnostic	4
74400	Diagnostic	18
74410	Diagnostic	6
74415	Diagnostic	6
74430	Diagnostic	4
74440	Diagnostic	5
74455	Diagnostic	4
74485	Diagnostic	6

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE DIRECT PE INPUT DATABASE—Continued

HCPCS	Procedure type	ED053 Minutes
74710	Diagnostic	4
74712	Diagnostic	68
74740	Diagnostic	5
75557	Diagnostic	45
75559	Diagnostic	58
75561	Diagnostic	50
75563	Diagnostic	66
75571	Diagnostic	13
75572	Diagnostic	25
75573	Diagnostic	38
75574	Diagnostic	35
75600	Diagnostic	6
75605	Diagnostic	11
75625	Diagnostic	11
75630	Diagnostic	13
75635	Diagnostic	50
75658	Diagnostic	13
75705	Diagnostic	20
75710	Diagnostic	11
75716	Diagnostic	13
75726	Diagnostic	11
75731	Diagnostic	11
75733	Diagnostic	13
75736	Diagnostic	11
75741	Diagnostic	13
75743	Diagnostic	16
75746	Diagnostic	11
75756	Diagnostic	11
75791	Diagnostic	33
75809	Diagnostic	5
75820	Diagnostic	7
75822	Diagnostic	11
75825	Diagnostic	11
75827	Diagnostic	11
75831	Diagnostic	11
75833	Diagnostic	14
75840	Diagnostic	11
75842	Diagnostic	14
75860	Diagnostic	11
75870	Diagnostic	11
75872	Diagnostic	11
75880	Diagnostic	7
75885	Diagnostic	14
75887	Diagnostic	14
75889	Diagnostic	11
75891	Diagnostic	11
75893	Diagnostic	6
75901	Diagnostic	11
75902	Diagnostic	13
75962	Diagnostic	6
75966	Diagnostic	13
75978	Diagnostic	6
75984	Diagnostic	8
75989	Diagnostic	12
76000	Diagnostic	3
76010	Diagnostic	3
76080	Diagnostic	6
76098	Diagnostic	3
76100	Diagnostic	6
76101	Diagnostic	6
76102	Diagnostic	6
76120	Diagnostic	5
76376	Diagnostic	8
76380	Diagnostic	10
76390	Diagnostic	28
76506	Diagnostic	10
76536	Diagnostic	12
76604	Diagnostic	9
76700	Diagnostic	14

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE DIRECT PE INPUT DATABASE—Continued

HCPCS	Procedure type	ED053 Minutes
76705	Diagnostic	11
76706	Diagnostic	13
76770	Diagnostic	13
76775	Diagnostic	11
76776	Diagnostic	13
76800	Diagnostic	14
76801	Diagnostic	18
76805	Diagnostic	18
76811	Diagnostic	35
76813	Diagnostic	23
76815	Diagnostic	8
76816	Diagnostic	18
76817	Diagnostic	13
76818	Diagnostic	35
76819	Diagnostic	28
76820	Diagnostic	13
76821	Diagnostic	13
76825	Diagnostic	45
76826	Diagnostic	11
76830	Diagnostic	13
76831	Diagnostic	30
76856	Diagnostic	13
76857	Diagnostic	10
76870	Diagnostic	10
76872	Diagnostic	20
76873	Diagnostic	40
76881	Diagnostic	18
76885	Diagnostic	20
76886	Diagnostic	15
76936	Diagnostic	71
76942	Diagnostic	19
76970	Diagnostic	8
77012	Diagnostic	11
77014	Diagnostic	9
77021	Diagnostic	53
77053	Diagnostic	5
77054	Diagnostic	5
77058	Diagnostic	50
77059	Diagnostic	55
77072	Diagnostic	3
77074	Diagnostic	5
77075	Diagnostic	6
77076	Diagnostic	12
77084	Diagnostic	15
78012	Diagnostic	8
78013	Diagnostic	13
78014	Diagnostic	13
78015	Diagnostic	31
78016	Diagnostic	49
78018	Diagnostic	29
78070	Diagnostic	13
78071	Diagnostic	18
78072	Diagnostic	23
78075	Diagnostic	38
78102	Diagnostic	18
78103	Diagnostic	22
78104	Diagnostic	20
78135	Diagnostic	48
78140	Diagnostic	40
78185	Diagnostic	16
78190	Diagnostic	40
78195	Diagnostic	30
78201	Diagnostic	16
78202	Diagnostic	20
78205	Diagnostic	20
78206	Diagnostic	25
78215	Diagnostic	13
78216	Diagnostic	22
78226	Diagnostic	13

TABLE 4—CODES WITH PROFESSIONAL PACS WORKSTATION IN THE DIRECT PE INPUT DATABASE—Continued

HCPCS	Procedure type	ED053 Minutes
78227	Diagnostic	18
78230	Diagnostic	19
78231	Diagnostic	23
78232	Diagnostic	28
78258	Diagnostic	27
78261	Diagnostic	21
78262	Diagnostic	25
78264	Diagnostic	13
78265	Diagnostic	18
78266	Diagnostic	23
78278	Diagnostic	18
78290	Diagnostic	18
78291	Diagnostic	31
78300	Diagnostic	15
78305	Diagnostic	22
78306	Diagnostic	11
78315	Diagnostic	11
78320	Diagnostic	24
78579	Diagnostic	8
78580	Diagnostic	13
78582	Diagnostic	15
78597	Diagnostic	13
78598	Diagnostic	13
78600	Diagnostic	16
78601	Diagnostic	18
78605	Diagnostic	21
78606	Diagnostic	22
78607	Diagnostic	29
78610	Diagnostic	10
78630	Diagnostic	24
78635	Diagnostic	36
78645	Diagnostic	32
78647	Diagnostic	15
78650	Diagnostic	40
78660	Diagnostic	16
78700	Diagnostic	17
78701	Diagnostic	18
78707	Diagnostic	22
78708	Diagnostic	32
78709	Diagnostic	40
78710	Diagnostic	21
78740	Diagnostic	30
78761	Diagnostic	20
78800	Diagnostic	28
78801	Diagnostic	32
78802	Diagnostic	24
78803	Diagnostic	43
78804	Diagnostic	35
78805	Diagnostic	25
78806	Diagnostic	23
78807	Diagnostic	37
79440	Diagnostic	24
G0106	Diagnostic	24
G0120	Diagnostic	24
G0297	Diagnostic	18
G0365	Diagnostic	20
G0389	Diagnostic	9

(2) Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule (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) Clinical Labor Tasks Associated With Digital Imaging

In CY 2015 PFS rulemaking, we noted that the RUC recommendation regarding inputs for digital imaging services indicated that, as each code is reviewed under the misvalued code initiative, the clinical labor tasks associated with digital technology (instead of film) would need to be addressed. When we reviewed that recommendation, we did not have the capability of assigning standard clinical labor times for the hundreds of individual codes since the direct PE input database did not previously allow for comprehensive adjustments for clinical labor times based on particular clinical labor tasks. Therefore, consistent with the recommendation, we proposed to remove film-based supply and equipment items but maintain clinical labor minutes that were assigned based on film technology.

As noted in the paragraphs above, we continue to improve the direct PE input database by specifying for each code the minutes associated with each clinical labor task. Once completed, this work would allow adjustments to be made to minutes assigned to particular clinical labor tasks related to digital technology that occur in multiple codes, consistent with the changes that were made to individual supply and equipment items. In the meantime, we believe it would be appropriate to establish standard times for clinical labor tasks associated with all digital imaging services for purposes of reviewing individual services at present, and for possible broad-based standardization once the changes to the direct PE input database facilitate our ability to adjust time across services. During the CY 2016 PFS rulemaking cycle, we proposed appropriate standard minutes for five different clinical labor tasks associated with services that use digital imaging technology. In the CY 2016 PFS final rule with comment period (80 FR 70901), we finalized appropriate standard minutes for four of those five activities, which are listed in Table 5.

TABLE 5—CLINICAL LABOR TASKS ASSOCIATED WITH DIGITAL IMAGING TECHNOLOGY

Clinical labor task	Typical minutes
Availability of prior images confirmed	2
Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	2
Review examination with interpreting MD	2
Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	1

We did not finalize standard minutes for the activity ''Technologist QC's images in PACS, checking for all images, reformats, and dose page.'' We agreed with commenters that this task may require a variable length of time depending on the number of images to be reviewed. We stated that it may be appropriate to establish several different standard times for this clinical labor task for a low/medium/high quantity of images to be reviewed, in the same fashion that the clinical labor assigned to clean a surgical instrument package has two different standard times depending on the use of a basic pack (10 minutes) or a medium pack (30 minutes). We solicited public comment and feedback on this subject, with the anticipation of including a proposal in the CY 2017 proposed rule.

We received many comments suggesting that this clinical labor activity should not have a standard time value. Commenters stated that the number of minutes varies significantly for different imaging modalities; and the time is not simply based on the quantity of images to be reviewed, but also the complexity of the images. The commenters recommended that time for this clinical labor activity should be assigned on a code by code basis. We agree with the commenters that the amount of clinical labor needed to check images in a PACS workstation may vary depending on the service. However, we do not believe that this precludes the possibility of establishing standards for clinical labor tasks as we have done in the past by creating multiple standard times, for example, those assigned to cleaning different kinds of scopes. We continue to believe that the use of clinical labor standards provides greater consistency among codes that share the same clinical labor tasks and can improve relativity of values among codes. We proposed to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We proposed 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, and 4 minutes as the standard for the complex case. We proposed the simple case of 2 minutes as the standard for the typical procedure code involving routine use of imaging. These values are based upon a review of the existing minutes assigned for this clinical labor activity; we have determined that 2 minutes is the

duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We proposed to use 2 minutes for services involving routine X-rays (simple), 3 minutes for services involving CTs and MRIs (intermediate), and 4 minutes for the most highly complex services, which would exceed these more typical cases. We solicited comments regarding the most accurate category—simple, intermediate, or complex for existing codes, and in particular what criteria might be used to identify complex cases systematically.

The following is summary of the comments we received regarding the ongoing standardization of clinical labor tasks, and our specific proposal regarding the clinical labor task, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.''

Comment: Many commenters restated their opposition to the principle of establishing standard values for clinical labor tasks. Commenters contended that clinical labor tasks were highly variable across different specialties, that the standardization process would disrupt the relativity of direct PE inputs across the PFS, and that the proposed standard times were too low and underestimated the staffing time needed to carry out the tasks in question. Commenters stressed that each code should be evaluated on an individual basis. One commenter expressed support for the overall concept regarding efforts to streamline the time for clinical labor activities.

Response: We note the objections raised by the commenters to the process of standardizing time values for clinical labor tasks. However, as we have stated previously, we believe the establishment of standards can provide greater consistency among codes that share the same clinical labor tasks, as well as improve relativity of values among codes. We also note that we do evaluate each code on an individual basis for direct PE inputs, and establishing clinical labor standards assists in that process of individual review. We continue to allow clinical labor times above the standard values for individual services, provided that there is a compelling rationale to explain why that particular service requires additional clinical labor time above and beyond the standard. We believe that establishing a range of standard minutes for this particular digital imaging clinical labor task will provide clarity and help maintain relativity across a wide range of imaging services.

Comment: One commenter requested a broad study of the actual clinical labor times associated with digital imaging.

Response: We appreciate the importance of incorporating robust, auditable, and routinely updated data sources for use in the determination of RVUs. We welcome stakeholder information on the availability of such data, while we continue to consider the best means of acquiring such data.

Comment: Several commenters addressed our specific proposal for the clinical labor task, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' Commenters requested that, short of no standard times at all, the establishment of categories for this clinical labor task should be as follows: Simple (2 min); intermediate (3 min), complex (4 min) and highly complex (5 min).

Response: We appreciate the suggestion from the commenters to adopt a categorization system very similar to our proposal, with the addition of an extra category for highly complex services valued at 5 minutes. We agree with this addition to our proposal, as it will allow for additional specificity in classifying different types of imaging services, including those that are unusually complex. However, we note that we proposed to define the simple case of 2 minutes as the standard for the typical procedure code involving routine use of imaging, and we believe only a small number of codes with more complex forms of digital imaging would typically involve more time for the task. We proposed to use 2 minutes for services involving routine X-rays (the simple case), and 3 minutes for services involving CTs and MRIs (the intermediate case). We seek recommendations from the RUC and other stakeholders and we intend to request feedback from commenters through future rulemaking to assist in identifying what we believe would be the small number of services that fall into the complex (4 min) and highly complex (5 min) categories, and the specific basis used to set the two categories apart from one another. In the meantime, we will consider individual codes on a case by case basis for this clinical labor task.

After considering the comments received, we are finalizing a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page'' as follows: Simple (2 min); intermediate (3 min), complex (4 min) and highly complex (5 min). We are also finalizing our criteria for determining the simple and intermediate categories as proposed.

(b) Pathology Clinical Labor Tasks

As with the clinical labor tasks associated with digital imaging, many of the currently assigned times for the specialized clinical labor tasks associated with pathology services are not consistent across codes. In reviewing past RUC recommendations for pathology services, we have not identified information that supports the judgment that the same tasks take significantly more or less time depending on the individual service for which they are performed, especially given the high degree of specificity with which the tasks are described. We continue to believe that, in general, a clinical labor task will tend to take the same amount of time to perform for one individual service as the same clinical labor task when it is performed in a clinically similar service.

Therefore, we developed standard times for clinical labor tasks that we have used in finalizing direct PE inputs in recent years, starting in the CY 2012 PFS final rule with comment period (76 FR 73213). These times were based on our review and assessment of the current times included for these clinical labor tasks in the direct PE input database. We proposed in the CY 2016 PFS proposed rule to establish standard times for a list of 17 clinical labor tasks related to pathology services, and solicited public feedback regarding our proposed standards. Many commenters stated in response to our proposal that they did not support the standardization of clinical labor activities across pathology services. Commenters stated that establishing a single standard time for each clinical labor task was infeasible due to the differences in batch size or number of blocks across different pathology procedures. Several commenters indicated that it might be possible to standardize across codes with the same batch sizes, and urged us to consider pathology-specific details, such as batch size and block number, in the creation of any future standard times for clinical labor tasks related to pathology services.

As we stated in the CY 2016 PFS proposed rule, we developed the proposed standard times based on our review and assessment of the current times included for these clinical labor tasks in the direct PE input database. We believe that, generally speaking, clinical labor tasks with the same description are comparable across different pathology procedures. We believe this to be true based on the comparability of clinical labor tasks in

non-pathology services, as well as the high degree of specificity with which most clinical labor tasks for pathology services are described relative to clinical labor tasks associated with other PFS services. We concurred with commenters that accurate clinical labor times for pathology codes may be dependent on the number of blocks or batch size typically used for each individual service. However, we also believe that it is appropriate and feasible to establish ''per block'' standards or standards varied by batch size assumptions for many clinical labor activities that would be comparable across a wide range of individual services. We have received detailed information regarding batch size and number of blocks during review of individual pathology services on an intermittent basis in the past. We requested regular submission of these details on the PE worksheets supplied by the RUC as part of the review process for pathology services, as a means to assist in the determination of the most accurate direct PE inputs.

We also stated our belief that many of the clinical labor activities for which we proposed to establish standard times were tasks that do not depend on number of blocks or batch size. Clinical labor activities such as ''Clean room/equipment following procedure'' and ''Dispose of remaining specimens'' would typically remain standard across different services without varying by block number or batch size, with the understanding that additional time may be required above the standard value for a clinical labor task that is part of an unusually complex or difficult service. As a result, we ultimately finalized standard times for 6 of the 17 proposed clinical labor activities in the CY 2016 final rule with comment period (80 FR 70902). We have listed the finalized standard times in Table 6. We are taking no further action on the remaining 11 clinical labor activities in this final rule, pending further action by the RUC (see below).

TABLE 6—STANDARD TIMES FOR CLINICAL LABOR TASKS ASSOCIATED WITH PATHOLOGY SERVICES

Clinical labor task	Standard clinical labor time (minutes)
Accession specimen/prepare for examination	4
Assemble and deliver slides with paperwork to pathologists	0.5
Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation	0.5
Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure)	1
Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste	1
Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable)	1

We remain committed to the process of establishing standard clinical labor times for tasks associated with pathology services. This may include establishing standards on a per-block or per-batch basis, as we indicated during the previous rulemaking cycle. However, we are aware that the PE Subcommittee of the RUC is currently working to standardize the pathology clinical labor activities they use in making their recommendations. We believe the RUC's efforts to narrow the current list of several hundred pathology clinical labor tasks to a more manageable number through the consolidation of duplicative or highly similar activities into a single description may serve PFS relativity and facilitate greater transparency in PFS ratesetting. We also believe that the RUC's standardization of pathology clinical labor tasks would facilitate our capacity to establish standard times for pathology clinical labor tasks in future rulemaking. Therefore, we did not propose any additional changes to clinical labor tasks associated with pathology services.

(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 would 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 is 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 video scope 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 plan to propose input prices for these equipment items through future rulemaking.

We proposed these changes only for the reviewed codes that make use of scopes; this applies to the codes in the Flexible Laryngoscope family (CPT codes 31572, 31573, 31574, 31575, 31576, 31577, 31578, 31579) (see section II.L) and the Laryngoplasty family (CPT codes 31551, 31552, 31553, 31554, 31580, 31584, 31587, 31591, 31592) (see section II.L) along with updated prices for the equipment items related to scopes utilized by these services. 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.

The following is a summary of the comments we received on this separate pricing structure for scopes, scope video systems, and scope accessories.

Comment: Many commenters addressed our general proposal to reclassify scopes and their related equipment items. Commenters expressed their support for the decision to remove the scopes from the proposed scope packages, and the proposed definition of the scope video system based on the current endoscopy video system equipment item (ES031). There were no comments opposing the general principle behind reclassifying scopes and scope equipment.

Response: We appreciate the support from the commenters for the broad project to clarify these issues related to scopes.

Comment: Many commenters also requested that CMS delay implementing the scope proposal until additional time could be devoted to the subject. Several commenters asked CMS to wait to make any changes until the RUC could form a PE Subcommittee to address this issue. For codes with proposed CY 2017 values, commenters urged CMS to adopt the RUC-recommended direct PE inputs instead of the proposed direct PE inputs, pending anticipated RUC recommendations on the subject. Another commenter requested that CMS make no change for CY 2017 for any endoscopy procedures until proper identification of the capital and disposable cost inputs could be confirmed.

Response: We appreciate commenters' interests in making certain that there is appropriate opportunity for stakeholders to provide feedback and recommendations on the reclassification of scopes and related scope equipment. This was our primary rationale for limiting proposed changes regarding these kinds of inputs to codes reviewed for the current CY 2017 rule cycle, that is, the Flexible Laryngoscope and Laryngoplasty families of codes. Because these codes are under current review; however, we believe that they should be valued according to a scheme that accurately describes the scope equipment typically used in the services. As a result, we continue to believe that our proposed classification system for scopes is the more sound methodology to use for valuation of these two families of codes for CY 2017. However, we note that we would expect to include examination of these codes as part of any broader proposal we would make regarding scope equipment items, in response to new recommendations on the subject.

We look forward to receiving recommendations from the upcoming RUC PE Subcommittee regarding scopes and related scope equipment items. We note that in order for these recommendations to be considered for CY 2018 rulemaking, we would need to receive these recommendations by the same February deadline for the submission of recommendations on code valuations.

Comment: Many commenters disagreed with the CMS proposal to price the endoscopy video system (ES031) at a price of $15,045.00. Some commenters stated that CMS should use the submitted invoices for the pricing of this equipment, which recommended a price of $49,400.00. One commenter stated that the proposed amount did not accurately reflect the current price of GI endoscopy video systems. Another commenter stated that CMS had defined the endoscopy video system as containing five items: (1) A monitor; (2) a processor; (3) a form of digital capture; (4) a cart; and (5) a printer. However, the commenter pointed out that CMS had not included a price for the digital capture device, which the commenter stressed was a significant part of the overall cost and needed to be included in the equipment's pricing. The commenter submitted a series of new invoices for endoscopy video system and requested that CMS incorporate them into the pricing of the equipment.

Response: We appreciate the feedback from the commenters about pricing, especially the submission of new data in the form of additional invoices. We agree that the cost of a digital capture device should be included in the cost of the endoscopy video system; it was our belief that the digital capture device was included in the cost of the processor. We appreciate the clarification from the commenters indicating that this is not the case, and that the digital capture device is a separately priced component of the video system. As a result, we are averaging the price of the digital capture device on the two submitted invoices and pricing it at $18,346.00. We will add this into the overall cost of the endoscopy video system.

For the other four components of the video system, we are finalizing the prices as proposed. The invoices submitted for these components indicate that they are different forms of equipment with different product IDs and different prices. For example, our price for the processor comes from a ''Video Processor with keyboard & video cable'' (CV–180) as opposed to the newly submitted invoice for a ''Viscera Elite Video System'' (OTV–S190). These are two distinct equipment items, and we do not have any data to indicate that the equipment on the newly submitted invoices is more typical in its use than the equipment that we are currently using to price the endoscopy video system.

Therefore, we are finalizing the price of the endoscopy video system at $33,391.00, based on component prices of $9,000.00 for the processor, $18,346.00 for the digital capture device, $2,000.00 for the monitor, $2,295.00 for the printer, and $1,750.00 for the cart.

Comment: A few commenters also addressed the pricing of related scope accessories. They stated that the proposed price for the fiberscope, flexible, rhinolaryngoscopy (ES020) was decreased by 33 percent based on one unrepresentative invoice and that this price undervalued the actual cost. Similarly, commenters stated that the proposed price for the stroboscopy system (ES065) at $19,100 was much lower than the manufacturer average invoice pricing. The proposed prices for the channeled and non-channeled flexible video rhinolaryngoscopes (ES064 and ES063 respectively) were also both two to three times lower than the manufacturer's average invoice price. One commenter submitted additional invoices for pricing these scopes and scope accessories.

Response: We appreciate the submission of this additional pricing data for review. Although many commenters stated that the price of the stroboscopy system was too low, only one commenter supplied additional invoices for the same equipment item that we defined in the proposed rule, the StrobeLED system, and these invoices reflected lower prices than the one we had proposed. These invoices reflected prices of $16,431.00 and $15,000.00. We are averaging these together with our previously submitted price of $19,100.00 for the stroboscopy system, which results in a new price of $16,843.87.

When we reviewed the invoices for the channeled and non-channeled flexible video rhinolaryngoscopes (ES064 and ES063 respectively), we found that the product numbers indicated that these were different equipment items than the scopes that we priced in the proposed rule. As we mentioned for the pricing of the endoscopy video system, we have no data to indicate that use of these particular rhinolaryngoscopes would be typical, as opposed to the rhinolaryngoscopes that we proposed to use to establish prices in the proposed rule. As a result, we are maintaining our current prices for these scopes pending the submission of additional information.

We similarly found that the invoices with recommended price increases for the endoscope, rigid, sinoscopy (ES013) from the current price of $2,414.17 to $4,024.00 and for the videoscope, colonoscopy (ES033) from $23,650.00 to $37,273.00 related to different equipment items that we do not believe are a better reflection of the typical case than the item we currently use. We did not propose to make price changes for these scopes, and we have not incorporated these equipment items into the new scope classification system. As we stated previously, we are currently limiting the scope changes to the CPT codes under review for CY 2017 and their associated equipment items. We will consider pricing changes for the rest of the scopes and associated scope equipment as part of the broader scope reclassification and pricing effort in future rulemaking.

We received invoices for a series of equipment items listed as ''other capital inputs not included in CMS estimate'' as part of this collection of invoices. Since these equipment items were not included in the original recommendations or our proposed valuations for the Flexible Laryngoscope and Laryngoplasty families of codes, we are not adding them to our equipment database at this time. We will consider the addition of these equipment items as part of the broader recommendations from the RUC PE Subcommittee on the scope classification project.

We did not receive an invoice or other data to support a change in the pricing of the fiberscope, flexible, rhinolaryngoscopy (ES020).

Comment: Many commenters objected to the use of a vendor quote for pricing of the scope equipment. Commenters requested that specialty societies should also be allowed to submit quotes for pricing as they are easier to obtain than paid invoices. Commenters also stated that the use of vendor prices created transparency issues and asked CMS to explain why they are appropriate to use rather than invoices supplied by specialties. One commenter stated that a single invoice was not an adequate sample to use as a pricing input for many types of endoscopic equipment.

Response: We are always interested in investigating multiple data sources for use in pricing supplies and equipment, provided that the information can be verified as accurate. We agree with the commenter that a single voluntarily submitted invoice may not be an adequate source for making wide ranging pricing decisions. We prefer to have pricing information from multiple data sources whenever possible, which may include information obtained from vendors of medical supplies and equipment. We continue to believe that there are risks of bias in submission of price quotes used for purposes of ratesetting. However, given the way we use these prices in the current ratesetting methodologies, we believe the risk of bias is located in submission of overstated, not understated prices. Therefore, we believe it is reasonable to assume that practitioners would generally be able acquire particular items at the prices vendors submit to CMS.

After consideration of comments received, we are finalizing our proposals as detailed in the proposed rule, with the updated prices for the endoscopy video system and the stroboscopy system.

(4) Technical Corrections to Direct PE Input Database and Supporting Files

Subsequent to the publication of the CY 2016 PFS final rule with comment period, stakeholders alerted us to several clerical inconsistencies in the direct PE database. We proposed to correct these inconsistencies as described below and reflected in the CY 2017 direct PE input database displayed on our Web site under downloads for the CY 2017 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

For CY 2017, we proposed the following technical corrections:

- For CPT codes 72081–72084, a stakeholder informed us that the equipment time for the PACS workstation (ED050) should be equal to the clinical labor during the service period; the equipment time formula we used for these codes for CY 2016 erroneously included 4 minutes of preservice clinical labor. We agree with the stakeholder that the PACS workstation should use the standard equipment time formula for a PACS workstation for these codes. As a result, we proposed to refine the ED050 equipment time to 21 minutes for CPT code 72081, 36 minutes for CPT code 72082, 44 minutes for CPT code 72083, and 53 minutes for CPT code 72084 to reflect the clinical labor time associated with these codes. This same commenter also indicated that a number of clinical labor activities had been entered in the database in the incorrect service period for CPT codes 37215, 50432, 50694, and 72081. These clinical labor activities were incorrectly listed in the ''postservice'' period instead of the ''service post'' period. We proposed to make these technical corrections as well so that the minutes are assigned to the appropriate service period within the direct PE input database.
- Another stakeholder alerted us that ileoscopy CPT codes 44380, 44381 and 44382 did not include the direct PE input equipment item called the Gomco suction machine (EQ235) and indicated that this omission appeared to be inadvertent. We agreed that it was. We have included the item EQ235 in the final direct PE input database for CPT code 44380 at a time of 29 minutes, for CPT code 44381 at a time of 39 minutes, and CPT code 44382 at a time of 34 minutes.

The PE RVUs displayed in Addendum B on our Web site were calculated with the inputs displayed in the CY 2017 direct PE input database.

Comment: One commenter expressed support for the proposed technical corrections to these services.

Response: We appreciate the support from the commenter. After consideration of comments received, we are finalizing these technical corrections.

Comment: Several commenters contacted CMS during the comment period after noticing that six services where CMS proposed to accept the refinement panel work RVU did not contain the updated work RVU in the

Addendum B file for the proposed rule. These commenters requested that CMS address these discrepancies.

Response: We appreciate the assistance from the commenters in recognizing these discrepancies. We have corrected them and assigned the refinement panel work RVUs to the six services in question.

Comment: One commenter stated that there were potential technical errors in the clinical labor inputs for CPT codes 88329, 88331, 88360, and 88361.

Response: We have reviewed these codes and they do not contain technical errors. The clinical labor inputs were adjusted in the CY 2016 rule cycle as a result of CMS refinement (80 FR 70981–70983).

(5) Restoration of Inputs

Several of the PE worksheets included in the RUC recommendations for CY 2016 contained time for the equipment item ''xenon light source'' (EQ167). Because there appeared to be two special light sources already present (the fiberoptic headlight and the endoscope itself) in the services for which this equipment item was recommended by the RUC, we believed that the use of only one of these light sources would be typical and proposed to remove the xenon light equipment time. In the CY 2016 PFS final rule with comment period, we restored the xenon light (EQ167) and removed the fiberoptic headlight (EQ170) with the same number of equipment minutes for CPT codes 30300, 31295, 31296, 31297, and 92511.

We received comments expressing approval for the restoration of the xenon light. However, the commenters also stated that the two light sources were not duplicative, but rather, both a headlight and a xenon light source are required concurrently for otolaryngology procedures when scopes are utilized. The commenters requested that the fiberoptic headlight be restored to these codes.

We agreed with the commenters that the use of both light sources would be typical for these procedures. Therefore, we proposed in the CY 2017 proposed rule to add the fiberoptic headlight (EQ170) to CPT codes 30300, 31295, 31296, 31297, and 92511 at the same number of equipment minutes as the xenon light (EQ167).

Comment: One commenter expressed appreciation for the CMS proposal to restore the fiberoptic headlight to the codes in question. The commenter also stated that it had supplied invoices for LED lights, which are significantly less expensive than the xenon light source, as it was this commenter's understanding that xenon lights are no longer the typical light source for these procedures and they are no longer widely available for purchase from vendors. The commenter expressed support for retaining the xenon light as the standard light source line item for all endoscopy codes if that remained CMS' preference.

Response: We appreciate the support for our proposal from the commenter, as well as the submission of additional information regarding the typical light source for these procedures. We will add the LED light source to our equipment database at the submitted invoice price of $1,915.00. However, we will not replace the xenon light with the LED light at this time, as we believe the subject deserves further consideration. We will consider proposing this change in future rulemaking.

Comment: We received new invoices for the xenon light equipment from a different commenter which averaged out to a price of $12,298.00.

Response: We are finalizing our proposed price of $7,000.00 for the xenon light source. Since we received a comment stating that xenon lights are no longer a typical light source for procedure use, and that they have been supplanted by the use of LED lights, we are viewing the current input as a proxy item, and therefore, do not believe that it would be appropriate to increase the cost of the xenon light source at this time. We will consider making a proposal to address this subject in future rulemaking.

After consideration of comments received, we are finalizing our proposal to add the fiberoptic headlight (EQ170) to CPT codes 30300, 31295, 31296, 31297, and 92511 at the same number of equipment minutes as the xenon light (EQ167).

(6) 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 2017, we proposed the following price updates for existing direct PE inputs:

Several commenters wrote to discuss the price of the Antibody Estrogen Receptor monoclonal (SL493). We received information including three invoices with new pricing information regarding the SL493 supply. We proposed to use this information to propose for the supply item SL493 a price of $14.00 per test, which is the average price based on the invoices that we received in total for the item.

Comment: Several commenters supported the proposed price increase and urged CMS to finalize the proposal.

Response: We appreciate the support from the commenters. After consideration of comments received, we are finalizing the price of the Antibody Estrogen Receptor monoclonal (SL493) supply at $14.00 as proposed.

We also proposed to update the price for two supplies in response to the submission of new invoices. The proposed price for ''antigen, venom'' supply (SH009) reflects an increase from $16.67 to $20.14 per milliliter, and the proposed price for ''antigen, venom, tri-vespid'' supply (SH010) reflects an increase from $30.22 to $44.05 per milliliter.

Comment: Several commenters stated that they strongly supported the proposed price updates for antigen supplies and urged CMS to finalize the proposal.

Response: We appreciate the support from the commenters. After consideration of comments received, we are finalizing the price of the ''antigen, venom'' (SH009) and ''antigen, venom, tri-vespid'' (SH010) supplies as proposed.

We proposed to remove the laser tip, diffuser fiber supply (SF030) and replace it with the laser tip, bare (single use) supply (SF029) for CPT code 31572 (formerly placeholder code 317X1). We did not propose a price change for the SF030 supply.

Comment: In reference to CPT code 52648, a commenter stated that the price for the laser tip, diffuser fiber supply (SF030) was decreasing from $850 to $197.50. The commenter stated that the methodology for this adjustment was opaque, unanticipated, and not proposed for comment in the proposed rule. The commenter stated that the $850 supply cost would be more appropriate for the laser tip, diffuser fiber supply.

Response: We stated in the CY 2017 proposed rule (81 FR 46247) that we did not believe that the submitted invoice for the laser tip, diffuser supply at $197.50 was current enough to establish a new price for the supply. As a result, we proposed to remove the laser tip, diffuser fiber supply (SF030) and replaced it with the laser tip, bare (single use) supply (SF029) for CPT code 31572 (Laryngoscopy, flexible; with ablation or destruction of lesion(s) with laser, unilateral), as we did not believe that it was appropriate to use a supply with an outdated invoice. However, we inadvertently set the price of the laser tip, diffuser fiber supply to

$197.50 in the proposed direct PE input database in contradiction of our written proposal. We apologize for the confusion caused by this error. In the final direct PE input database, we are restoring the price of the laser tip, diffuser fiber supply to $850.00, since we did not intend to propose a change the price of this supply. We are also requesting the submission of additional current pricing information for the laser tip, diffuser fiber supply, given the significant difference between the $197.50 and $850.00 prices.

Comment: A commenter submitted two invoices containing pricing data for a Cook Biopsy device.

Response: While we appreciate the submission of this pricing information from the commenter, we are unable to determine which supply or equipment item these invoices were in reference to. The invoices were not mentioned in the text of the commenter's letter. We request that invoices submitted for pricing updates should contain clear documentation regarding the item in question: its name, the CMS supply/equipment code that it references (if any), the unit quantity if the item is shipped in boxes or batches, and any other information relevant for pricing.

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 2017, we note that some stakeholders have submitted invoices for new, revised, or potentially misvalued codes after the February deadline established for code valuation recommendations. To be considered for a given year's proposed rule, we generally need to receive invoices by the same February deadline. In similar fashion, we generally need to receive invoices by the end of the comment period for the proposed rule in order to consider them for supply and equipment pricing in the final rule for that calendar year. Of course, we consider invoices submitted as public comments during the comment period following the publication of the proposed rule when relevant for services with values open for comment, and will consider any other invoices received after February and/or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices as finalized in the CY 2011 final rule with comment period (75 FR 73205).

(7) Radiation Treatment Delivery Practice Expense RVUs

Comment: Several commenters noticed that there was a 10 percent decrease in the proposed Non Facility PE RVUs for HCPCS code G6011 despite proposed changes in direct PE inputs. Commenters requested an explanation for why this decrease was taking place, and referenced section 3 of the Patient Access and Medicare Protection Act (PAMPA) (Pub. L. 114–115, enacted December 18, 2015), which requires CMS to maintain the associated ''definitions, units, and inputs'' for certain radiation treatment and related services for CY 2017 and CY 2018. Several commenters stated that they believed that this decrease in the PE RVU was in violation of section 1848(c)(2)(C)(i–ii) of the Act (added by section 3 of the PAMPA), which requires inputs for these services to remain unchanged for CY 2017 and 2018.

Response: We agree with the commenters that we did not propose to change any of the direct PE inputs for HCPCS code G6011, and we understand the proposed change in the nonfacility PE RVUs would generally not be expected absent a corresponding change in direct PE inputs. However, the change in the PE RVU for HCPCS code G6011 is caused by a significant shift in the specialties furnishing the service in the Medicare claims data. In the claims data we used to establish the PE RVUs for CY 2016, dermatology furnished 51 percent of the services, while radiation oncology furnished 43 percent. The most recent claims data reflects a major shift, with radiation oncology now furnishing about 85 percent of the services and dermatology only about 6 percent. The decrease in the PE RVU between CY 2016 and CY 2017 resulted from this shift in specialty mix, as the specialties actually furnishing the service, reflected in the claims data, have a higher percentage of direct PE relative to indirect PE, and therefore, a lower percentage of indirect PE, than the specialties that were previously furnishing the service in the claims data. In other words, consistent with the established methodology for allocating indirect PE to services, a specialty mix with a lower percentage of indirect PE results in fewer indirect PE RVUs being allocated and a lower overall PE RVU for the code even though the direct PE inputs have remained the same. This kind of shift is relatively unusual outside of low-volume codes, but it is consistent with our established methodology for allocating indirect PE to services. We believe that in many cases, the change in specialty utilization for a particular service would warrant a re-examination of the direct PE inputs for the service under the misvalued code initiative. Given the statutory provision that prohibits us from changing the direct PE inputs prior to CY 2019 or considering these services as potentially misvalued, we will consider this issue further for future rulemaking.

We recognize that this change would be unanticipated, but we do not believe there is a straightforward, transparent way to offset the change since the statutory provision requires that we maintain the direct inputs for the PE RVUs. We note that this change is unique among the radiation therapy and related imaging codes where the maintenance of inputs has generally resulted in payment rate stability for these services.

B. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be composed of three components: Work, PE, and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based. Malpractice RVUs for new codes after 1991 were extrapolated from similar existing codes or as a percentage of the corresponding work RVU. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. In the CY 2015 PFS final rule with comment period, we implemented the third review and update of MP RVUs. For a 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 comprised 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 adjust (or scale) the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work RVU (or, if greater, the 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 is applied for the new/revised code and source code, but the work RVU for the new/revised code is used to adjust the MP RVUs for risk.

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 for 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. We stated that under this approach, 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.

For CY 2016, we did not propose to discontinue our current approach for determining MP RVUs for new/revised codes. For the new and revised codes for which we proposed work RVUs and PE inputs, we also published the proposed MP crosswalks used to determine their MP RVUs. We address comments regarding valuation of new and revised codes in section II.L of this final rule, which makes clear the codes with interim final values for CY 2016 had newly proposed values for CY 2017, all of which were again open for comment. The MP crosswalks for new and revised codes with interim final values were established in the CY 2016 PFS final rule with comment period; we proposed these same crosswalks in the CY 2017 PFS proposed rule.

2. Updating Specialty Specific Risk Factors

The proposed CY 2017 GPCI update (eighth update), discussed in section II.E of this final rule, reflects updated MP premium data, collected for the purpose of proposing updates to the MP GPCIs. Although we could have used the updated MP premium data obtained for the purposes of the proposed eighth GPCI update to propose updates to the specialty risk factors used in the calculation of MP RVUs, this would not be consistent with the policy we previously finalized in the CY 2016 PFS final rule with comment period. In that rule, 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. Additionally, consistent with the statutory requirement at section 1848(e)(1)(C) of the Act, only one half of the adjustment to MP GPCIs would be applied for CY 2017 based on the new MP premium data. As such, we did not think it would be appropriate to propose to update the specialty risk factors for CY 2017 based on the updated MP premium data that is reflected in the proposed CY 2017 GPCI update. Therefore, we did not propose to update the specialty-risk factors based on the new premium data collected for the purposes of the 3-year GPCI update for CY 2017 at this time. However, we solicited comment on whether we should consider doing so, perhaps as early as for 2018, prior to the fourth review and update of MP RVUs that must occur no later than CY 2020.

The following is summary of the comments we received on whether we should consider updating the specialty-risk factors based on the new premium data collected for the purposes of the 3-year GPCI update, perhaps as early as for 2018, prior to the fourth review and update of MP RVUs that must occur no later than CY 2020.

Comment: We received few comments regarding this issue. Some commenters, including the RUC, recommended that CMS use the updated MP premium data collected as part of the CY 2017 GPCI update in the creation of the MP RVUs for CY 2017. One commenter stated that CMS should follow its normal process to update MP RVUs for CY 2020. Another commenter supported the technical and policy changes that CMS made related to the MP RVUs for the CY 2016 PFS, and appreciated CMS' reluctance to change direction a year later and use the updated malpractice premium data gathered for the purpose of the GPCI update, in advance of the next 5-year review of the MP RVUs, to propose updates to the specialty risk factors used in the calculation of MP RVUs. The commenter suggested that CMS consider using the updated data to update the specialty-risk factors in the MP RVU methodology as early as CY 2018, noting that by CY 2018, the adjustment of the malpractice GPCIs would be complete, so the potential disconnect in the use of the updated premium data would no longer be an issue.

Response: We appreciate the commenters' feedback. In response to the commenters who recommended that CMS use the updated MP premium data collected as part of the CY 2017 GPCI update in the creation of the MP RVUs for CY 2017, we reiterate that we did not propose to update the specialty-risk factors based on the new premium data collected for the purposes of the 3-year GPCI update for the CY 2017 MP RVUs. Instead, we solicited comment on whether we should consider doing so prior to the next 5-year interval, perhaps as early as for CY 2018. We will 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.

Comment: One commenter stated that CPT code 93355 should be added to the MP RVUs Invasive Cardiology Outside of Surgical Range list so that the surgical risk factor is applied when calculating the MP RVU.

Response: We did not previously propose to include this code on the list of Invasive Cardiology Outside of Surgical Range when we updated MP risk factors for CY 2015 and we did not propose the change in the CY 2017 PFS proposed rule. We will consider that request for future rulemaking in conjunction with the next update of MP risk factors.

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 MACs that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system.

Originating sites, which can be one of several types of sites specified in the statute where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system, are paid a facility fee under the PFS for each Medicare telehealth service. The statute specifies both the types of entities that can serve as originating sites and the geographic qualifications for originating sites. With regard to geographic qualifications, § 410.78(b)(4) limits originating sites to those located in rural health professional shortage areas (HPSAs) or in a county that is not included in a metropolitan statistical area (MSA).

Historically, we have defined rural HPSAs to be those located outside of MSAs. Effective January 1, 2014, we modified the regulations regarding originating sites to define rural HPSAs as those located in rural census tracts as determined by the 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 the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

An entity participating in a federal telemedicine demonstration project that has been approved by, or received funding from, the Secretary as of December 31, 2000 is eligible to be an originating site regardless of its geographic location.

Effective January 1, 2014, we also changed our policy so that geographic status for an originating site would be established and maintained on an annual basis, consistent with other telehealth payment policies (78 FR 74400). Geographic status for Medicare telehealth originating sites for each calendar year is now based upon the status of the area as of December 31 of the prior calendar year.

For a detailed history of telehealth payment policy, see 78 FR 74399.

2. Adding Services to the List of Medicare Telehealth Services

As noted previously, in the CY 2003 PFS final rule (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 (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.

For the list of telehealth services, see the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*. Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, qualifying requests submitted before the end of CY 2016 will be considered for the CY 2018 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 the CMS 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 2017

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 2015 to add various services as Medicare telehealth services effective for CY 2017. The following presents a discussion of these requests, and our decisions regarding additions to the CY 2017 telehealth list. Of the requests received, we found that four services were sufficiently similar to ESRD-related services currently on the telehealth list to qualify on a category 1 basis. Therefore, we proposed to add the following services to the telehealth list on a category 1 basis for CY 2017:

- CPT codes 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; 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).

As we indicated in the CY 2015 final rule with comment period (80 FR 41783), for the ESRD-related services (CPT codes 90963–90966) added to the telehealth list for CY 2016, the required clinical examination of the catheter access site must be furnished face-to-face ''hands on'' (without the use of an interactive telecommunications system) by a physician, CNS, NP, or PA. This requirement also applies to CPT codes 90967–90970.

While we did not receive a specific request, we also proposed to add two advance care planning services to the telehealth list. We have determined that these services are similar to the annual wellness visits (HCPCS codes G0438 & G0439) currently on the telehealth list:

- CPT codes 99497 (advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), or surrogate); and 99498 (advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes (list separately in addition to code for primary procedure)).

We also received requests to add services to the telehealth list that do not meet our criteria for Medicare telehealth services. We did not propose to add the following procedures for observation care, emergency department visits, critical care E/M, psychological testing, and physical, occupational and speech therapy, for the reasons noted:

a. Observation Care: CPT Codes—

- 99217 (observation care discharge day management (this code is to be utilized to report all services provided to a patient on discharge from ''observation status'' if the discharge is on other than the initial date of ''observation status.'' To report services to a patient designated as ''observation status'' or ''inpatient status'' and discharged on the same date, use the codes for observation or inpatient care services [including admission and discharge services, 99234–99236 as appropriate.]));
- 99218 (initial observation care, per day, for the evaluation and management of a patient which requires these three 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 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 family's needs. Usually, the problem(s) requiring admission to ''observation status'' are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit);
- 99219 (initial observation care, per day, for the evaluation and management of a patient, which requires these three key components: A comprehensive history; a comprehensive examination; and medical decision making of moderate complexity. Counseling and 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 family's needs. Usually, the problem(s) requiring admission to ''observation status'' are of moderate severity.

Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit);

• 99220 (initial observation care, per day, for the evaluation and management of a patient, which requires these three key components: A comprehensive history; a comprehensive examination; and medical decision making of high complexity. Counseling and 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 family's needs. Usually, the problem(s) requiring admission to ''observation status'' are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit);

• 99224 (subsequent observation care, per day, for the evaluation and management of a patient, which requires at least two of these three key components: Problem focused interval history; problem focused examination; medical decision making that is straightforward or of low complexity. Counseling and 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 family's needs. Usually, the patient is stable, recovering, or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit);

• 99225 (subsequent observation care, per day, for the evaluation and management of a patient, which requires at least two of these three key components: An expanded problem focused interval history; an expanded problem focused examination; medical decision making of moderate complexity. Counseling and 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 family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit);

• 99226 (subsequent observation care, per day, for the evaluation and management of a patient, which requires at least two of these three key components: A detailed interval history; a detailed examination; medical decision making of high complexity. Counseling and 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 family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit);

• 99234 (observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these three 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 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 family's needs. Usually the presenting problem(s) requiring admission are of low severity. Typically, 40 minutes are spent at the bedside and on the patient's hospital floor or unit);

• 99235 (observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these three key components: A comprehensive history; a comprehensive examination; and medical decision making of moderate complexity. Counseling and 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 family's needs. Usually the presenting problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit);

• 99236 (observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these three key components: A comprehensive history; a comprehensive examination; and medical decision making of high complexity. Counseling and 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 family's needs. Usually the presenting problem(s) requiring admission are of high severity. Typically, 55 minutes are spent at the bedside and on the patient's hospital floor or unit);

The request to add these observation services referenced various studies supporting the use of observation units. The studies indicated that observation units provide safe, cost effective care to patients that need ongoing evaluation and treatment beyond the emergency department visit by having reduced hospital admissions, shorter lengths of stay, increased safety and reduced cost. Additional studies cited indicated that observation units reduce the work load on emergency department physicians, and reduce emergency department overcrowding.

In the CY 2005 PFS proposed rule (69 FR 47510), we considered a request but did not propose to add the observation CPT codes 99217–99220 to the list of Medicare telehealth services on a category two basis for the reasons described in that rule. The most recent request did not include any information that would cause us to question the previous evaluation under the category one criterion, which has not changed, regarding the significant differences in patient acuity between these services and services on the telehealth list. While the request included evidence of the general benefits of observation units, it did not include specific information demonstrating that the services described by these codes provided clinical benefit when furnished via telehealth, which is necessary for us to consider these codes on a category two basis. Therefore, we did not propose to add these services to the list of approved telehealth services.

b. Emergency Department Visits: CPT Codes—

• 99281 (emergency department visit for the evaluation and management of a patient, which requires these three key components: A problem focused history; a problem focused examination; and straightforward medical decision making. Counseling and 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 family's needs. Usually, the presenting problem(s) are self-limited or minor);

• 99282 (emergency department visit for the evaluation and management of a patient, which requires these three key components: An expanded problem focused history; an expanded problem focused examination; and medical decision making of low complexity. Counseling and 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 family's needs. Usually, the presenting problem(s) are of low to moderate severity);

• 99283 (emergency department visit for the evaluation and management of a patient, which requires these three key components: An expanded problem focused history; an expanded problem focused examination; and medical decision making of moderate complexity. Counseling and 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 family's needs. Usually, the presenting problem(s) are of moderate severity);

• 99284 (emergency department visit for the evaluation and management of a patient, which requires these three key components: A detailed history; a detailed examination; and medical decision making of moderate complexity. Counseling and 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 family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function); and

• 99285 (emergency department visit for the evaluation and management of a patient, which requires these three key components within the constraints imposed by the urgency of the patient's clinical condition and mental status: A comprehensive history; a comprehensive examination; and medical decision making of high complexity. Counseling and 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 family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function).

In the CY 2005 PFS proposed rule (69 FR 47510), we considered a request but did not propose to add the emergency department visit CPT codes 99281–99285 to the list of Medicare telehealth services for the reasons described in that rule.

The current request to add the emergency department E/M services stated that the codes are similar to outpatient visit codes (CPT codes 99201–99215) that have been on the telehealth list since CY 2002. As we noted in the CY 2005 PFS final rule, while the acuity of some patients in the emergency department might be the same as in a physician's office; we believe that, in general, more acutely ill patients are more likely to be seen in the emergency department, and that difference is part of the reason there are separate codes describing evaluation and management visits in the Emergency Department setting. The practice of emergency medicine often requires frequent and fast-paced patient reassessments, rapid physician interventions, and sometimes the continuous physician interaction with ancillary staff and consultants. This work is distinctly different from the pace, intensity, and acuity associated with visits that occur in the office or outpatient setting. Therefore, we did not propose to add these services to the list of approved telehealth services on a category one basis.

The requester did not provide any studies supporting the clinical benefit of managing emergency department patients with telehealth which is necessary for us to consider these codes on a category two basis. Therefore, we did not propose to add these services to the list of approved telehealth services on a category two basis.

Many requesters of additions to the telehealth list urged us to consider the potential value of telehealth for providing beneficiaries access to needed expertise. We note that if clinical guidance or advice is needed in the emergency department setting, a consultation may be requested from an appropriate source, including consultations that are currently included on the list of telehealth services.

c. Critical Care Evaluation and Management: CPT Codes—

• 99291 (critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); and 99292 (critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (list separately in addition to code for primary service).

We previously considered and rejected adding these codes to the list of Medicare telehealth services in the CY 2009 PFS final rule (74 FR 69744) on a category 1 basis because, due to the acuity of critically ill patients, we did not believe critical care services are similar to any services on the current list of Medicare telehealth services. In that rule, we said that critical care services must be evaluated as category 2 services. Because we considered critical care services under category 2, we needed to evaluate whether these are services for which telehealth can be an adequate substitute for a face-to-face encounter, based on the category 2 criteria at the time of that request. We had no evidence suggesting that the use of telehealth could be a reasonable surrogate for the face-to-face delivery of this type of care.

The American Telemedicine Association (ATA) submitted a new request for CY 2016 that cited several studies to support adding these services on a category 2 basis. To qualify under category 2, we would need evidence that the service furnished via telehealth is still described accurately by the requested code and produces a clinical benefit for the patient via telehealth. However, in reviewing the information provided by the ATA and a study titled, ''Impact of an Intensive Care Unit Telemedicine Program on Patient Outcomes in an Integrated Health Care System,'' published July 2014 in *JAMA Internal Medicine,* which found no evidence that the implementation of ICU telemedicine significantly reduced mortality rates or hospital length of stay, which could be indicators of clinical benefit. Therefore, we stated that we do not believe that the submitted evidence demonstrates a clinical benefit to patients. Therefore, we did not propose to add these services on a category 2 basis to the list of Medicare telehealth services for CY 2016 (80 FR 71061).

This year, requesters cited additional studies to support adding critical care services to the Medicare telehealth list on a category 2 basis. Eight of the studies dealt with telestroke and one with teleneurology. Telestroke is an approach that allows a neurologist to provide remote treatment to vascular stroke victims. Teleneurology offers consultations for neurological problems from a remote location. It may be initiated by a physician or a patient, for conditions such as headaches, dementia, strokes, multiple sclerosis and epilepsy.

However, according to the literature, the management of stroke via telehealth requires more than a single practitioner and is distinct from the work described by the above E/M codes, 99291 and 99292. One additional study cited involved pediatric patients, while another noted that the Department of Defense has used telehealth to provide critical care services to hospitals in Guam for many years. Another reference study indicated that consulting intensivists thought that telemedicine consultations were superior to telephone consultations. In all of these cases, we believe the evidence demonstrates that interaction between these patients and distant site practitioners can have clinical benefit.

However, we do not agree that the kinds of services described in the studies are those that are included in the above critical care E/M codes 99291 and 99292. We note that CPT guidance makes clear that a variety of other services are bundled into the payment rates for critical care, including gastric intubations and vascular access procedures among others We do not believe these kinds of services are furnished via telehealth. Public comments, included cited studies, can be viewed at *https://www.regulations.gov/#!documentDetail;D=CMS-2015-0081-0002*. Therefore, we did not propose to add CPT codes 99291 or 99292 to the list of Medicare telehealth services for CY 2017.

However, we are persuaded by the requests that we recognize the potential benefit of critical care consultation services that are furnished remotely. We note that there are currently codes on the telehealth list that could be reported when consultation services are furnished to critically ill patients. In consideration of these public requests, we recognize that there may be greater resource costs involved in furnishing these services relative to the existing telehealth consultation codes. We also agree with the requesters that there may be potential benefits of remote care by specialists for these patients. For these reasons, we think it would be advisable to create a coding distinction between telehealth consultations for critically ill patients, for example stroke patients, relative to telehealth consultations for other hospital patients. Such a coding distinction would allow us to recognize the additional resource costs in terms of time and intensity involved in furnishing such services, under the conditions where remote, intensive consultation is required to provide access to appropriate care for the critically ill patient. We recognize that the current set of E/M codes, including current CPT codes 99291 and 99292, may not adequately describe such services because current E/M coding presumes that the services are occurring in-person, in which case the expert care would be furnished in a manner described by the current codes for critical care.

Therefore, we proposed to make payment through new HCPCS codes G0508 and G0509, initial and subsequent, used to describe critical care consultations furnished via telehealth. This new coding would provide a mechanism to report an intensive telehealth consultation service, initial or subsequent, for the critically ill patient, such as a stroke patient, under the circumstance when a qualified health care professional has in-person responsibility for the patient but the patient benefits from additional services from a distant-site consultant specially trained in providing critical care services. We proposed limiting these services to once per day per patient. Like the other telehealth consultations, these services would be valued relative to existing E/M services.

More details on the new coding (G0508 and G0509) and valuation for these services are discussed in section II.L. of this final rule and the final RVUs for this service are included in Addendum B of this final rule, including a summary of the public comments we received and our responses to the comments. Like the other telehealth consultation codes, we proposed that these services would be added to the telehealth list and would be subject to the geographic and other statutory restrictions that apply to telehealth services.

d. Psychological Testing: CPT Codes—

- 96101 (psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, *e.g.*, MMPI, Rorschach, WAIS), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report);
- 96102 psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, *e.g.*, MMPI and WAIS), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face);
- 96118 Neuropsychological testing (*e.g.*, Halstead-Reitan neuropsychological battery, Wechsler memory scales and Wisconsin card sorting test), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report); and,
- 96119 Neuropsychological testing (*e.g.*, Halstead-Reitan neuropsychological battery, Wechsler memory scales and Wisconsin card sorting test), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face).

Requesters indicated that there is nothing in the Minnesota Multiphasic Personality Inventory (MMPI), the Rorschach inkblot test, the Wechsler Adult Intelligence Scale (WAIS), the Halstead-Reitan Neuropsychological Battery and Allied Procedures, or the Wisconsin Card Sorting Test (WCST), that cannot be done via telehealth nor is different than neurological tests done for Parkinson's disease, seizure medication side effects, gait assessment, nor any of the many neurological examinations done via telehealth with the approved outpatient office visit and inpatient visit CPT codes currently on the telehealth list. As an example, requesters indicated that the MPPI is administered by a computer, which generates a report that is interpreted by the clinical psychologist, and that the test requires no interaction between the clinician and the patient.

We previously considered the request to add these codes to the Medicare telehealth list in the CY 2015 final rule with comment period (79 FR 67600). We decided not to add these codes, indicating that these services are not similar to other services on the telehealth list because they require close observation of how a patient responds. We noted that the requesters did not submit evidence supporting the clinical benefit of furnishing these services via telehealth so that we could evaluate them on a category 2 basis. While we acknowledge that requesters believe that some of these tests require minimal, if any, interaction between the clinician and patient, we disagree. We continue to believe that successful completion of the tests listed as examples in these codes require the clinical psychologist to closely observe the patient's response, which cannot be performed via telehealth. Some patient responses, for example, sweating and fine tremors, may be missed when the patient and examiner are not in the same room. Therefore, we did not propose to add these services to the list of Medicare telehealth services for CY 2017.

e. Physical and Occupational Therapy and Speech-Language Pathology Services: CPT Codes—

- 92507 (treatment of speech, language, voice, communication, and auditory processing disorder; individual); and, 92508 (treatment of speech, language, voice, communication, and auditory processing disorder; group, 2 or more individuals); 92521 (evaluation of speech fluency (*e.g.*, stuttering, cluttering)); 92522 (evaluation of speech sound production (*e.g.*, articulation, phonological process, apraxia, dysarthria)); 92523 (evaluation of speech sound production (*e.g.*, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression

(*e.g.*, receptive and expressive language)); 92524 (behavioral and qualitative analysis of voice and resonance); (evaluation of oral and pharyngeal swallowing function); 92526 (treatment of swallowing dysfunction or oral function for feeding); 92610 (evaluation of oral and pharyngeal swallowing function); CPT codes 97001 (physical therapy evaluation); 97002 (physical therapy re-evaluation); 97003 (occupational therapy evaluation); 97004 (occupational therapy re-evaluation); 97110 (therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility); 97112 (therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, or proprioception for sitting or standing activities); 97116 (therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)); 97532 (development of cognitive skills to improve attention, memory, problem solving (includes compensatory training), direct (one-on-one) patient contact, each 15 minutes); 97533 (sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes); 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); 97537 (community/work reintegration training (*e.g.*, shopping, transportation, money management, avocational activities or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes); 97542 (wheelchair management (*e.g.*, assessment, fitting, training), each 15 minutes); 97750 (physical performance test or measurement (*e.g.*, musculoskeletal, functional capacity), with written report, each 15 minutes); 97755 (assistive technology assessment (*e.g.*, to restore, augment or compensate for existing function, optimize functional tasks and maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes); 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); 97761 (prosthetic training, upper and lower extremity(s), each 15 minutes); and 97762 (checkout for orthotic/prosthetic use, established patient, each 15 minutes).

The statute defines who is an authorized practitioner of telehealth services. Physical therapists, occupational therapists and speech-language pathologists are not authorized practitioners of telehealth under section 1834(m)(4)(E) of the Act, as defined in section 1842(b)(18)(C) of the Act. Because the above services are predominantly furnished by physical therapists, occupational therapists and speech-language pathologists, we do not believe it would be appropriate to add them to the list of telehealth services at this time. One requester suggested that we can add telehealth practitioners without legislation, as evidenced by the addition of nutritional professionals. However, we do not believe we have such authority and note that nutritional professionals are included as practitioners in the definition at section 1834(b)(18)(C)(vi) of the Act, and thus, are within the statutory definition of telehealth practitioners. Therefore, we did not propose to add these services to the list of Medicare telehealth services for CY 2017.

In summary, we proposed to add the following codes to the list of Medicare telehealth services beginning in CY 2017 on a category 1 basis:

- ESRD-related services 90967 through 90970. The required clinical examination of the catheter access site must be furnished face-to-face ''hands on'' (without the use of an interactive telecommunications system) by a physician, CNS, NP, or PA.
- Advance care planning (CPT codes 99497 and 99498).
- Telehealth Consultations for a Patient Requiring Critical Care Services (G0508 and G0509).

The following is summary of the comments we received regarding the proposed addition of services to the list of Medicare telehealth services:

Comment: Many commenters supported one or more of our proposals to add ESRD-related services (CPT codes 90967, 90968, 90969 and 90970) and advance care planning services (CPT codes 99497 and 99498) to the list of Medicare telehealth services for CY 2017.

Response: We appreciate the commenters' support for the proposed additions to the list of Medicare telehealth services. After consideration of the public comments received, we are finalizing our proposal to add these services to the list of Medicare telehealth services for CY 2017 on a category 1 basis.

Comment: Many commenters also supported the proposal to make payment through new codes, initial and subsequent, used to describe critical care consultations furnished via telehealth. Commenters indicated that the codes will improve patient outcomes and quality of care.

Response: We thank the commenters for their support. We believe the new coding G0508 and G0509 would provide a mechanism to report an intensive telehealth consultation service, initial or subsequent, for the critically ill patient, for example a stroke patient, under the circumstance when a qualified health care professional has in-person responsibility for the patient but the patient benefits from additional services from a distant-site consultant specially trained in furnishing critical care services. After consideration of the public comments received, we are finalizing our proposal to add these critical care consultation services to the list of Medicare telehealth services for CY 2017 on a category 1 basis. We are finalizing these services as limited to once per day per patient.

We are also finalizing our proposal to make payment for these critical care consultation services through new codes G0508 and G0509, initial and subsequent, used to describe critical care consultations furnished via telehealth. More details on the new coding and valuation for these services are discussed in section II.L. of this final rule and the final RVUs for this service are included in Addendum B of this final rule. Like the other telehealth consultation codes, we proposed and are finalizing that these services would be added to the telehealth list and would be subject to the geographic and other statutory restrictions that apply to telehealth services.

Comment: Several commenters agreed with our decision not to add psychological and neuropsychological testing services to the telehealth list, noting that the face-to-face contact between the psychologist or technician and the beneficiary is critical for detecting behaviors related to test taking, such as movements or other nonverbal signals that could be missed by using current telehealth media.

A few commenters disagreed with our decision not to add psychological and neuropsychological testing services. Commenters cited general benefits, such as increased access to care, improved health outcomes, and as a remedy to address provider shortages. One commenter maintained that the requested codes are similar to many

neurological examinations done via telehealth with the approved outpatient office visit and inpatient visit CPT codes currently on the telehealth list.

Response: As noted above, we previously considered the request to add these codes to the telehealth list, on a category 1 basis, in the CY 2015 final rule with comment period (79 FR 67600). We decided not to add these codes, indicating that these services are not similar to other services on the telehealth list because they require close observation of how a patient responds. Commenters provided no evidence of clinical benefit, which is necessary to support adding these services on a category 2 basis. Therefore, we are not adding these services to the list of Medicare list telehealth services for CY 2017.

Comment: A few commenters disagreed with our decision not to add observation care and emergency department visits. Commenters cited general benefits, such as improved quality of care, reduced physician workload, reduced emergency department overcrowding, and reduced shortage of available specialty services. Concerning CPT codes 99281–99283, one commenter indicated that none of these codes include what is categorized as a ''detailed'' or ''comprehensive'' history or exam; none of these codes include complexity in medical decision making that is categorized as ''high;'' and none of these codes include presenting problems of ''high'' or ''high severity/immediate significant threat to life or physiological function.''

Response: As noted above, we previously considered and rejected adding these codes to the list of Medicare telehealth services in the CY 2005 PFS final rule (69 FR 66276) on a category 1 basis because of the difference in typical patient acuity relative to any services on the current list of Medicare telehealth services. While CPT codes 99281–99283 may not include a detailed or comprehensive history or exam or a high level of medical decision making, we do not agree that these codes are similar to outpatient visit codes (CPT codes 99201–99215) currently on the list of Medicare telehealth services. As previously stated, more acutely ill patients are more likely to be seen in the emergency department, and that difference is part of the reason there are separate codes describing evaluation and management visits in the Emergency Department setting. The work in an Emergency Department setting is distinctly different from the pace, intensity, and acuity associated with visits that occur in the office or outpatient setting. Commenters provided no evidence of clinical benefit for these services when furnished via telehealth specifically, which is necessary to support adding these services on a category 2 basis. Therefore, we are not adding these services to the list of Medicare telehealth services for CY 2017.

We remind stakeholders that if consultative telehealth services are required for patients where emergency department or observation care services would ordinarily be reported, multiple codes describing consultative services are currently on the telehealth list and can be used to bill for such telehealth services.

Comment: Concerning various services primarily furnished by physical therapists, occupational therapists, and speech-language pathologists, commenters recognized that a statutory change is required to allow such services to be added to the list of Medicare telehealth services.

Response: We appreciate commenters recognizing the statutory limitation on adding these services. Therefore, we are not adding these services to the list of Medicare telehealth services for CY 2017.

4. Place of Service (POS) Code for Telehealth Services

We have received multiple requests from various stakeholders to establish a POS code to identify services furnished via telehealth. These requests have come from other payers, but may also be related to confusion concerning whether to use the POS where the distant site physician is located or the POS where the patient is located. The process for establishing POS codes is managed by the POS Workgroup within CMS, is available for use by all payers, and is not contingent upon Medicare PFS rulemaking. We noted in the CY 2017 proposed rule (81 FR 46184) that, if such a POS code were created, in order to make it valid for use in Medicare, we would have to determine the appropriate payment rules associated with the code. Therefore, we proposed how a POS code for telehealth would be used under the PFS with the expectation that, if such a code is available, it would be used as early as January 1, 2017. We proposed that the physicians or practitioners furnishing telehealth services would be required to report the telehealth POS code to indicate that the billed service is furnished as a telehealth service from a distant site. As noted below, since the publication of the CY 2017 proposed rule, the telehealth POS code has been created.

Our requirement for physicians and practitioners to use the telehealth POS code to report that telehealth services were furnished from a distant site would improve payment accuracy and consistency in telehealth claims submission. Currently, for services furnished via telehealth, we have instructed practitioners to report the POS code that would have been reported had the service been furnished in person. However, some practitioners use the POS where they are located when the service is furnished, while others use the POS corresponding to the patient's location.

Under the PFS, the POS code determines whether a service is paid using the facility or non-facility practice expense relative value units (PE RVUs). The facility rate is paid when a service is furnished in a location where Medicare is making a separate facility payment to an entity other than the physician or practitioner that is intended to reflect the facility costs associated with the service (clinical staff, supplies and equipment). We note that in accordance with section 1834(m)(2)(B) of the Act, the payment amount for the telehealth facility fee paid to the originating site is a national fee, paid without geographic or site of service adjustments that generally are made for payments to different kinds of Medicare providers and suppliers. In the case of telehealth services, we believe that facility costs (clinical staff, supplies, and equipment) associated with furnishing the service would generally be incurred by the originating site, where the patient is located, and not by the practitioner at the distant site. The statute requires Medicare to pay a fee to the site that hosts the patient. This is analogous to the circumstances under which the facility PE RVUs are used to pay for services under the PFS. Therefore, we proposed to use the facility PE RVUs to pay for telehealth services reported by physicians or practitioners with the telehealth POS code. We note that there are only three codes on the telehealth list with a difference greater than 1.0 PE RVUs between the facility PE RVUs and the non-facility PE RVUs. We did not anticipate that this proposal would result in a significant change in the total payment for the majority of services on the telehealth list. Moreover, many practitioners already use a facility POS when billing for telehealth services (those that report the POS of the originating site where the beneficiary is located). The policy to use the telehealth POS code for telehealth services would not affect payment for

telehealth services for these practitioners.

The POS code for telehealth would not apply to originating sites billing the facility fee. Originating sites are not furnishing a service via telehealth since the patient is physically present in the facility. Accordingly, the originating site would continue to use the POS code that applies to the type of facility where the patient is located.

We also proposed a change to § 414.22(b)(5)(i)(A) that addresses the PE RVUs used in different settings. These revisions would improve clarity regarding our current policies. Specifically, we proposed to amend this section to specify that the facility PE RVUs are paid for practitioner services furnished via telehealth under § 410.78. In addition, we proposed a change to resolve any potential ambiguity and clarify that payment under the PFS is made at the facility rate (facility PE RVUs) when services are furnished in a facility setting paid by Medicare, including in off-campus provider based departments. As proposed, the regulation reflected the policy being proposed, for CY 2017 only, to pay the physician the nonfacility rate for services furnished in an off-campus provider based department that was not excepted under section 603 of the Bipartisan Budget Act of 2015. Finally, to streamline the existing regulation, we also proposed to delete § 414.32 of our regulation that refers to the calculation of payments for certain services prior to 2002.

The following is summary of the comments we received regarding the proposal to use a POS code for services furnished via telehealth:

Comment: Many commenters supported the proposal to use the POS code for telehealth, indicating that it would clarify and simplify billing requirements, improve payment accuracy and consistency in telehealth claims submissions, and provide more reliable data regarding telehealth services.

Response: We appreciate the support for this proposal.

Comment: One commenter asked us to reconsider the proposal, noting that the AMA's CPT Editorial Panel has adopted a telehealth modifier for those medical services that are currently covered telehealth services by Medicare or other payers, which obviates the need for the POS code.

Response: The POS code was requested by other payers, and we continue to believe that adopting it for use in the Medicare program would provide consistency in reporting and identifying services furnished via telehealth. We have had longstanding HCPCS modifiers for telehealth. While these modifiers were not adopted by CPT, they have been available for use by other payers. Despite the availability of these HCPCS modifiers noting telehealth services, payers have requested creation of the new POS code. Therefore, we do not understand why introduction of a new CPT modifier as opposed to a HCPCS modifier would obviate the need for a POS code. Instead, we agree with other payers that the POS code would provide consistency in reporting and identifying services furnished via telehealth, since it eliminates the need for service-specific rules regarding appropriate POS reporting for telehealth services.

Comment: Another commenter stated that use of the POS code, or originating site restrictions, would place additional administrative barriers for telepsychiatric access.

Response: We note that the POS is a required field on the professional claim, regardless of whether the service is furnished via telehealth. Since a selection needs to be made, we believe that requiring the selection of a specific code is no more burdensome than requiring the claim to specify the POS appropriate to either the setting of the telehealth patient or the setting of the distant site practitioner. The POS code does not entail any new originating site restrictions.

Comment: Various commenters asked for clarification of the following:

- Whether the POS code would replace the GT modifier.
- Whether the description of telehealth as a service furnished via an interactive audio and video telecommunications system applies to the POS code as it does to the GT modifier.
- How to ensure proper payment when the distant site practitioner is at a facility, but the patient is not.

Response: Under current policy, use of the GT and GQ modifiers certifies that the service meets the telehealth requirements, and would continue to be required. The POS code would be used in addition to the GT and GQ modifiers. We did not propose to implement a change in the requirement to use either the GT and GQ modifier because at the time of the proposed rule, we did not know whether the telehealth POS code would be made effective for January 1, 2017. However, because under our proposal the POS code would serve to identify telehealth services furnished under section 1834(m) of the Act via an interactive audio and video telecommunications system, we believe that we should consider eliminating the required use of the GT and GQ telehealth modifiers, and we may revisit this question through future rulemaking. Like the modifiers, use of the POS code certifies that the service meets the telehealth requirements. Distant site providers will be paid using the facility PE RVUs, regardless of their location. The setting of the patient does not affect the payment to the distant site provider.

Comment: Commenters also asked for clarification that the proposal to adopt the telehealth POS relates solely to payment, and not to licensure requirements. The commenter noted that practitioners who furnish telehealth services must adhere to the standard of care and licensure rules, regulations and laws of the state where the patient is located, just as the practitioner would in a traditional face-to-face encounter.

Response: The commenters are correct that the purpose of our POS proposal is to assist in determining proper payment. It will also help us to accurately track telehealth utilization and spending. The proposal to adopt the telehealth POS code has no bearing on state licensure requirements or other state regulations. We appreciate the commenters' request for clarification.

Comment: Several commenters supported the proposal to use the facility PE RVUs for telehealth services. One commenter said paying some telehealth services at non-facility rates creates undesirable financial incentives to prefer telehealth services over services that are furnished in person at the originating site.

Response: We appreciate the support for the proposal and agree with the commenter's articulation regarding the importance of developing payment rates that reflect the relative resource costs of furnishing the services and that do not create unintended financial incentives.

Comment: Many other commenters opposed the proposal. Commenters stated that it would result in lower fees for telehealth services furnished by psychologists. Commenters also stated that PE costs increase for services furnished via telehealth due to the costs of HIPAA-compliant telecommunication equipment.

One commenter remarked that use of a POS code should not be the basis for reducing payments and that many codes would experience a significant payment change. The commenter noted that a 1.0 RVU reduction would result in a $36 payment reduction for the service. One commenter stated CMS should propose budget neutral PE and originating site fees, based on data, for CY 2018. One commenter noted that there are no facility PE RVUs for several codes.

Response: We do not believe that use of the telehealth POS code produces a significant payment change in the vast majority of circumstances. For distant site practitioners who are already paid using the facility PE RVUs and for services where there is no payment difference between the facility and non-facility PE RVUs, there will be no change in payment as a result of the telehealth POS code.

There is utilization data for 56 of the 81 codes on the telehealth list. For these codes, 20 are not paid differently based on site of service, and 27 codes are paid differently by fewer than 0.5 RVUs. There are only three codes on the telehealth list with a difference greater than 1.0 PE RVUs between the facility PE RVUs and the non-facility PE RVUs.

Concerning psychotherapy and psychological testing services, we note that for the vast majority of psychiatric services the difference between the two rates is very small. For example, the difference between the facility and non-facility national rates for 45 minutes of psychotherapy is 0.02 RVUs per service: Less than $1.00. The differences between the facility PE RVUs and non-facility PE RVUS ranges from 0.01–0.03 RVUs for nine of the psychological testing codes on the Medicare telehealth list, and 0.12 RVUs lower for two other codes. We do not consider these reductions significant, nor do we have any evidence that practice expense costs are greater for furnishing such services via telehealth than for furnishing a face-to-face service. Commenters provided no evidence that practice expense costs for services furnished via telehealth are greater, due to the requirement for HIPAA-compliant equipment, than for furnishing in-person services, even in the facility setting.

There are a few HCPCS codes on the telehealth list that do not have a calculated facility PE RVU. For these services, the non-facility PE RVUs would serve as a proxy, and therefore, there would be no payment change for these codes.

Finally, we note that the originating site facility fee is established by statute (section 1834(m)(2)(B) of the Act) and is not affected by this proposal.

We note that we believe that payment using the facility PE RVUs for telehealth services is consistent our belief that the direct practice expense costs are generally incurred at the location of the beneficiary and not by the distant site practitioner. After reviewing the current list of telehealth services in the context of the comments, we continue to believe this is accurate.

After consideration of the public comments received, we are finalizing our proposal to use the POS code for telehealth and to use the facility PE RVUs to pay for telehealth service reported by physicians or practitioners with the telehealth POS code for CY 2017. However, we understand commenters' concerns and will consider the concerns regarding use of the facility payment rate as we monitor utilization of telehealth services. We will welcome information from stakeholders regarding any potential unintended consequences of the payment policy. We will also consider the applicability of the facility rate to any codes newly added to the list of telehealth services.

We have updated the POS code list on our Web site at *https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html* to include POS 02: Telehealth (Descriptor: The location where health services and health related services are provided or received, through telecommunication technology). The new code will be used for services furnished on or after January 1, 2017.

We are finalizing proposed revisions to our regulation at § 414.22(b)(5)(i)(A) that addresses the PE RVUs used in different settings as described above, except that we are not finalizing the proposed change that would have resulted in the payment of the nonfacility rate for services furnished in off-campus provider based departments that are not excepted under Section 603 of the Bipartisan Budget Act of 2015 since we are finalizing that payments to such non-excepted PBDs will be made under the PFS. In a separate interim final rule with comment period issued in conjunction with the CY 2017 OPPS/ASC final rule with comment period (see Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program; Establishment of Physician Fee Schedule Payment Rates for Nonexcepted Items and Services Billed by Applicable Departments of a Hospital), we are finalizing other payment policies for nonexcepted items and services furnished by such non-excepted off-campus provider based departments. Accordingly, physicians furnishing services in such provider-based departments will continue to be paid the facility rate. We are also finalizing the proposal to delete § 414.32 of our regulation that refers to the calculation of payments for certain services prior to 2002.

We remind the public that we are currently soliciting requests to add services to the list of Medicare telehealth services. To be considered during PFS rulemaking for CY 2018, these requests must be submitted and received by December 31, 2016. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

5. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act establishes the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002, at $20.00. For telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The originating site facility fee for telehealth services furnished in CY 2016 is $25.10. The MEI increase for 2017 is 1.2 percent and is based on the most recent historical update through 2016Q2 (1.6 percent), and the most recent historical MFP through calendar year 2015 (0.4 percent). Therefore, for CY 2017, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or $25.40. The Medicare telehealth originating site facility fee and the MEI increase by the applicable time period is shown in Table 6.

TABLE 6—THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE AND MEI

[Increase by the applicable time period]

Time period	MEI increase	Facility fee
10/01/2001–12/31/2002	N/A	$20.00
01/01/2003–12/31/2003	3.0	20.60
01/01/2004–12/31/2004	2.9	21.20
01/01/2005–12/31/2005	3.1	21.86
01/01/2006–12/31/2006	2.8	22.47
01/01/2007–12/31/2007	2.1	22.94
01/01/2008–12/31/2008	1.8	23.35
01/01/2009–12/31/2009	1.6	23.72

TABLE 6—THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE AND MEI—Continued

[Increase by the applicable time period]

Time period	MEI increase	Facility fee
01/01/2010–12/31/2010	1.2	24.00
01/01/2011–12/31/2011	0.4	24.10
01/01/2012–12/31/2012	0.6	24.24
01/01/2013–12/31/2013	0.8	24.43
01/01/2014–12/31/2014	0.8	24.63
01/01/2015–12/31/2015	0.8	24.83
01/01/2016–12/31/2016	1.1	25.10
01/01/2017–12/31/2017	1.2	25.40

D. 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.B. of this final 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 the 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 also 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 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 over 1,671 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, we finalized our policy to consolidate the review of physician work and PE at the same time (76 FR 73055 through 73958), and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 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, we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes (73 FR 38589). In the fourth Five-Year Review (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.

3. Validating RVUs of Potentially Misvalued Codes

Section 1848(c)(2)(L) of the Act requires the Secretary to establish a formal process to validate RVUs under the PFS. The Act specifies that the validation process may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work. The Secretary is directed, as part of the validation, to validate a sampling of the work RVUs of codes identified through any of the 16 categories of potentially misvalued codes specified in section 1848(c)(2)(K)(ii) of the Act. Furthermore, the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes, including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the validation of RVUs of services.

In the CY 2011 PFS proposed rule (75 FR 40068) and CY 2012 PFS proposed rule (76 FR 42790), we solicited public comments on possible approaches, methodologies, and data sources that we should consider for a validation process. A summary of the comments along with our responses are included in the CY 2011 PFS final rule with comment period (75 FR 73217) and the CY 2012 PFS final rule with comment period (73054 through 73055).

We contracted with two outside entities to develop validation models for RVUs.

Given the central role of time in establishing work RVUs and the concerns that have been raised about the current time values used in rate setting, we contracted with the Urban Institute to develop empirical time estimates based on data collected from several health systems with multispecialty group practices. The Urban Institute collected data by directly observing the delivery of services and through the use of electronic health records for services selected by the contractor in consultation with CMS and is using this data to produce objective time estimates. We expect the final Urban Institute report will be made available on the CMS Web site later this year.

The second contract is with the RAND Corporation, which used available data to build a validation model to predict work RVUs and the individual components of work RVUs, time and intensity. The model design was informed by the statistical methodologies and approach used to develop the initial work RVUs and to identify potentially misvalued procedures under current CMS and RUC processes. RAND consulted with a technical expert panel on model design issues and the test results. The RAND report is available under downloads on the Web site for the CY 2015 PFS final rule with comment period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1612-FC.html*.

After posting RAND's report on the models and results on our Web site, we received comments indicating that the models did not adequately address global surgery services due to the lack of available data on included visits. Therefore, we modified the RAND contract to include the development of G-codes that could be used to collect data about post-surgical follow-up visits on Medicare claims to meet the requirements in section 1848(c)(8)(B) of the Act regarding collection of data on global services. Our discussion related to this data collection requirement is in section II.D.6. Also, the data from this project would provide information that would allow the time for these services to be included in the model for validating RVUs.

4. CY 2017 Identification and Review of Potentially Misvalued Services

a. 0-Day Global Services That Are Typically Billed With an Evaluation and Management (E/M) Service With Modifier 25

Because routine E/M is included in the valuation of codes with 0-, 10-, and 90-day global periods, Medicare only makes separate payment for E/M services that are provided in excess of those considered included in the global procedure. In such cases, the physician would report the additional E/M service with Modifier 25, which is defined as a significant, separately identifiable E/M service performed by the same physician on the day of a procedure above and beyond other services provided or beyond the usual preservice and postservice care associated with the procedure that was performed. Modifier 25 allows physicians to be paid for E/M services that would otherwise be denied as bundled.

In reviewing misvalued codes, both CMS and the RUC have often considered how frequently particular codes are reported with E/M codes to account for potential overlap in resources. Some stakeholders have expressed concern with this policy especially with regard to the valuation of 0-day global services that are typically billed with a separate E/M service with the use of Modifier 25. For example, when we established our valuation of the osteopathic manipulative treatment (OMT) services, described by CPT codes 98925–98929, we did so with the understanding that these codes are usually reported with E/M codes.

For our CY 2017 proposal (81 FR 46187), we investigated Medicare claims data for CY 2015 and found that 19 percent of the codes that described 0-day global services were billed over 50 percent of the time with an E/M with Modifier 25. Since routine E/M is included in the valuation of 0-day global services, we believed that the routine billing of separate E/M services may have indicated a possible problem with the valuation of the bundle, which is intended to include all the routine care associated with the service.

In the proposed rule (81 FR 46187), we stated that reviewing the procedure codes typically billed with an E/M with Modifier 25 may be one avenue to appropriate valuation for these services. Therefore, we developed and proposed a screen for potentially misvalued codes that identified 0-day global codes billed with an E/M 50 percent of the time or more, on the same day of service, with the same physician and same beneficiary. We included a list of codes with total allowed services greater than 20,000. There are 83 codes that met the proposed criteria for the screen and were proposed as potentially misvalued. We also sought comment regarding additional ways to address appropriate valuations for all services that are typically billed with an E/M with Modifier 25.

The following is the summary of the comments we received.

Comment: Several commenters disagreed with CMS' assertion that there is a possible valuation problem with the bundle when an E/M with Modifier 25 is typically reported on the same day of service as a 0-day global procedure. Commenters stated that billing an E/M with Modifier 25 pays physicians for the justifiable and appropriate services they render to patients; allowing for a patient-centered approach to care. Some commenters considered the possibility that there could be fraudulent billing practices when reporting an E/M with Modifier 25 and a few offered various solutions for rectifying the problem from a program integrity perspective. For example, one commenter suggested that further education on the appropriate use of Modifier 25 or penalty for misuse would be effective alternatives to combat inappropriate billing while another commenter suggested investigating the diagnosis coding for services.

Commenters overwhelmingly opposed any change to billing policies or standard valuation for 0-day services that are billed with an E/M with Modifier 25.

Response: We appreciate commenters' perspective on this issue. While we understand the commenters' views, since routine E/M is included in the valuation of 0-day global services we continue to believe that the routine billing of separate E/M services may still indicate a possible problem with the valuation of the global period or the assignment of the global period for particular codes, given that the period is intended to include all the routine care associated with the service. As discussed below, we are finalizing some of the 0-day global services as potentially misvalued. We will also continue to consider this issue for future rulemaking.

Comment: Several commenters expressed appreciation for the identification of an objective screen and reasonable query. While some commenters were accepting of the screen as proposed, others stated their preference for the screen to be withdrawn entirely or limited in scope, with some commenters suggesting the screen be limited to the codes that met the criteria and for which the overlap had not already been considered by the RUC in developing recommended values. Several thousand commenters suggested withdrawing or limiting the scope of this screen, particularly as it pertains to the OMT codes.

Response: Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(K) of the Act identifies several categories of services as potentially misvalued, including codes for services where there may be efficiencies when a service is furnished at the same time as other services, along with codes as determined appropriate by the Secretary. Based on the comments received, we understand that stakeholders would have us identify as potentially misvalued only those individual codes with obvious overlapping resource costs when typically reported with an E/M, rather than consider the issue of misvaluation of the global period more broadly. In response to these comments, we are finalizing the use of our screen for 0-day global services that are typically billed with an E/M with Modifier 25 as a mechanism for identifying services that are potentially misvalued.

Because we recognize that the primary purpose in displaying lists of misvalued codes in rulemaking has been to seek recommendations regarding appropriate valuation from stakeholders, including the RUC, for 2017 we are only identifying the services for which we believe there might be the kind of misvaluation the RUC and the medical specialty societies recognize. Based on the comments from these organizations, we believe that for codes reviewed in the past 5 years, the RUC has already addressed that kind of misvaluation. In other words, commenters have made clear that external review of these services is likely to be limited to clear overlap in resource costs, but will not address the broader concerns we have about developing rates for services that include routine E/M when evaluation and management is also routinely separately reported. As a result, we will continue to consider that issue for future rulemaking. We note that we are required under statute to improve the valuation of the 10- and 90-day global periods, and therefore, we will consider this issue in that context, as well.

Comment: While some commenters supported our review of the 83 codes that were proposed as potentially

misvalued through the screen, the majority of commenters, including the RUC, stated that the codes detailed in Table 7 did not meet the criteria for the screen because they were either reviewed in the last 5 years and/or are not typically reported with an E/M, and therefore, should be removed. While commenters largely disagreed on the list of proposed codes, most agreed that the services they believed met the screen criteria should be reviewed.

TABLE 7—CODES REQUESTED TO BE REMOVED FROM THE LIST OF POTENTIALLY MISVALUED SERVICES

HCPCS	Long descriptor
11000	Removal of inflamed or infected skin, up to 10% of body surface.
11100	Biopsy of single growth of skin and/or tissue.
11300	Shaving of 0.5 centimeters or less skin growth of the trunk, arms, or legs.
11301	Shaving of 0.6 centimeters to 1.0 centimeters skin growth of the trunk, arms, or legs.
11302	Shaving of 1.1 to 2.0 centimeters skin growth of the trunk, arms, or legs.
11305	Shaving of 0.5 centimeters or less skin growth of scalp, neck, hands, feet, or genitals.
11306	Shaving of 0.6 centimeters to 1.0 centimeters skin growth of scalp, neck, hands, feet, or genitals.
11307	Shaving of 1.1 to 2.0 centimeters skin growth of scalp, neck, hands, feet, or genitals.
11310	Shaving of 0.5 centimeters or less skin growth of face, ears, eyelids, nose, lips, or mouth.
11311	Shaving of 0.6 centimeters to 1.0 centimeters skin growth of face, ears, eyelids, nose, lips, or mouth.
11312	Shaving of 1.1 to 2.0 centimeters skin growth of face, ears, eyelids, nose, lips, or mouth.
11740	Removal of blood accumulation between nail and nail bed.
11900	Injection of up to 7 skin growths.
11901	Injection of more than 7 skin growths.
12001	Repair of wound (2.5 centimeters or less) of the scalp, neck, underarms, trunk, arms and/or legs.
12002	Repair of wound (2.6 to 7.5 centimeters) of the scalp, neck, underarms, genitals, trunk, arms and/or legs.
12004	Repair of wound (7.6 to 12.5 centimeters) of the scalp, neck, underarms, genitals, trunk, arms and/or legs.
12011	Repair of wound (2.5 centimeters or less) of the face, ears, eyelids, nose, lips, and/or mucous membranes.
12013	Repair of wound (2.6 to 5.0 centimeters) of the face, ears, eyelids, nose, lips, and/or mucous membranes.
17250	Application of chemical agent to excessive wound tissue.
20550	Injections of tendon sheath, ligament, or muscle membrane.
20552	Injections of trigger points in 1 or 2 muscles.
20553	Injections of trigger points in 3 or more muscles.
20600	Aspiration and/or injection of small joint or joint capsule.
20604	Arthrocentesis, aspiration and/or injection, small joint or bursa (eg, fingers, toes); with ultrasound guidance, with permanent recording and reporting.
20605	Aspiration and/or injection of medium joint or joint capsule.
20606	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting.
20610	Aspiration and/or injection of large joint or joint capsule.
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting.
20612	Aspiration and/or injection of cysts.
29125	Application of non-moveable, short arm splint (forearm to hand).
29515	Application of short leg splint (calf to foot).
30901	Simple control of nose bleed.
30903	Complex control of nose bleed.
31231	Diagnostic examination of nasal passages using an endoscope.
31238	Control of nasal bleeding using an endoscope.
31500	Emergent insertion of breathing tube into windpipe cartilage using an endoscope.
31575	Diagnostic examination of voice box using flexible endoscope.
31579	Examination to assess movement of vocal cord flaps using an endoscope.
31645	Aspiration of lung secretions from lung airways using an endoscope.
32551	Removal of fluid from between lung and chest cavity, open procedure.
32554	Removal of fluid from chest cavity.
40490	Biopsy of lip.
46600	Diagnostic examination of the anus using an endoscope.
51701	Insertion of temporary bladder catheter.
51702	Insertion of indwelling bladder catheter.
51703	Insertion of indwelling bladder catheter.
56605	Biopsy of external female genitals.
57150	Irrigation of vagina and/or application of drug to treat infection.
57160	Fitting and insertion of vaginal support device.
58100	Biopsy of uterine lining.
64418	Injection of anesthetic agent, collar bone nerve.
65222	Removal of foreign body, external eye, cornea with slit lamp examination.
67810	Biopsy of eyelid.
67820	Removal of eyelashes by forceps.
68200	Injection into conjunctiva.
69100	Biopsy of ear.
69200	Removal of foreign body from ear canal.
69210	Removal of impact ear wax, one ear.
69220	Removal of skin debris and drainage of mastoid cavity.
92511	Examination of the nose and throat using an endoscope.
92941	Insertion of stent, removal of plaque and/or balloon dilation of coronary vessel during heart attack, accessed through the skin.
92950	Attempt to restart heart and lungs.

TABLE 7—CODES REQUESTED TO BE REMOVED FROM THE LIST OF POTENTIALLY MISVALUED SERVICES—Continued

HCPCS	Long descriptor
98925	Osteopathic manipulative treatment to 1–2 body regions.
98926	Osteopathic manipulative treatment to 3–4 body regions.
98927	Osteopathic manipulative treatment to 5–6 body regions.
98928	Osteopathic manipulative treatment to 7–8 body regions.
98929	Osteopathic manipulative treatment to 9–10 body regions.

Response: After considering the comments received, we are significantly reducing the number of codes identified as potentially misvalued. We agree with commenters that the majority of the codes that we are not finalizing have been recently reviewed. Due to a drafting error in the proposed rule, we stated that we had exempted codes that had been reviewed in the past 5 years. While that exclusion has been standard for many other misvalued code screens, we did not intend to apply it in this case, given our concerns with the valuation of the global period when E/M visits are routinely reported at the same time. As displayed in the proposed rule, the list of codes reflected our intention to include codes that have been recently reviewed. Regardless, we understand based on comments that any review by stakeholders for recently reviewed codes would be likely to result in similar valuation. Therefore, we do not believe that we should include codes reviewed in the past 5 years on this list of misvalued codes, given the limited nature of the likely review. Regarding the accuracy of which of the codes are typically reported with E/M codes, we note that our review included analysis was based on more recent, full claims data than had yet been made public. In the interest of transparency, we are finalizing the list of services based on the publically available data.

TABLE 8—LIST OF POTENTIALLY MISVALUED SERVICES IDENTIFIED THROUGH THE SCREEN FOR 0-DAY GLOBAL SERVICES THAT ARE TYPICALLY BILLED WITH AN EVALUATION AND MANAGEMENT (E/M) SERVICE WITH MODIFIER 25

HCPCS	Long descriptor
11755	Biopsy of finger or toe nail.
20526	Injection of carpal tunnel.
20551	Injections of tendon attachment to bone.
20612	Aspiration and/or injection of cysts.
29105	Application of long arm splint (shoulder to hand).
29540	Strapping of ankle and/or foot.
29550	Strapping of toes.
43760	Change of stomach feeding, accessed through the skin.
45300	Diagnostic examination of rectum and large bowel using an endoscope.
57150	Irrigation of vagina and/or application of drug to treat infection.
57160	Fitting and insertion of vaginal support device.
58100	Biopsy of uterine lining.
64405	Injection of anesthetic agent, greater occipital nerve.
64455	Injections of anesthetic and/or steroid drug into nerve of foot.
65205	Removal of foreign body in external eye, conjunctiva.
65210	Removal of foreign body in external eye, conjunctiva or sclera.
67515	Injection of medication or substance into membrane covering eyeball.
G0168	Wound closure utilizing tissue adhesive(s) only.
G0268	Removal of impacted cerumen (one or both ears) by physician on same date of service as audiologic function testing.

b. End-Stage Renal Disease Home Dialysis Services (CPT Codes 90963 Through 90970)

In the CY 2004 PFS final rule with comment period (68 FR 63216), we established new Level II HCPCS G-codes for end-stage renal disease (ESRD) services and established payment for those codes through monthly capitation payment (MCP) rates. For ESRD center-based patients, payment for the G-codes varied based on the age of the beneficiary and the number of face-to-face visits furnished each month (for example, 1 visit, 2–3 visits and 4 or more visits). We believed that many physicians would provide 4 or more visits to center-based ESRD patients and a small proportion will provide 2–3 visits or only one visit per month. Under the MCP methodology, to receive the highest payment, a physician would have to provide at least four ESRD-related visits per month. However, payment for home dialysis MCP services only varied by the age of beneficiary. Although we did not initially specify a frequency of required visits for home dialysis MCP services, we stated that we expect physicians to provide clinically appropriate care to manage the home dialysis patient.

The CPT Editorial Panel created new CPT codes to replace the G-codes for monthly ESRD-related services, and we accepted the new codes for use under the PFS in CY 2009. The CPT codes created were 90963–90966 for monthly ESRD-related services for home dialysis patient and CPT codes 90967–90970 for dialysis with less than a full month of services.

In a GAO report titled ''END-STAGE RENAL DISEASE Medicare Payment Refinements Could Promote Increased Use of Home Dialysis'' dated October 2015, *http://www.gao.gov/products/GAO-16-125*, the GAO stated that experts and stakeholders they interviewed indicated that home dialysis could be clinically appropriate for at least half of patients. Also, at a meeting in 2013, the chief medical officers of 14 dialysis facility chains jointly estimated that a realistic target for home dialysis would be 25 percent of dialysis patients. The GAO noted that CMS data showed that about 10 percent of adult Medicare dialysis patients use home dialysis as of March 2015.

In the report, the GAO noted that CMS intended for the existing payment structure to create an incentive for physicians to prescribe home dialysis, because the monthly payment rate for managing the dialysis care of home patients, which requires a single in-person visit, was approximately equal to the rate for managing and providing two to three visits to ESRD center-based patients. However, GAO found that, in 2013, the rate of $237 for managing home patients was lower than the average payment of $266 and maximum payment of $282 for managing ESRD center-based patients. The GAO stated that this difference in payment rates may discourage physicians from prescribing home dialysis.

Physician associations and other physicians GAO interviewed stated that the visits with home patients are often longer and more comprehensive than in-center visits; this is in part because physicians may conduct visits with individual home patients in a private setting, but they may be able to more easily visit multiple in-center patients on a single day as they receive dialysis. The physician associations GAO interviewed also said that they may spend a similar amount of time outside of visits to manage the care of home patients and that they are required to provide at least one visit per month to perform a complete assessment of the patient.

It is important to note that, as stated in the CY 2011 PFS final rule with comment period (75 FR 73296), we believe that furnishing monthly face-to-face visits is an important component of high quality medical care for ESRD patients being dialyzed at home and generally would be consistent with the current standards of medical practice. However, we also acknowledged that extenuating circumstances may arise that make it difficult for the MCP physician (or NPP) to furnish a visit to a home dialysis patient every month. Therefore, we allow Medicare contractors the discretion to waive the requirement for a monthly face-to-face visit for the home dialysis MCP service on a case-by-case basis, for example, when the MCP physician's (or NPP's) notes indicate that the MCP physician (or NPP) actively and adequately managed the care of the home dialysis patient throughout the month.

The GAO recommended, and we agreed, that CMS examine Medicare policies for monthly payments to physicians to manage the care of dialysis patients and revise them if necessary to ensure that these policies are consistent with our goal of encouraging the use of home dialysis among patients for whom it is appropriate. Therefore, we proposed to identify CPT codes 90963 through 90970 as potentially misvalued codes based on the volume of claims submitted for these services relative to those submitted for facility ESRD services.

The following is summary of the comments we received.

Comment: Commenters supported the proposal to identify these codes as potentially misvalued and supported CMS' goal of encouraging the use of home dialysis among patients for whom it is appropriate. Some commenters suggested we establish parity between payment for four ESRD-related visits per month for in-center dialysis patients and payment for the care of home dialysis patients for an entire month. One commenter cautioned that CMS should also consider factors other than payment that play a critical role in whether a patient decides to use a home dialysis modality as outlined in a recent GAO report and requested that CMS work closely with nephrologists on this issue. One commenter encouraged CMS to focus on incentives for the adult population separately from pediatrics as they see no benefit from reanalysis of the pediatric home and daily dialysis CPT codes 90963–90965 and 90967–90969.

Response: We appreciate all of the comments and agree that CPT codes 90963 through 90970 should be identified as potentially misvalued. After considering the comments, we are finalizing the addition of CPT codes 90963 through 90970 to the list of potentially misvalued codes. We will also continue to consider these issues for future rulemaking.

c. Direct PE Input Discrepancies

i. Appropriate Direct PE Inputs Involved in Procedures Involving Endoscopes

In the proposed rule (81 FR 46190), we stated that stakeholders had raised concerns about potential inconsistencies with the inputs and the prices related to endoscopic procedures in the direct PE database. Upon review, we noted that there are 45 different pieces of endoscope related-equipment and 25 different pieces of endoscope related-supplies that are currently associated with these services. Relative to other kinds of equipment items in the direct PE input, these items are much more varied and used for many fewer services. Given the frequency with which individual codes can be reviewed and the importance of standardizing inputs for purposes of maintaining relativity across PFS services, we believed that this unusual degree of variation was likely to result in code misvaluation. To facilitate efficient review of this particular kind of misvaluation, and because we believed that stakeholders would prefer the opportunity to contribute to such standardization, we requested that stakeholders like the AMA RUC review and make recommendations on the appropriate endoscopic equipment and supplies typically provided in all endoscopic procedures for each anatomical body region, along with their appropriate prices.

The following is summary of the comments we received.

Comment: Many commenters stated that the RUC is the appropriate resource for the review of appropriate direct PE inputs involved in procedures involving endoscopes and urged CMS to work with the RUC to address this issue. Additionally, the RUC stated that due to the complexity of this issue and the need to incorporate input from various specialty societies that the RUC planned to form a workgroup of the PE subcommittee to review the issue.

Response: We appreciate the comments and will review any recommendation provided to us by the RUC for use in future rulemaking, consistent with our normal review processes.

ii. Appropriate Direct PE Inputs in the Facility Post-Service Period When Post-Operative Visits Are Excluded

In the proposed rule (81 FR 46190), we identified a potential inconsistency in instances where there are direct PE inputs included in the facility postservice period even though post-operative visit is not included in a service. We identified 13 codes affected by this issue and stated that we were unclear if the discrepancy was caused by inaccurate direct PE inputs or inaccurate post-operative data in the work time file. We requested that stakeholders including the AMA RUC review these discrepancies and provide their recommendations on the appropriate direct PE inputs for the codes.

The following is summary of the comments we received.

Comment: The RUC stated that for CPT codes 21077 (Impression and preparation of eye socket prosthesis), 21079 (Impression and custom preparation of temporary oral prosthesis), 21080 (Impression and custom preparation of permanent oral prosthesis), 21081 (Impression and custom preparation of lower jaw bone prosthesis), 21082 (Impression and custom preparation of prosthesis for

roof of mouth enlargement), 21083 (Impression and custom preparation of roof of mouth prosthesis), and 21084 (Impression and custom preparation of speech aid prosthesis) the practice expense time in the postservice period in the facility setting is completely distinct from the physician post-operative visit and that time must be accounted for the manufacture and fitting of the prosthetics. The RUC stated that the following codes all had inaccurate post-operative data in the work time file and provided recommendations on appropriate post-operative visits: CPT codes 28636 (Insertion of hardware to foot bone dislocation with manipulation, accessed through the skin), 28666 (Insertion of hardware to toe joint dislocation with manipulation, accessed through the skin), 43652 (Incision of vagus nerves of stomach using an endoscope), 47570 (Connection of gall bladder to bowel using an endoscope), and 66986 (Exchange of lens prosthesis). Additionally, another commenter stated that CPT code 46900 (Chemical destruction of anal growths) also had inaccurate post-operative data in the work time file and provided a recommendation on the appropriate post-operative visit.

Response: We thank stakeholders for their comments. We will review the recommendations provided to us by the AMA RUC and other commenters and will consider for future rulemaking, consistent with our normal review processes.

d. Insertion and Removal of Drug Delivery Implants—CPT Codes 11981 and 11983

In the proposed rule (81 FR 46190), we stated that stakeholders had urged CMS to create new coding describing the insertion and removal of drug delivery implants for buprenorphine hydrochloride, formulated as a 4 rod, 80 mg, long acting subdermal drug implant for the treatment of opioid addiction. The stakeholders suggested that current coding describing insertion and removal of drug delivery implants was too broad and that new coding was needed to account for specific additional resource costs associated with particular treatment. We identified existing CPT codes 11981 (Insertion, non-biodegradable drug delivery implant), 11982 (Removal, non-biodegradable drug delivery implant), and 11983 (Removal with reinsertion, non-biodegradable drug delivery implant) as potentially misvalued codes and sought comment and information regarding whether the current resource inputs in work and practice expense for the codes appropriately accounted for variations in the service relative to which devices and related drugs are inserted and removed.

The following is summary of the comments we received.

Comment: One commenter stated that CMS should create distinct codes and payment levels for a four-rod implant as opposed to the one-rod implant detailed in CPT codes 11981–11983. In contrast, another commenter stated that the identified codes adequately describe the work and practice expense for drug implant delivery and removal services. Additionally, another commenter stated the codes should be removed from the potentially misvalued list. The RUC stated that a coding change proposal had been submitted for the services under the CPT process and that the RUC anticipated providing relevant recommendations for CY 2018.

Response: We thank stakeholders for their comments. We will review new coding and recommended valuations for future rulemaking, consistent with our normal review processes.

5. Valuing Services That Include Moderate Sedation as an Inherent Part of Furnishing the Procedure

The CPT manual identifies more than 400 diagnostic and therapeutic procedures (listed in Appendix G) for which the CPT Editorial Panel has determined that moderate sedation is an inherent part of furnishing the procedure. In developing RVUs for these services, we include the relative resources associated with moderate sedation in the valuation since the CPT codes include moderate sedation as an inherent part of the procedure. Therefore, practitioners only report the procedure code when furnishing the service. Endoscopic procedures constitute a significant portion of the services identified in Appendix G. In the CY 2015 PFS proposed rule (79 FR 40349), we noted that it appeared that practice patterns for endoscopic procedures were changing, with anesthesia increasingly being separately reported for these procedures, meaning that the relative resources associated with sedation were no longer incurred by the practitioner reporting the Appendix G procedure. We indicated that, in order to reflect apparent changes in medical practice, we were considering establishing a uniform approach to the appropriate valuation of all Appendix G services for which moderate sedation is no longer inherent, rather than addressing the issue at the procedure level as individual codes are revalued. We solicited public comment on approaches to the appropriate valuation of these services.

In the CY 2016 PFS proposed rule (80 FR 41707), we again solicited public comment and recommendations on approaches to address the appropriate valuation of moderate sedation related to Appendix G services. Following our comment solicitation, the CPT Editorial Panel created CPT codes for separately reporting moderate sedation services in association with the elimination of Appendix G from the CPT manual for CY 2017. This coding change would provide for payment for moderate sedation services only in cases where they are furnished. In addition to providing recommended values for the new codes used to separately report moderate sedation, the RUC provided a methodology for revaluing all services previously identified in Appendix G, without moderate sedation, in order to make appropriate corresponding adjustments for the procedural services. The RUC recommended this methodology to address moderate sedation valuation generally instead of recommending that it be addressed as individual codes are reviewed. The RUC's recommended methodology would remove work RVUs for moderate sedation from Appendix G codes based on a code-level assessment of whether the procedures are typically furnished to straightforward patients or more difficult patients. Based on its recommended methodology, the RUC recommended removal of fewer RVUs from each of the procedural services than it recommended for valuing the moderate sedation services. If we were to use the RUC-recommended values for both the moderate sedation codes and the Appendix G procedural codes without refinement, overall payments for these procedures, when moderate sedation is furnished, would increase relative to the current payment.

We direct readers to section II.L. of this final rule, which includes more detail regarding our valuation of the new moderate sedation codes, our methodology for revaluation of the procedural codes previously identified in Appendix G, and discussion and responses to the public comments we received regarding our proposal. We believe that the RVUs assigned under the PFS should reflect the overall relative resources of PFS services, regardless of how many codes are used to report the services. Therefore, our methodology for valuation of Appendix G procedural services maintains current resource assumptions for the procedures when furnished with moderate sedation and redistributes the RVUs associated with moderate sedation (previously

included in the Appendix G procedural codes) to other PFS services. We believe that this methodology for revaluation of Appendix G services without moderate sedation is consistent with our general principle that the overall relative resources for the procedures do not change based solely on changes in coding.

We also noted in the CY 2017 PFS proposed rule that stakeholders presented information to CMS regarding specialty group survey data for physician work. The stakeholders shared survey results for physician work involved in furnishing moderate sedation that demonstrated a significant bimodal distribution between procedural services furnished by gastroenterologists (GI) and procedural services furnished by other specialties. Since we believe that gastroenterologists furnish the highest volume of services previously identified in Appendix G, and services primarily furnished by gastroenterologists prompted the concerns that led to our identification of changes in medical practice and potentially duplicative payment for these codes, we have addressed the variations between GI and other specialties in our review of the new moderate sedation CPT codes and their recommended values. We again direct readers to section II.L. of this final rule where we discuss our establishment of an endoscopy-specific moderate sedation G-code that augments the new CPT codes for moderate sedation, the public comments we received, and our finalized valuations reflecting the differences in the physician survey data between GI and other specialties.

6. Collecting Data on Resources Used in Furnishing Global Services

a. Background

(1) Current Payment Policy for Global Packages

Under the PFS, certain services, such as surgery, are valued and paid for as part of global packages that include the procedure and the services typically furnished in the periods immediately before and after the procedure. For each of these global packages, we establish a single PFS payment that includes payment for particular services that we assume to be typically furnished during the established global period. There are three primary categories of global packages that are labeled based on the number of post-operative days included in the global period: 0-day; 10-day; and 90-day. The 0-day global packages include the surgical procedure and the pre-operative and post-operative services furnished by the physician on the day of the service. The 10-day global packages include these services and, in addition, visits related to the procedure during the 10 days following the day of the procedure. The 90-day global packages include the same services as the 0-day global codes plus the pre-operative services furnished one day prior to the procedure and post-operative services during the 90 days immediately following the day of the procedure. Section 40.1 of Chapter 12 of the Claims Processing Manual (Pub. 100–04) defines the global surgical package to include the following services related to the surgery when furnished during the global period by the same physician or another practitioner in the same group practice:

- *Pre-operative Visits:* Pre-operative visits after the decision is made to operate beginning with the day before the day of surgery for major procedures and the day of surgery for minor procedures;
- *Intra-operative Services:* Intra-operative services that are normally a usual and necessary part of a surgical procedure;
- *Complications Following Surgery:* All additional medical or surgical services required of the surgeon during the post-operative period of the surgery because of complications that do not require additional trips to the operating room;
- *Post-operative Visits:* Follow-up visits during the post-operative period of the surgery that are related to recovery from the surgery;
- *Post-surgical Pain Management:* By the surgeon; and
- *Miscellaneous Services:* Items such as dressing changes; local incisional care; removal of operative pack; removal of cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints; insertion, irrigation and removal of urinary catheters, routine peripheral intravenous lines, nasogastric and rectal tubes; and changes and removal of tracheostomy tubes.

In the CY 2015 PFS proposed and final rules we extensively discussed the problems with accurate valuation of 10- and 90-day global packages. Our concerns included the fact that we do not use actual data on services furnished to update the rates, questions regarding the accuracy of our current assumptions about typical services, whether we will be able to adjust values on a regular basis to reflect changes in the practice of medicine and health care delivery, and how our global payment policies affect what services are actually furnished (79 FR 67582 through 67585). In finalizing a policy to transform all 10- and 90-day global codes to 0-day global codes in CY 2017 and CY 2018, respectively, to improve the accuracy of valuation and payment for the various components of global packages, including pre- and post-operative visits and the procedure itself, we stated that we were adopting this policy because it is critical that PFS payment rates be based upon RVUs that reflect the relative resources involved in furnishing the services. We also stated our belief that transforming all 10- and 90-day global codes to 0-day global packages would:

- Increase the accuracy of PFS payment by setting payment rates for individual services that more closely reflect the typical resources used in furnishing the procedures;
- Avoid potentially duplicative or unwarranted payments when a beneficiary receives post-operative care from a different practitioner during the global period;
- Eliminate disparities between the payment for E/M services in global periods and those furnished individually;
- Maintain the same-day packaging of pre- and post-operative physicians' services in the 0-day global packages; and
- Facilitate the availability of more accurate data for new payment models and quality research.

(2) Data Collection & Revaluation of Global Packages Required by MACRA

Section 523(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015) added section 1848(c)(8)(A) of the Act, which prohibits the Secretary from implementing the policy, described above, that would have transformed all 10-day and 90-day global surgery packages to 0-day global packages.

Section 1848(c)(8)(B) of the Act, which was also added by section 523(a) of the MACRA, requires us to collect data to value surgical services. Section 1848(c)(8)(B)(i) of the Act requires us to develop, through rulemaking, a process to gather information needed to value surgical services from a representative sample of physicians, and requires that the data collection begin no later than January 1, 2017. The collected information must include the number and level of medical visits furnished during the global period and other items and services related to the surgery and furnished during the global period, as appropriate. This information must be reported on claims at the end of the global period or in another manner specified by the Secretary. Section 1848(c)(8)(B)(ii) of the Act requires that,

every 4 years, we reassess the value of this collected information; and allows us to discontinue the collection of this information if the Secretary determines that we have adequate information from other sources to accurately value global surgical services. Section 1848(c)(8)(B)(iii) of the Act specifies that the Inspector General shall audit a sample of the collected information to verify its accuracy. Section 1848(c)(9) of the Act (added by section 523(b) of the MACRA) authorizes the Secretary, through rulemaking, to delay up to 5 percent of the PFS payment for services for which a physician is required to report information under section 1848(c)(8)(B)(i) of the Act until the required information is reported.

Section 1848(c)(8)(C) of the Act, which was also added by section 523(a) of the MACRA, requires that, beginning in CY 2019, we must use the information collected as appropriate, along with other available data, to improve the accuracy of valuation of surgical services under the PFS.

(3) Public Input

As noted above, section 1848(c)(8)(C) of the Act mandates that we use the collected data to improve the accuracy of valuation of surgery services beginning in 2019. We described in the CY 2015 PFS final rule (79 FR 67582 through 67591) the limitations and difficulties involved in the appropriate valuation of the global packages, especially when the resources and the related values assigned to the component services are not defined. To gain input from stakeholders on implementation of this data collection, we sought comment on various aspects of this task in the CY 2016 proposed rule (80 FR 41707 through 41708). We solicited comments from the public regarding the kinds of auditable, objective data (including the number and type of visits and other services furnished during the post-operative period by the practitioner furnishing the procedure) needed to increase the accuracy of the valuation and payment for 10- and 90-day global packages. We also solicited comment on the most efficient means of acquiring these data as accurately and efficiently as possible. For example, we sought information on the extent to which individual practitioners or practices may currently maintain their own data on services furnished during the post-operative period, and how we might collect and objectively analyze those data and use the results for increasing the accuracy of the values beginning in CY 2019.

We received many comments in response to the comment solicitation in the CY 2016 proposed rule regarding potential methods of valuing the individual components of the global surgical package. A large number of comments expressed strong support for our proposal to hold an open door forum or town hall meetings with the public. In response, we held a national listening session on January 20, 2016. Prior to the listening session, the topics for which guidance was being sought were sent electronically to those who registered for the session and made available on our Web site. The topics were:

- Capturing the types of services typically furnished during the global period.
- Determining the representative sample for the claims-based data collection.
- Determining whether we should collect data on all surgical services or, if not, which services should be sampled.
- Potential for designing data collection elements to interface with existing infrastructure used to track follow-up visits within the global period.
- Consideration of using the 5 percent withhold until required information is furnished to encourage reporting.

The 658 participants in the national listening session provided valuable information on this task. A written transcript and an audio recording of this session are available at *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2016-01-20-MACRA.html.*

b. Data Collection Required To Accurately Value Global Packages

Resource-based valuation of individual physicians' services is a critical foundation for Medicare payment to physicians. It is essential that the RVUs under the PFS be based as closely and accurately as possible on the actual resources used in furnishing specific services to make appropriate payment and preserve relativity among services. For global surgical packages, this requires using objective data on all of the resources used to furnish the services that are included in the package. Not having such data for some components may significantly skew relativity and create unwarranted payment disparities within the PFS.

The current valuations for many services valued as global packages are based upon the total package as a unit rather than by determining the resources used in furnishing the procedure and each additional service/visit and summing the results. As a result, we do not have the same level of information about the components of global packages as we do for other services. To value global packages accurately and relative to other procedures, we need accurate information about the resources—work, PEs and malpractice—used in furnishing the procedure, similar to what is used to determine RVUs for all services. In addition we need the same information on the post-operative services furnished in the global period (and pre-operative services the day before for 90-day global packages). Public comments about our CY 2015 proposal to value all global services as 0-day global services and pay separately for additional post-operative services when furnished indicated that there were no reliable data available on the value of the underlying procedure that did not also incorporate the value of the post-operative services, reinforcing our view that more data are needed across the board.

While we believe that most of the services furnished in the global period are visits for follow-up care, we do not have accurate information on the number and level of visits typically furnished because those billing for global services are not required to submit claims for post-operative visits. A May 2012 Office of Inspector General (OIG) report, titled Cardiovascular Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided (*http://oig.hhs.gov/oas/reports/region5/50900054.pdf*) found that for 202 of the 300 sampled cardiovascular global surgeries, the Medicare payment rates were based on a number of visits that did not reflect the actual number of services provided. Specifically, physicians provided fewer services than the visits included in the payment calculation for 132 global surgery services and provided more services than were included in the payment calculations for 70 services. Similar results were found in OIG reports titled ''Musculoskeletal Global Surgery Fees Often Did Not Reflect The Number Of Evaluation And Management Services Provided'' (*http://oig.hhs.gov/oas/reports/region5/50900053.asp*) and ''Review of Cataract Global Surgeries and Related Evaluation and Management Services, Wisconsin Physicians Service Insurance Corporation Calendar Year 2003, March 2007.'' (*http://oig.hhs.gov/oas/reports/region5/50600040.pdf*).

Claims data plays a major role in PFS ratesetting. Specifically, Medicare claims data are a primary driver in the allocation of indirect PE RVUs and MP RVUs across the codes used by

particular specialties, and in making overall budget neutrality and relativity adjustments. In most cases, a claim must be filed for all visits. Such claims provide information such as the place of service, the type and, if relevant, the level of the service, the date of the service, and the specialty of the practitioner furnishing the services. Because we have not required claims reporting of visits included in global surgical packages, we do not have any of this information for the services bundled in the package.

In addition to the lack of information about the number and level of visits actually furnished, the current global valuations rely on crosswalks to E/M visits, based upon the assumption that the resources, including work, used in furnishing pre- and post-operative visits are similar to those used in furnishing E/M visits. We are unaware of any studies or surveys that verify this assertion. Although we generally value the visits included in global packages using the same direct PE inputs as are used for E/M visits, for services for which the RUC recommendations include specific PE inputs in addition to those typically included for E/M visits, we generally use the additional inputs in the global package valuation. In contrast, when a visit included in a global package would use fewer resources than a comparable E/M service, the RUC generally does not include recommendations to decrease the PE inputs of the visit included in the global package, and we have not generally made comparable reductions. Another inconsistency with our current global package valuation approach is that even though we effectively assume that the E/M codes are appropriate for valuing pre- and post-operative services, the indirect PE inputs used for calculating payments for global services are based upon the specialty mix furnishing the global service, not the specialty mix of the physicians furnishing the E/M services, resulting in a different valuation for the E/M services contained in global packages than for separately billable E/M services. There is a critical need to obtain complete information if we are to value global packages accurately and in a way that preserves relativity across the fee schedule.

In response to the requirement of section 1848(c)(8)(B)(i) of the Act that we develop, through rulemaking, a process to gather information needed to value surgical services, we proposed a rigorous data collection effort to provide us the data needed to accurately value the 4,200 codes with a 10- or 90-day global period. Using our authority under sections 1848(c)(2)(M) and (c)(8)(B)(i) of the Act, we proposed to gather the data needed to determine how to best structure global packages with post-operative care that is typically delivered days, weeks or months after the procedure and whether there are some procedures for which accurate valuation for packaged post-operative care is not possible. Finally, we indicated that these data would provide useful information to assess the resources used in furnishing pre- and post-operative care in global periods. To accurately do so, we need to know the volume and costs of the resources typically used.

We proposed a three-pronged approach to collect timely and accurate data on the frequency of and the level of pre- and post-operative visits and the resources involved in furnishing the pre-operative visits, post-operative visits, and other services for which payment is included in the global surgical payment. By analyzing these data, we would not only have the most comprehensive information available on the resources used in furnishing these services, but also would be able to determine the appropriate packages for such services. Specifically, the proposal included:

- A requirement for claims-based reporting about the number and level of pre- and post-operative visits furnished for 10- and 90-day global services.
- A survey of a representative sample of practitioners about the activities involved in and the resources used in providing a number of pre- and post-operative visits during a specified, recent period of time, such as two weeks.
- A more in-depth study, including direct observation of the pre- and post-operative care delivered in a small number of sites, and a separate survey module for practitioners practicing in ACOs.

The information collected and analyzed through the activities would be the first comprehensive look at the volume and level of services in a global period, and the activities and inputs involved in furnishing global services. The data from these activities would ultimately inform our revaluation of global surgical packages as required by statute.

To expand awareness of the proposal for data collection, we held a national listening session in which CMS reviewed the proposal for participants. Subsequent to this national listening session, we held a town hall meeting at the CMS headquarters in which participants, in person and virtual, shared their views on the proposal with CMS. The transcript from these town halls is available on the CMS Web site with the CY 2017 final rule downloads.

(1) Statutory Authority for Data Collection

As described in this section of the final rule, section 1848(c)(8)(B)(i) of the Act requires us to develop, through rulemaking, a process to gather information needed to value surgical services from a representative sample of physicians. The statute requires that the collected information include the number and level of medical visits furnished during the global period and other items and services related to the surgery and furnished during the global period, as appropriate.

In addition, section 1848(c)(2)(M) of the Act, which was added to the Act by section 220 of the PAMA, authorizes the Secretary to collect or obtain information on resources directly or indirectly related to furnishing services for which payment is made under the PFS. Such information may be collected or obtained from any eligible professional or any other source. Information may be collected or obtained from surveys of physicians, other suppliers, providers of services, manufacturers, and vendors. That section also authorizes the Secretary to collect information through any other mechanism determined appropriate. When using information gathered under this authority, the statute requires the Secretary to disclose the information source and discuss the use of such information in the determination of relative values through notice and comment rulemaking.

As described in this section of the final rule, to gain information to assist CMS in determining the appropriate packages for global services and to revalue those services, CMS needs more information on the resources used in furnishing such services. Through the claims-based data collection and the study we are finalizing in this final rule, we would have better information about the actual number of services furnished to Medicare beneficiaries to use in valuation for these codes than has been typically available, such as from RUC surveys that reflect practitioner's estimates of the number of services typically furnished. We anticipate that such efforts would inform how to more regularly collect data on the resources used in furnishing physicians' services. To the extent that such mechanisms prove valuable, they may be used to collect data for valuing other services. To achieve this significant data collection, we proposed to collect data under the authority of both section 1848(c)(8)(B) and (c)(2)(M) of the Act.

(2) Claims-Based Data Collection

We proposed a claims-based data collection that would have required all those providing 10- or 90-day global services to report on services furnished during the global period using a series of G-codes specially created for this purpose, beginning January 1, 2017.

In response to the comments submitted on the proposal, we are finalizing a claims-based data collection that differs from this proposal in the following significant ways:

- CPT code 99024 will be used for reporting post-operative services rather than the proposed set of G-codes. Reporting will not be required for pre-operative visits included in the global package or for services not related to patient visit.
- Reporting will be required only for services related to codes reported annually by more than 100 practitioners and that are reported more than 10,000 times or have allowed charges in excess of $10 million annually.
- Practitioners are encouraged to begin reporting post-operative visits for procedures furnished on or after January 1, 2017, but the mandatory requirement to report will be effective for services related to global procedures furnished on or after July 1, 2017.
- Only practitioners who practice in groups with 10 or more practitioners in Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island will be required to report. Practitioners who only practice in smaller practices or in other geographic areas are encouraged to report data, if feasible.

Given that the data collection will be limited to only some states, a subset of global services, and only to those who practice in larger practices the information collected through claims for global packages services will not parallel the claims data that are available in pricing other PFS services. However, we believe that the information collected through this data collection will be a significant improvement over the information currently available to value these services and will be supplemented with information obtained through other mechanisms.

In the following sections, we discuss the comments on each element of our data collection proposal, our responses and our final decision.

(a) Information To Be Reported

A key element of claims-based reporting is using codes that appropriately reflect the services furnished. In response to the comment solicitation in the CY 2016 PFS proposed rule and the input received via the January 2016 listening session, we received numerous recommendations for the information to be reported on claims. The most frequently recommended approach was for practitioners to report the existing CPT code for follow-up visits included in the surgical package (CPT 99024—Postoperative follow-up visit, normally included in the surgical package, to indicate that an E/M service was performed during a postoperative period for a reason(s) related to the original procedure). Others suggested using this code for outpatient visits and using length of stay data to estimate the number of inpatient visits during the global period. In response to our concerns that CPT code 99024 would provide only the number of visits and not the level of visits as required by the statute, one commenter suggested using modifiers in conjunction with CPT code 99024 to indicate the level of the visit furnished. Others recommended using existing CPT codes for E/M visits to report post-operative care. One commenter suggested that CMS analyze data from a sample of large systems and practices that are using electronic health records that require entry of some CPT code for every visit to capture the number of post-operative visits. After noting that the documentation requirements and PEs required for post-operative visits differ from those of E/M visits outside the global period, one commenter encouraged us to develop a separate series of codes to capture the work of the post-operative services and to measure, not just estimate, the number and complexity of visits during the global period.

Other commenters opposed the use of a new set of codes or the use of modifiers to report post-operative visits. Commenters also noted several issues for us to consider in developing data collection mechanisms, including that many post-operative services do not have CPT codes to bill separately, that surgeons perform a wide range of collaborative care services, and that patient factors, including disease severity and comorbidities, influence what post-operative care is furnished.

To assist us in determining appropriate coding for claims-based reporting, we added a task to the RAND validation contract for developing a model to validate the RVUs in the PFS, which was awarded in response to a requirement in the Affordable Care Act. Comments that we received on the validation report suggested the models did not adequately address global surgery services due to the lack of available data on visits included in the global package. Therefore, we modified the validation contract to include the development of G-codes that could be used to collect data about post-surgical follow-up visits on Medicare claims for valuing global services under MACRA so that this time could be included in the model for validating RVUs.

To inform its work on developing coding for claims-based reporting, the contractor conducted interviews with surgeons and other physicians/non-physician practitioners (NPP) who provide post-operative care. A technical expert panel (TEP), convened by the contractor, reviewed the findings of the interviews and provided input on how to best capture care provided in the post-operative period on claims.

In summarizing the input from the interviews and the TEP, the contractor indicated that several considerations were important in developing a claims-based method for capturing post-operative services. First, a simple system to facilitate reporting was needed. Since it was reported that a majority of post-operative visits are straightforward, the contractor found that a key for any proposed system is identifying the smaller number of complex post-operative visits. Another consideration was not using the existing CPT E/M structure to capture postoperative care because of concerns that E/M codes are inadequately designed to capture the full scope of post-operative care and that using such codes might create confusion. Another consideration was that the TEP was most enthusiastic about a set of codes that used site of care, time, and complexity to report visits. The contractor also believed it was important to distinguish—particularly in the inpatient setting—between circumstances where a surgeon is providing primary versus secondary management of a patient. Finally, a mechanism for reporting the postoperative care occurs outside of in-person visits and by clinical staff was needed. The report noted that in the inpatient setting in particular, surgeons spend considerable time reviewing test results and coordinating care with other practitioners.

After reviewing various approaches, a set of time-based, post-operative visit codes that could be used for reporting care provided during the post-operative period was recommended.

The recommended codes distinguish services by the setting of care and whether they are furnished by a physician/NPP or by clinical staff. All codes are intended to be reported in 10-minute increments. A copy of the report

is available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*.

We proposed the following no-pay codes be used for reporting on claims the services actually furnished but not paid separately because they are part of global packages.

TABLE 9—PROPOSED GLOBAL SERVICE CODES

Inpatient	GXXX1	Inpatient visit, typical, per 10 minutes, included in surgical package.
	GXXX2	Inpatient visit, complex, per 10 minutes, included in surgical package.
	GXXX3	Inpatient visit, critical illness, per 10 minutes, included in surgical package.
Office or Other Outpatient	GXXX4	Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package.
	GXXX5	Office or other outpatient visit, typical, per 10 minutes, included in surgical package.
	GXXX6	Office or other outpatient visit, complex, per 10 minutes, included in surgical package.
Via Phone or Internet	GXXX7	Patient interactions via electronic means by physician/NPP, per 10 minutes, included in surgical package.
	GXXX8	Patient interactions via electronic means by clinical staff, per 10 minutes, included in surgical package.

(i) Coding for Inpatient Global Service Visits

Our proposal included three codes for reporting inpatient pre- and post-operative visits that distinguish the intensity involved in furnishing the services. Under this proposal, visits that involve any combination or number of the services listed in Table 10, which were recommended by the contractor as those in a typical visit, would be reported using GXXX1. Based on the findings from the interviews and the TEP, the report indicated that the vast majority of inpatient post-operative visits would be expected to be reported using GXXX1.

TABLE 10—ACTIVITIES INCLUDED IN TYPICAL VISIT (GXXX1 & GXXX5)

Review vitals, laboratory or pathology results, imaging, progress notes.
Take interim patient history and evaluate post-operative progress.
Assess bowel function.
Conduct patient examination with a specific focus on incisions and wounds, post-surgical pain, complications, fluid and diet intake.
Manage medications (for example, wean pain medications).
Remove stitches, sutures, and staples.
Change dressings.
Counsel patient and family in person or via phone.
Write progress notes, post-operative orders, prescriptions, and discharge summary.
Contact/coordinate care with referring physician or other clinical staff.
Complete forms or other paperwork.

Under our proposal, inpatient pre- and post-operative visits that are more complex than typical visits but do not qualify as critical illness visits would be coded using GXXX2 (Inpatient visit, complex, per 10 minutes, included in surgical package). To report this code, the practitioner would be required to furnish services beyond those included in a typical visit and have documentation that indicates what services were provided that exceeded those included in a typical visit. In the proposed rule, we noted some circumstances that might merit the use of the complex visit code are secondary management of a critically ill patient where another provider such as an intensivist is providing the primary management, primary management of a particularly complex patient such as a patient with numerous comorbidities or high likelihood of significant decline or death, management of a significant complication, or complex procedures outside of the operating room (For example, significant debridement at the bedside).

The highest level of inpatient pre- and post-operative visits, critical illness visits (GXXX3—Inpatient visit, critical illness, per 10 minutes, included in surgical package) would be reported when the physician is providing primary management of the patient at a level of care that would be reported using critical care codes if it occurred outside of the global period. This involves acute impairment of one or more vital organ systems such that there is a high probability of imminent or life threatening deterioration in the patient's condition.

Similar to how time is now counted for the existing CPT critical care codes, we proposed that all time spent engaged in work directly related to the individual patient's care would count toward the time reported with the inpatient visit codes; this includes time spent at the immediate bedside or elsewhere on the floor or unit, such as time spent with the patient and family members, reviewing test results or imaging studies, discussing care with other staff, and documenting care.

(ii) Coding for Office and Other Outpatient Global Services Visits

For the three codes in our proposal that would be used for reporting post-operative visits in the office or other outpatient settings, codes, time would be defined as the face-to-face time with patient, which reflects the current rules for time-based outpatient codes.

Like GXXX1, GXXX5 (Office or other outpatient visit, typical, per 10 minutes, included in surgical package) would be used for reporting any combination of activities in Table 10 under our proposal.

We proposed only face-to-face time spent by the practitioner with the patient and their family members would count toward the time reported with the office visit codes.

(iii) Coding for Services Furnished via Electronic Means

Services that are furnished via phone, the internet, or other electronic means outside the context of a face-to-face visit would be reported using GXXX7 when furnished by a practitioner and GXXX8 when provided by clinical staff under our proposal. We proposed that practitioners would not report these services if they are furnished the day before, the day of, or the day after a visit as we believe these would be included in the pre- and post-service activities in the typical visit. However, we proposed that these codes be used to report non-face-to-face services provided by clinical staff prior to the primary procedure since global surgery codes are typically valued with assumptions regarding pre-service clinical labor time. Given that some practitioners have indicated that services they furnish commonly include activities outside the face-to-face service, we believed it was important to capture information about those activities in both the pre- and post-service periods. We also believed these requirements to report on clinical

labor time are consistent with and no more burdensome than those used to report clinical labor time associated with chronic care management services, which similarly describe care that takes place over more than one patient encounter.

In addition, we proposed for services furnished via interactive telecommunications that meet the requirements of a Medicare telehealth service visit, the appropriate global service G-code for the services would be reported with the GT modifier to indicate that the service was furnished ''via interactive audio and video telecommunications systems.''

(iv) Rationale for Use of G-Codes

After considering the contractor report, the comments in response to the comment solicitation in the CY 2016 proposed rule and other stakeholder input that we have received, and our needs for data to fulfill our statutory mandate and to value surgical services appropriately, we proposed this new set of codes because we believe it provides us the most robust data upon which to determine the most appropriate way and amounts to pay for PFS surgical services. We noted that these proposed codes would provide data of the kind that can reasonably collected through claims data and that reflect what we believe are key issues in the valuation of post-operative care—where the service is provided, who furnishes the service, its relative complexity, and the time involved in the service.

We solicited public comments about all aspects of these codes, including the nature of the services described, the time increment, and any other areas of interest to stakeholders. We noted particular interest in any pre- or post-operative services furnished that could not be appropriately captured by these codes. We solicited comments on whether the proposed codes were appropriate for collecting data on pre-operative services. We also sought comment on any activities that should be added to the list of activities in Table 10 to reflect typical pre-operative visit activities.

(v) Alternative Approach to Coding

In making the proposal for G-codes, we noted that many stakeholders had expressed strong support for the use of CPT code 99024 (Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a post-operative period for a reason(s) related to the original procedure) to collect data on post-operative care. In response to stakeholders noting that practitioners are familiar with this existing CPT code and the burden on practitioners would be minimized by only having to report that a visit occurred, not the level of the visit, we noted that we did not believe that this code alone would provide the information that we need for valuing surgical services nor do we believe it alone can meet the statutory requirement that we collect data on the number and level of visits. Given the strong support for the use of CPT code 99024, we solicited comments specifically on how we could use this code to capture the statutorily required data on the number and level of visits and the data that we would need to value global services in the future.

We also discussed in the proposed rule our concern that using CPT code 99024 with modifiers to indicate to which of the existing levels of E/M codes the visit corresponds may not accurately capture what drives greater complexity in post-operative visits. We noted that as outlined in the contractor's report, E/M billing requirements are built upon complexity in elements such as medical history, review of systems, family history, social history, and how many organ systems are examined. In the context of a post-operative visit, many of these elements may be irrelevant. The contractor's report also notes that there was significant concern from interviewees and the expert panel about documentation that is required for reporting E/M codes. Specifically, they stated that documentation requirements for surgeons to support the relevant E/M visit code would place undue administrative burden on surgeons given that many surgeons currently use minimal documentation when they provide a postoperative visit. We also noted that to value surgical packages accurately we need to understand the activities involved in furnishing post-operative care and as discussed above, we lack information that would demonstrate that activities involved in post-operative care are similar to those in E/M services. In addition, the use of modifiers to report levels of services is more difficult to operationalize than using unique HCPCS codes. However, we sought comments on whether, and if so, why, practitioners would find it easier to report CPT code 99024 with modifiers corresponding to the proposed G-code levels rather than the new G-codes, as proposed. We also sought comment on whether practitioners would find it difficult to use this for pre-operative visits since the CPT code descriptor specifically defines it as a ''post-operative follow-up'' service.

We also sought comment on whether time of visits could alone be a proxy for the level of visit. If pre- and post-operative care varies only by the time the practitioner spends on care so that time could be a proxy for complexity of the service, then we could use the reporting of CPT code 99024 in 10-minute increments to meet the statutory requirement of collecting claims-based data on the number and level of visits. In addition to comments on whether time is an accurate proxy for level of visit, we solicited comment on the feasibility and desirability of reporting CPT code 99024 in 10-minute increments.

The following is a summary of the comments that we received on our proposal to use G-codes for reporting the services furnished during the pre- and post-operative periods of 10- and 90-day global services.

Comment: Many commenters offered critiques of the G-codes. Most objected to reporting using the proposed G-codes. Some commenters raised concerns with the code definitions. These included: Lack of alignment with clinical workflow, failure to adequately account for variation in complexity and medical decision-making, and use of the term ''typical'' to define visits in a different way than the term is generally used in PFS valuations. One commenter suggested that CMS should require care plans for outpatient visits in the post-operative period. It was also suggested that the complex visit code could be improved by using a term other than ''complex'' in the definition. A commenter questioned whether that vast majority of cases would be complex instead of ''typical,'' since the definition of ''complex'' included management of a patient with multiple comorbidities and most Medicare beneficiaries have multiple comorbidities. A commenter also suggested that CMS refine the G-codes to distinguish physician visits from NPP visits. In addition, several commenters objected to the proposed G-codes for on-line and telephone services because they believed it would be nearly impossible to track these data and extremely burdensome to do so. Commenters indicated that the G-codes were not well-defined overall and should not be used without testing to determine their validity.

Response: We appreciate the detailed comments on the design of the G-codes and the concerns regarding their limitations in appropriately reflecting the services furnished in 10- and 90-day global periods. These comments provide information for how the G-codes could

be modified to better reflect services furnished in global periods, however, as is discussed at the outset of this section, we are not using the proposed G-codes for this data collection effort.

Comment: Most commenters objected to using codes based on time increments and the proposed 10-minute increments, specifically. Some stated that reporting of services by time did not reflect the way surgeons practiced and would divert practitioners from patient care. One commenter stated that it was not feasible for practitioners to collect time data for every task that they or their clinical staff performed. Another stated that requesting physicians and/or their staff to use a stop-watch to, in effect, conduct time and motion studies for all their non-operating room patient care activities is an incredible burden. Another stated that reporting time in 10-minute increments ''is untenable,'' noting that, except for a few specialties, physicians do not think of providing care in terms of timed increments. The commenter added that surgeons, in particular, are not accustomed to reporting time for all pre- and post-operative visits and to do so would be a huge disruption to workflow. In addition to objections about the burden of reporting time data, some commenters objected to the use of time data as a factor in valuations.

Three organizations commented that it was appropriate to collect time data, but recommended that we do so based upon 15-minute increments as these were more familiar to physicians than the proposed 10-minue increments. In addition, some other groups, including MedPAC, agreed that data on time was needed for valuations.

Response: Time is a key factor in valuing physician services under the physician fee schedule. Section 1848(c)(1) of the Act defines the work component as the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service. We also note that time-based codes are used by practitioners for a range of services in the PFS including psychotherapy, anesthesiology and critical care services. Critical care services are notable because these services are likely to be furnished intermittently as many commenters suggested is typical for post-operative follow-up services. Since issues have not been raised about the difficulty of using the current critical care codes, it is unclear why reporting of time would be burdensome and disruptive of care in this area. We have no reason to believe the documentation of time is more difficult or burdensome for those furnishing 10- and 90-day global services than for other practitioners. However, based on the comments, it is clear that many practitioners would perceive reporting of time involved in furnishing these services to be a significant increase in burden relative to existing practice. Before implementing a change considered by so many to be so burdensome, we are exploring other ways of obtaining information that can be used to improve the accuracy of valuing these services. Accordingly, we are not finalizing, at this time, the requirement to use time-based codes.

Comment: Many commenters stated that the use of these codes would be costly, requiring extensive education of practitioners and staff and necessitating updates to EHR systems and billing software. Some also noted the cost of processing additional claims. Many commenters noted that this would be particularly difficult as this additional administrative burden would come at the same time practitioners are adjusting the Merit-based Incentive Payment System (MIPS). One commenter provided the results of a survey of surgical practitioners in 20 specialties in which 30 percent of respondents stated that the cost of integrating the new G-codes into their practice would cost more than $100,000 and only about 10 percent stated that it would cost less than $25,000.

Some commenters expressed specific concern about the documentation burden that would come from using these codes. On the other hand, other commenters suggested that providers of visits during the global surgical services should be held to the same documentation standards as providers of E/M services. One stated that the ''administrative burden on surgeons should be no different and certainly no less than that on non-surgeons when it comes to documenting a visit with a patient. If many surgeons currently use minimal documentation when they provide a post-operative visit that is no excuse for expecting the same inadequate level of documentation going forward. To require anything less than the same level of documentation for all clinicians providing E/M services would be irresponsible and unfair and would defeat the very purpose of documenting the actual types and extent of these services in the post-operative period.''

Response: The need for accurate, complete and useful data must be balanced with administrative burden and cost. We articulated that using a select number of G-codes based on time would impose a burden on providers, but that burden is necessary for us to comply with the statutory requirement to gather the data necessary to value global procedures. We note that CPT routinely incorporates more than 100 new codes in annual updates, and for this reason we did not anticipate that the inclusion of eight new G-codes was likely to present significant challenges to EHR systems or other infrastructure. Based on the comments we received, however, it is clear that the majority of stakeholders believe the burden is much greater than we had assumed. In general, we agree with commenters that comparable documentation is appropriate for all physicians furnishing and being paid by Medicare for similar services.

Comment: Several commenters noted that the difficulties of using these codes would affect the accuracy of the data reported. One commenter stated that the G-code proposal would be impossible to implement and ''at the very least'' would yield incomplete and unreliable results.

Response: We agree with commenters that implementation burden is an important consideration in determining how practitioners should report on care provided in the post-operative period and that if practitioners find the reporting requirements to be excessive and require great expenditures to incorporate into their practice, the accuracy of the data could be undermined. We considered this in determining the final policy described below.

Comment: Some commenters criticized the proposed G-codes because they were not directly linked to E/M codes or comparable to existing E/M codes. On the other hand, some commenters preferred the codes describing such visits not be linked or comparable to E/M codes to avoid confusion or unintentional, inappropriate payments. One commenter stated that the follow-up work performed within the global periods and the continuity work performed by cognitive physicians should not be represented by the same codes. Another commenter stated that the care required by a patient recovering from a procedure is fundamentally different from the typical follow-up of an established outpatient or inpatient, especially when there are multiple simultaneous interacting conditions, a single metastable chronic illness, or one or more acute exacerbated chronic illnesses that requires inpatient care and expertise.

Response: Commenters' belief that the work in follow-up visits included in the global package is not necessarily well described by the work of current E/M

codes is worth exploring. Current data does not allow us to determine the validity of these commenters' assertion but given its importance, we believe it is critical to gather data on whether follow-up visits provided in the post-operative period are different than other E/M services. To the extent the services in the post-operative period are different from other E/M services, it would not make sense to use E/M codes in valuing global services as is ostensibly the case under the current process the RUC uses in developing recommended values for PFS services.

Comment: Most commenters supported using CPT codes, rather than the proposed G-codes. A few pointed to the existing E/M codes, but most recommended that any claims-based reporting use CPT code 99024, an existing CPT code that describes post-operative services in a global period. Commenters noted that since this is a current CPT code the administrative burden would be much less than that associated with using the proposed new G-codes. These commenters suggest that practitioners are likely already familiar with the code, some already use it to track services within their practice, and some others already report it to other payers. Also, they suggest that because EHR and billing systems already include CPT code 99024, it will be less costly to implement than the proposal. Some also preferred using CPT code 99024 because unlike the proposed G-codes it does not require the reporting of time units.

Most commenters disagreed that time could be a proxy for the complexity of the visit and objected to reporting time for the same reasons discussed above. These commenters did not agree that CPT code 99024 could be reported in time units as a proxy for collecting the required information about the level of visits.

Three organizations disagreed, however, stating that time is a sufficient proxy for work relativity in post-operative visits and that the number units of CPT code 99024 could reflect the complexity involved. These commenters recommended reporting data in 15-minute intervals, rather than the proposed 10-minute increments, stating that physicians are familiar with 15-minute increments and thus the use of 15-minute increments would greatly reduce the administrative burden. They recommended that CMS clearly define how time is to be reported and suggested that the 8-minute rule is already a familiar concept that could be used.

Many commenters suggested that other approaches, such as a survey, clinical registries, or on-line portals be used to collect data on level of visits.

Several commenters stated that CMS should not collect data on the level of visits based on these commenters' perspective that there is no problem with the level of visits currently used in the valuation of global packages. One commenter pointed out that only 1 percent of all established patient office visits used in valuing 10-day and 90-day global surgery packages have a visit level above a CPT code 99213. Another commenter suggested that the survey be used to collect data on the level of visits. Others suggested that RUC surveys be used to measure level of visits.

Response: We understand that stakeholders believe that using CPT code 99024 rather than the proposed G-codes will significantly lower administrative burden and lower costs related to the collection of this data. We do not have data showing that the level of visits used in valuation of global packages are correct or incorrect; to the best of our knowledge, this has never been assessed outside of the RUC process. While the current valuations for global packages rely primarily on CPT codes 99212 and 99213 for the visit component, we do not agree that this means that the levels are accurate. Further, as some commenters have made clear, there is not consensus among stakeholders that the post-operative visits are equivalent to other E/M visits. Additionally, the relationship between the number and level of visits assumed to be in the global period and the overall work RVUs for the global codes is often unclear. For all of these reasons, we disagree with commenters that we do not need to collect data on the level of services.

In addition to the statutory reference to collecting data on the level of visits, we believe that code valuations can be more accurate with more complete information. While we continue to believe that data only on the number of visits furnished would not provide data on both the number and level of visits needed for valuation of services, data on the number of visits alone is an important input in valuing global packages and having accurate data on the number of visits could be a useful first step in analyzing the global packages.

After considering the comments, we are finalizing a requirement to report post-operative visits furnished during 10- and 90-day global periods. However, rather than using the proposed set of G-codes for this reporting, we are requiring that CPT code 99024 be used to report such visits. We will not, at this time, require time units or modifiers to distinguish levels of visits to be reported. Since this code is specifically limited to post-operative care, we are only requiring reporting of post-operative visits. We expect that the reporting of this information through Medicare claims will provide us with information about the actual number of visits furnished during the post-operative periods for many services reported using global codes. Because the number of visits is a major factor in valuation of global services, we believe that examination of such information, when available, can improve the accuracy of the global codes. The use of a simple code that practitioners are familiar with should facilitate the submission of accurate information. We expect practitioners to note the visit in the medical chart documenting the post-operative visit.

Since CPT code 99024 will only provide data on the number of visits and no data on the level or resources used in furnishing the visit, we believe this is only the first step in gathering the data required by Section 1848(c)(8). The proposed G-codes could have provided information to better understand the resources used in furnishing services during global periods and in valuation of such services assuming that they could be accurately reported. However, widespread concerns from groups representing the practitioners that would be reporting these services, including concerns about the burdens regarding and the inability of physicians to track time and the need to learn a new 8-code coding system, persuade us that we should pursue less burdensome ways of obtaining information. We will assess whether these methods will lead to the collection of necessary data, including data on time and intensity, of these services.

As suggested by commenters, we will explore whether the data collected from the survey that we are conducting, which is discussed later in this preamble, can provide information on the level of visits and other resources needed to value surgical services accurately. Stakeholders should be aware that since this a new approach for collecting data, and one that has not been used previously, we are concerned that additional or different reporting will be necessary to collect data on the number and level of visits and other information needed to value surgical services as required by Section 1848(c)(8).

b. Reporting of Claims

We proposed that the G-codes detailed above would be reported for services related to and within 10- and 90-day global periods for procedures furnished on or after January 1, 2017. Services related to the procedure furnished following recovery and otherwise within the relevant global period would be required to be reported. These codes would be included on claims filed through the usual process. Through this mechanism, we would collect all of the information reported on a claim for services, including information about the practitioner, service furnished, date of service, and the units of service. By not imposing special reporting requirements on these codes, we proposed to allow practitioners the flexibility to report the services on a rolling basis as they are furnished or to report all of the services on one claim once all have been furnished, as long as the filed claims meet the requirements for filing claims.

We did not propose any special requirements for inclusion of additional data on claims that could be used for linking the post-operative care furnished to a particular service. To use the data reported on post-operative visits for analysis and valuation, we proposed to link the data reported on post-operative care to the related procedure using date of service, practitioner, beneficiary, and diagnosis. While we believed this approach to matching would allow us to accurately link the preponderance of G-codes to the related procedure, we sought comment on the extent to which post-operative care may not be appropriately linked to related procedures whether we should consider using additional variables to link these aspects of the care, and whether additional data should be required to be reported to enable a higher percentage of matching.

The following is summary of the comments we received on our proposal to require reporting on pre- and post-operative care associated with all procedures with 10- and 90-day global periods.

Comment: Many commenters objected to the proposal to require reporting on post-operative services for all 10- or 90-day global services. Some suggested that many of the global services are low volume and have little impact on Medicare spending. It was also noted that it would be difficult to obtain a meaningful sample of low-volume services. Others discussed the burden of reporting on all services. The RUC recommended that CMS only require reporting on services that are furnished by more than 100 providers and that either are furnished more than 10,000 times or have allowed charges of more than $10 million annually to obtain meaningful data for valuation. The RUC noted that many procedures were infrequently furnished and thus useful data would not be obtained. This position was supported by a significant number of commenters. In response to the stated concern about having complete data when more than one surgical service is furnished during the global period, a commenter pointed out that a review of the 2014 Medicare 5 percent sample file shows that, two surgical global codes are performed on the same date of service, by the same physician, only 18 percent of the time.

Response: The commenters are correct that the vast majority of 10- and 90-day procedures are furnished infrequently and thus have little effect on Medicare expenditures or direct impact on the valuations of other services under the PFS. We proposed to collect data on all procedures since we believed the data we collected would be more accurate if physicians reported on all services as it would be routine and would not have required physicians to determine at each pre- and post-operative visit whether or not reporting the service was required. Moreover, as pointed out by commenters, we believe that reporting on all applicable services would have provided more complete data when multiple surgeries occurred during the global period.

Having specific data on all procedures would provide specific information for each service that Medicare pays for using a global period. In assessing the likely benefit of the additional data as compared to the burden of reporting based on the comments we received, we agree with commenters that collecting the data from high volume/high cost procedures could provide adequate information to improve the accuracy of valuation of global packages overall. Even if all practitioners reported data on all procedures, it is likely that we would not receive enough data on low-volume services for the data to be reliable for use in valuations. There are more than 1,500 services that are furnished less than 100 times per year. Because of this, data that we could collect on these services would be extremely limited. We also find that data on services with low volumes are not reliable due to variability from year to year. Since we often value related services by extrapolating data on one service to other services in the family, with adjustments as necessary to reflect variations in the procedure, the data gathered on high-volume services could similarly be used to value low-volume services in the same family. As a result we, believe that the data on high-volume services can improve the accuracy of values for all 10- and 90-day services.

After consideration of the comments, we are implementing a requirement for reporting on services that are furnished by more than 100 practitioners and are either furnished more than 10,000 times or have allowed charges of more than $10 million annually as recommended by the RUC and many other commenters. Under this policy, we estimate that we would collect data on about 260 codes that describe approximately 87 percent of all furnished 10- and 90-day global services and about 77 percent of all Medicare expenditures for 10- and 90-day global services under the PFS. Given that this data would provide information on the codes describing the vast majority of 10- and 90-day global services and expenditures, it will provide significant data for valuation. For 2017, we will use the CY 2014 claims data to determine the codes for which reporting is required and display the list on the CMS Web site. In subsequent years, we will update the list to reflect more recent claims data and publish a list of codes prior to the beginning of the reporting year. The services for which reporting is required will include successor codes to those deleted or modified since CY 2014 for which reporting would have been required if the code had not been deleted or modified.

The following is summary of the comments we received on our proposal to require claims-based reporting for services related to procedures furnished on or after January 1, 2017.

Comments: Many commenters expressed concerns regarding the difficulty of making the changes required to implement this new reporting by January 1, 2017. Some commenters noted that this change was coming at the same time as the new MIPS program. Some commenters stated that the statute required a process to be in place by January 1, 2017, but that CMS has flexibility regarding when to begin the required reporting. Some commenters suggested that CMS consider conducting the proposed survey before implementing any claims-based reporting.

Response: We proposed to begin required reporting on January 1, 2017, based upon the statutory language regarding both the collection and use of the data for revaluation of services. We understand that some practices will need to make modifications to their EHR and billing systems to report this data to

us. We also acknowledge that an opportunity for testing the systems and training will enhance the quality of data that we receive.

After consideration of comments, we are encouraging practitioners to begin reporting data on post-operative services for procedures furnished on or after January 1, 2017. However, the requirement to report will become mandatory for post-operative services related to procedures furnished on or after July 1, 2017 rather than as of January 1, 2017, as proposed. This delay will not negatively impact the use value of the collected data since we expect that data received early in the year might be less complete than data submitted once practitioners adjusted to the requirements. Also, by allowing time for practitioners to adjust EHR and billing software, to test such systems and to train staff, we think the quality of the data will be enhanced by providing flexibility with regard to the effective date of the requirement. Finally, because we are limiting required reporting to high-volume codes, meaningful data for CY 2017 should be available from 6 months of reporting. Our systems can now accept the post-operative visit data so practitioners can begin submitting such claims at any time.

c. Special Provisions for Teaching Physicians

We sought comment on whether special provisions are needed to capture the pre- and post-operative services provided by residents in teaching settings. If the surgeon is present for the key portion of the visit, should the surgeon report the joint time spent by the resident and surgeon with the patient? If the surgeon is not present for the key portion of the visit, should the resident report the service? If we value services without accounting for services provided by residents that would otherwise be furnished by the surgeon in non-teaching settings, subsequent valuations based upon the data we collect may underestimate the resources used, particularly for the types of surgeries typically furnished in teaching facilities. However, there is also a risk of overvaluing services if the reporting includes services that are provided by residents when those services would otherwise be furnished by a physician other than the surgeon, such as a hospitalist or intensivist, and as such, should not be valued in the global package.

Comment: We received only a few comments on this issue. Some commenters suggested using the CMS policies that apply to other services that teaching surgeons report to CMS for the reporting of CPT code 99024. More specifically, when the appropriate conditions are met they would use the GC or GE modifier to identify those services in which surgical residents are involved. One of these suggested that once we have the data we discuss with stakeholders how to use the data involving residents in future valuations. Others suggested that we capture data on resident's time as it could be important for valuation, especially for the more complex cases in a teaching facility setting. Some urged that we provide clear guidance on when the resident's time could be reported. One commenter stated that teaching physicians should be exempt from reporting requirements.

Response: These comments reinforce the importance of collecting data from teaching physicians and to do so using the existing Medicare rules that teaching physicians use in reporting services in which residents are involved in furnishing. Because we are finalizing data collection using CPT code 99024, the issues regarding the reporting of time data are no longer relevant.

After consideration of the comments, we are finalizing a requirement that teaching physicians will be subject to the reporting requirements in the same way that other physicians are. Such physicians should report CPT code 99024 only when the services furnished would meet the general requirements for reporting services and should use the GC or GE modifier as appropriate.

e. Who Reports

In both the comments on the CY 2016 proposed rule and in input from the January 2016 national listening session, there was a great deal of discussion regarding the challenges that we are likely to encounter in obtaining adequate data to support appropriate valuation. Some indicated that a broad sample and significant cooperation from physicians would be necessary to understand what is happening as part of the global surgical package. One commenter suggested that determining a representative sample would be difficult and, due to the variability related to the patient characteristics, it would be easier to have all practitioners report. Many suggested that we conduct an extensive analysis across surgical specialties with a sample that is representative of the entire physician community and covers the broad spectrum of the various types of physician practice to avoid problems that biased or inadequate data collection would cause. Suggestions of factors to account for in selecting a sample include specialty, practice size (including solo practices), practice setting, volume of claims, urban, rural, type of surgery, and type of health care delivery systems. Another commenter pointed out that small sample sizes may lead to unreliable data. Some commenters stated that requiring all practitioners to report this information is unreasonable and would be an insurmountable burden. A participant acknowledged that it would be difficult for practitioners to report on only certain procedures, while another stated that this would not be an administrative burden.

After considering the input of stakeholders on the CY 2016 proposed rule and at the January 2016 national listening session discussed above, we proposed that any practitioner who furnishes a procedure that is a 10- or 90-day global service report the pre- and post-operative services furnished on a claim using the proposed G-codes. We agreed with stakeholders that it would be necessary to obtain data from a broad, representative sample. However, as we struggled to develop a nationally representative sampling approach that would result in statistically reliable and valid data, it became apparent that we do not have adequate information about how post-operative care is delivered, how it varies and, more specifically, what drives variation in post-operative care to develop a sampling frame. In its work to develop the coding used for its study, the contractor found a range of opinions on what drives variation in post-operative care. (The report is available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/*.) Without information on what drives variation in pre- and post-operative care, we would have to speculate about the factors upon which to base a sample or assume that the variation in such care results from the same variables as are frequently identified for explaining variation in health care and clinical practice. In addition, we expressed concern about whether a sample could provide sufficient volume to value accurately the global package, except in the case of a few high-volume procedures.

In addition to concerns about achieving a statistically representative sample of all practitioners nationally, we noted in the proposed rule significant operational concerns with limiting data collection to a subset of practitioners or a subset of services. These include how to gain sufficient information on practitioners to stratify the sample, how to identify the

practitioners who must report, and for those who practice in multiple settings or with multiple groups in which settings the practitioner would report. We concluded that establishing the rules to govern which post-operative care should be reported based on our proposed G-codes would be challenging for us to develop and difficult for physicians to apply in the limited time between the issuance of the CY 2017 PFS final rule with comment period and the beginning of reporting on January 1, 2017. We do not believe that the same problems apply to the same extent to our final policy to use a single code that already exists to report services described only by codes reported in high volumes. For example, implementation of new sets of codes associated with annual PFS updates are often supported by informational and educational efforts undertaken by national organizations, like the national medical specialty societies. Given that many practitioners are already familiar with CPT code 99024 (as noted by many commenters), the need for such efforts is significantly mitigated.

We also noted in the proposed rule that the more robust the reported data, the more accurate our ultimate valuations can be. We stated that given the importance of data on visits in accurate valuations for global packages, collecting data on all pre- and post-operative visits in the global period is the best way to accurately value surgical procedures with global packages.

We recognized that reporting would require submission of additional claims by those practitioners furnishing global services, but indicated that we believed the benefits of accurate data for valuation of services merited the imposition of this requirement. By using the claims system to report the data, we believed the additional burden would be minimized and referred to stakeholder reports that many practitioners are already required by their practice or health care system to report a code for each visit for internal control purposes and some of these systems already submit claims for these services, which are denied. We noted that requiring only some physicians to report this information, or requiring reporting for only some codes, could actually be more burdensome to physicians than requiring this information from all physicians on all services because of the additional steps necessary to determine whether a report is required for a particular service and adopting a mechanism to assure that data is collected and reported when required. Moreover, we stated that the challenges with implementing a limited approach at the practice level as compared to a requirement for all global services would result in less reliable data being reported.

We noted that as we analyzed the data collected and made decisions about valuations, we would reassess the data needed and what should be required from whom. Through the data collected under our proposal, we indicated that we would have the information to assess whether the post-operative care furnished varies by factors such as specialty, geography, practice setting, and practice size, and thus, the information needed for a sample selection to be representative.

While section 1848(c)(8)(B) of the Act requires us to collect data from a representative sample of physicians on the number and level of visits provided during the global period, we stated that it does not prohibit us from collecting data from a broad set of practitioners. In addition, section 1848(c)(2)(M) of the Act authorizes the collection of data from a wide range of physicians. Given the benefits of more robust data, including avoiding sample bias, obtaining more accurate data, and facilitating operational simplicity, we noted that we believed collecting data on all post-operative care initially is the best way to undertake an accurate valuation of surgical services in the future.

The following is a summary of the comments that we received on our proposal to require all practitioners furnishing 10- or 90-day global services to submit claims for the pre- and post-operative services furnished.

Comment: Commenters overwhelmingly opposed requiring all practitioners to submit claims for postoperative services. Several reasons were cited for the opposition. The most significant reason was the administrative burden and costs to physicians. Many commenters also stated that requiring all practitioners who furnish 10- or 90-day global services to report data is counter to the statute because the statute refers to collection of data from a representative sample of physicians.

One commenter stated that requiring every practitioner to report these codes will be in many ways less representative than a targeted sample, explaining that given the limited time for education, only large, technologically rich practices will have the ability to properly report these services. The commenter noted that this will leave many, smaller or rural practices without the proper education and robust billing systems in place to adequately, if at all, report these G-codes. The commenter also noted that smaller, rural practices have smaller patient populations, which can often be older and sicker than the typical patient seen in a large practice and by creating a complex system that favors one type of practice, the collected data is more likely to be biased rather than representative. Another commenter suggested that a small number of representative practices could provide us with the same level of accuracy as collected data from all physicians.

Response: In response to commenters' opposition to our proposal to require all providers of covered services to report data, we acknowledge that the stakeholders describe a much larger burden from using the G-codes than we anticipated. On the other hand, we also believe that our final policy will result in a much lower burden than the proposed policy would have. As noted above, we are not finalizing the proposed requirements to use the G-codes or the proposed requirement to report on all 10- and 90-day global procedures and thus, we believe that the overall administrative burden is significantly reduced.

We do not agree with commenters that state that we do not have the statutory authority to require reporting by all practitioners furnishing certain services. We point commenters to section 1848(c)(2)(M) of the Act, which authorizes the collection of data to use in valuing PFS services. We continue to believe that section 1848(c)(8) of the Act requires us to collect data that is representative. We also continue to believe that requiring all practitioners to report is more likely to be representative than a sample given our lack of information about what drives variation in post-operative care. However, after considering the information presented by commenters regarding the difficulties that would be placed on many physicians by the proposal, we believe that requiring reporting by all practitioners for CY 2017 may present unforeseen, alternative impediments to the sample being nationally representative of all practitioners, such as practitioners being unable to report data accurately due to constraints of time, finances or technical ability.

Comment: We did not receive any comments on the appropriate sample size. Nor did we receive data on variations in the delivery of post-operative care in response to our concern that we lacked data on how post-operative care was delivered to select a representative sample. Many commenters stated that it was possible to select a representative sample, but none provided details on how to do so.

Several commenters suggested broadly sampling using the characteristics that are frequently used for health care sampling generally, such as geographic areas, urban and rural, practice types, practice sizes, specialties and academic and non-academic. One commenter recommended that we select a sample using geographical data to identify a sample including practices of all sizes. The commenter suggested, for example, that large hospital-based practices often have practice patterns that are different from the majority of the practicing physicians in suburban and rural areas. Another commenter stated that we should not only collect data from MSAs but also from rural and less urban areas.

One commenter suggested that we consider phasing in the requirement, perhaps starting with larger groups. The commenter stated that through one of these approaches we could avoid ''burdening providers with unfunded work that has not yet been tested.''

One commenter suggested that we use a geographic sampling approach similar to that one used for Comprehensive Care for Joint Replacement (CJR) model or the episode payment models proposed for cardiac and surgical hip/femur fraction and modify it to choose a geographic sampling unit of MSAs and non-MSAs.

Response: We agree with commenters that we could select a sample using an approach typically used in health care surveys or in Medicare models and other programs. To the extent that the delivery of post-operative care varies only based upon the criteria we selected, a sample based on being representative for that criteria would be likely to produce valid data.

However, instead of sampling by practice or practitioner or type of service, a geographic approach to sampling (for example, sampling all practitioners in a selected state) could help to alleviate the need to stratify the sample on a long list of criteria. By using broad geographical areas from varied areas of the country, we believe our sample will capture data from practitioners who practice in a variety of settings, single and multispecialty practices, urban and rural, a variety of medical specialties, and practitioners operating in both academic and non-academic institutions. Surgeons interviewed for the G-code development suggested that post-operative care might vary across these dimensions. A geographic approach could also mitigate some of the practical operational barriers. For example, we believe that by having all practitioners in the practice participate in reporting, we avoid concerns about incomplete data when a required reporter furnishes a procedure and another practitioner in the practice furnishes the post-operative visits. A geographic approach also makes it easier to educate practitioners on data collection requirements.

Comment: In response to operational difficulties with a representative sample, such as how to make sure participants were aware of the requirement to report and how to do so, one commenter stated that notifying a small targeted sample is a much smaller task than notifying the entire population of participating Medicare practitioners. They also stated that a targeted approach will encourage open dialogue between the participating practices and CMS, ensuring the data collected are reliable. Others suggested providing compensation for a sample of physicians to submit detailed data, would lead to capturing accurate data because they would more likely to understand and prioritize reporting because of their participation in this type of study.

Response: We disagree that it is operationally easier to notify a small segment of broadly diverse practitioners than the entire population of practitioners unless that small segment has a degree of cohesiveness, such as being in the same geographic area or specialty. We have long appreciated the stakeholder community's collaboration in broad communication efforts. In general, we have found that when something affects a small number of providers it does not receive the same response from entities that are critical for widespread adoption such as associations, who are key purveyors of information, and those developing software systems. We appreciate the suggestion that interaction among those that need to report will facilitate compliance and the quality of the data. With regard to compensation, we note that the statute provided for a 5 percent withhold to encourage compliance and we chose not to propose to implement this provision.

After consideration of the comments, we are finalizing a requirement for reporting that only applies to practitioners in selected states. In addition, those practicing only in small practices are excluded from required reporting. Those not required to report can do so voluntarily and we encourage them to do so.

Geographic Sample

As we noted in the proposed rule, we do not have adequate data on what drives variations in the delivery of pre- and post-operative care to design a sampling methodology that is certain to be representative. We also believe that submission by all practitioners would be consistent with our extensive use of claims data for other PFS services. Additionally, we understand the statute directs us to gather data from more than a select group of practitioners based on any particular attributes, such as gathering data only from ''efficient'' practices, consistent with longstanding recommendations from MedPAC regarding limiting data collection. We also believed that there were significant operational impairments to data reporting by a limited sample of physicians. In consideration of these factors, we proposed to require reporting by all physicians to make sure that the data we obtained reflected all services furnished. In light of the comments regarding the burden that would be created by requiring reporting by all physicians and the data that was actually needed for valuation, we think that reporting by a subset of practitioners could provide us valuable information on the number of visits typically furnished in global periods. This data could enhance the information we currently use to establish values for these services. While we acknowledge that we believe the data under this less burdensome approach will provide less information than necessary for optimal valuation for these services, we believe that the information on the number of actual visits from a subset of practitioners is preferable to the information on which we currently rely, which is the results of survey data reflecting respondents' assessment of the number of visits considered to be typical.

One commenter suggested that we could develop a geographic sample using a similar approach used by the Center for Medicare and Medicaid Innovation for the Comprehensive Care for Joint Replacement (CJR) or other proposed episode payment models, with an adjustment that would make certain we received data from rural, as well as urban areas. We reviewed these approaches and concluded that such an approach for sample selection could maximize the variability of the sample, mitigate some of our concerns, and provide a robust set of data for consideration.

Commenters suggested a sample should include geographic diversity. Studies show that health care delivery patterns often vary between geographic areas and while we have no specific information that the number of post-operative visits varies by geographic areas, it seems prudent to gather data from a variety of geographic areas to determine if there is such variation and

to account for it in our data collection if it exists. In order to maximize the variability of our limited sample, we are using a methodology that requires reporting from practices in 9 states of various sizes and from various geographic areas of the country. We are using whole states for the geographic areas rather than MSAs as are used for the CJR and proposed for other models for several reasons. First, MSAs are not used for geographic adjustments under the PFS. Indeed, practitioners in most states receive state-wide geographic adjustments under the PFS. Additionally, an MSA-based approach would, by definition, not include large rural areas, something mentioned by many commenters as an important factor in variation in medical practice, and therefore, a critical criterion for sampling. Also, due to a variety of governmental and institutional requirements, the practice of medicine is primarily a state-based activity and thus the use of states will reduce the number of practitioners for whom we have only partial data based on geographic location. In contrast, we believe that practitioners often practice across county lines or in more than one MSA. We also believe that the state-wide approach will be helpful for compliance and education because there are state medical associations in every state and specialty associations in many.

To make sure that we had states of a variety of sizes, we ranked states according to the number of Medicare beneficiaries in each state. We chose the number of Medicare beneficiaries to reflect the general need for Medicare services. We divided states into four groups: The top 5 states in terms of the number of Medicare beneficiaries (group 1); 6th through 15th largest states in terms Medicare beneficiaries (group 2); the 16th through 25th largest states in terms of Medicare beneficiaries (group 3); and all remaining states (26 including the District of Columbia, group 4). The states in each group are:

- Group 1—California, Florida, New York, Pennsylvania & Texas.
- Group 2—Georgia, Illinois, Massachusetts, Michigan, New Jersey, North Carolina, Ohio, Tennessee, Virginia, and Washington.
- Group 3—Alabama, Arizona, Indiana, Kentucky, Louisiana, Maryland, Minnesota, Missouri, Wisconsin, and South Carolina.
- Group 4—Alaska, Arkansas, Colorado, Connecticut, District of Columbia, Delaware, Hawaii, Idaho, Iowa, Kansas, Maine, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oklahoma, Oregon, Rhode Island, South Dakota, Utah, Vermont, West Virginia and Wyoming.

We also recorded the Census region for each state using the Census Bureau's nine regions (New England, Middle Atlantic, South Atlantic, East South Central, West South Central, East North Central, West North Central, Mountain, and Pacific). Puerto Rico and other territories were excluded.

To ensure a mix of states in terms of size (measured by number of Medicare beneficiaries), we selected 1 state at random from group 1, followed by 2 states each at random from groups 2 and 3, and lastly 4 states from group four. After each random selection, we eliminated the remaining states in the same Census region from the remaining groups for which selection was pending to maximize geographic variation in the selection of states. In the event that this process resulted in fewer than 9 selected states (for example if none of the three Middle Atlantic states—all in Group 1 and 2—were selected in the first three picks), the last selection(s) were made randomly from states in the remaining Census region from which selections previously had not been made.

Practitioners located in the following states who meet the criteria for required reporting will be required to report the data discussed in this section of the final rule:

- Florida.
- Kentucky.
- Louisiana.
- Nevada.
- New Jersey.
- North Dakota.
- Ohio.
- Oregon.
- Rhode Island.

Exclusion for Practitioners in Small Practices

In response to comment about the burden of our proposed requirement and the concern that the burden would result in the submission of data of poor quality, we are exempting practitioners who only practice in practices with fewer than 10 practitioners from the reporting. Based upon the comments, we believe larger practices are more likely to currently require practitioners to track all visits and often use CPT code 99024 to do so. Moreover, larger practices are more likely to have coding and billing staff that can more easily adapt to this claims-based requirement. The combination of experience with reporting CPT code 99024 and the staff and resource base to devote to developing the infrastructure for such reporting will result in greater accuracy from such practitioners. By excluding practitioners who only practice in practices with fewer than 10 practitioners, we estimate that about 45 percent of practitioners will not be required to report. In defining small practices, we reviewed other programs. We chose 10 practitioners as the threshold for reporting as practices of this size are large enough to support coding and billing staff, which will make this reporting less burdensome. Also, this is the same threshold used by the value-based modifier program for its phase-in of a new requirement because of concerns about the burden of small practices.

For this purpose, we define practices as a group of practitioners whose business or financial operations, clinical facilities, records, or personnel are shared by two or more practitioners. For the purposes of this reporting requirement, such practices do not necessarily need to share the same physical address; for example, if practitioners practice in separate locations but are part of the same delivery system that shares business or financial operations, clinical facilities, records, or personnel, all practitioners in the delivery system would be included when determining if the practice includes at least 10 practitioners. Because qualified non-physician practitioners may also furnish procedures with global periods, the exception for reporting post-operative visits applies only to practices with fewer than ten physicians and qualified non-physician practitioners regardless of specialty. We are including all practitioners and specialties in the count because the exception policy uses practice size as a proxy for the likely ability of the practice to meet the reporting requirements without undue administrative burden. We recognize that physicians and qualified non-physician practitioners furnish services under a variety of practice arrangements. In determining whether a practitioner qualifies for the exception based on size of the practice, all physicians and qualified non-physician practitioners that furnish services as part of the practice should be included. This would include all practitioners, regardless of whether they are furnishing services under an employment model, a partnership model, or an independent contractor model under which they practice as a group and share facility and other resources but continue to bill Medicare independently instead of reassigning benefits. We also recognize that practice size can fluctuate over the year and anticipate that practices will determine their eligibility for the exception based

on their expected staffing. Generally, practitioners in short-term locum tenens arrangements would not be included in the count of practitioners. When practitioners are also providing services in multiple settings, the count may be adjusted to reflect the estimated proportion of time spent in the group practice and other settings.

Although this policy excludes a significant number of practitioners, a majority of the global procedures furnished will be included in the reporting requirements and thus we will have data on a majority of services.

Several commenters also expressed concern that data from small practices be included to have complete information. If those practicing in small practices are motivated to report and either have the infrastructure to do so in place or the resources to develop such infrastructure, then, taken together, these attributes would minimize concerns with accuracy of data from small practices. Accordingly, we are encouraging, but not requiring, small practices to report the visits. As we collect data, we will explore mechanisms to appropriately use the voluntarily submitted claims data. Analysis of this and other data we are able to procure will allow us to assess whether the number of post-operative visits varies based upon the size of practice. To the extent that it does and that we do not have adequate data on the practice patterns in small practices from voluntarily submitted data and other sources, we will reconsider for future notice and comment rulemaking the exemption of practitioners in small practices from the reporting requirements.

The claims data received from practitioners in these states will provide more information about the number of visits typically provided in post-operative periods than is available from any other source. Through analysis of this data, we hope to learn more about what drives variations in the delivery of post-operative care. Many of the characteristics that were suggested by commenters, such as size of practice, type of practice, geographic, urban/rural, academic, hospital based, specialty, etc., will be able to be evaluated using the claims data. Moreover, we hope to be able to stratify the data received based upon comparisons to the national characteristics so that the submitted claims data can contribute to improved valuation of PFS services.

In summary, our claims-based data collection policy requires that, for procedures furnished on or after July 1, 2017, practitioners who practice in practices that includes of 10 or more practitioners in Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island will be required to report on claims data on post-operative visits furnished during the global period of a specified procedure using CPT code 99024. The specified procedures are those that are furnished by more than 100 practitioners and either are nationally furnished more than 10,000 times annually or have more than $10 million in annual allowed charges. The final list of codes subject to required reporting will be available on the CMS Web site. Although required reporting begins for global procedures furnished on or after July 1, 2017, we encourage all practitioners to begin reporting for procedures furnished on or after January 1, 2017, if feasible. Similarly, we encourage those practicing in practices with fewer than 10 practitioners to report data if they can do so.

(1) Survey of Practitioners

We agreed with commenters on the CY 2016 proposed rule and at the listening session that we need more information than is currently provided on claims and that we should utilize a number of different data sources and collection approaches to collect the data needed to assess and revalue global surgery services. In addition to the claims-based reporting, we proposed to survey a large, national sample of practitioners and their clinical staff in which respondents would report information about approximately 20 discrete pre-operative and post-operative visits and other global services like care coordination and patient training. This sample would be stratified based upon specialty and geography, as well as by physician volume (procedures billed) and practice setting. The proposed survey would produce data on a large sample of pre-operative and post-operative visits and is being designed so that we could analyze the data collected in conjunction with the claims-based data that we would be collecting. We expect to obtain data from approximately 5,000 practitioners.

We noted that, if our proposal was finalized, RAND would develop and conduct this survey. RAND would also assist us in collecting and analyzing data for this survey and the claims-based data. While the primary data collection would be via a survey instrument, semi-structured interviews would be conducted and direct observations of post-operative visits would occur in a small number of pilot sites to inform survey design, validate survey results, and collect information that is not conducive to survey-based reporting.

Our proposed sampling approach would sample practitioners rather than specific procedures or visits to streamline survey data collection and minimize respondent burden. Specifically, we will use a random sample from a frame of practitioners who billed Medicare for more than a minimum threshold of surgical procedures with a 10- or 90-day global period (for example, 200 procedures) in the most recent available prior year of claims data. The sampling frame would provide responses from approximately 5,000 practitioners, stratified by specialty, geography, and practice type. Based upon preliminary analysis, we believe this number of participants will allow us to collect information on post-operative care following the full range of CPT level-2 surgical procedure code groups. For many common types of post-operative visits, we anticipate a standard deviation of the time distribution at around 9 minutes. To achieve a 95 percent confidence intervals with a width of 2 minutes, we would need 311 reported post-operative visits per procedure/procedure group. The most comprehensive approach would be to sample sufficient practitioners to observe 311 post-operative visits for each HCPCS procedure, but this approach would be cost- and time-prohibitive. Since post-operative care following similar procedures may involve similar activities and times even if there are differences in the number of visits, we proposed to sample differentially by specialty to maximize our ability to estimate attributes of post-operative care for the largest range of procedures.

Sample sizes for each specialty will be determined on the basis of number of procedures billed by the specialty and number of practitioners billing, assuming a uniform distribution of procedures across the year, an average of 2 post-operative visits by each patient and an equal distribution of procedures across practitioners within a specialty. If the procedure represented only 5 percent of total billed procedures for the specialty, we could expect only one of 20 visits sampled and reported by each practitioner would be for the particular procedure, and thus we would need to sample 311 practitioners within the specialty to achieve the target precision level on estimated post-operative visit time.

We propose targeting 311 reporting practitioners from each specialty which is the only specialty contributing at least 5 percent of billings for any one

procedure group code, defined as procedures sharing a CPT level 2 heading. For other specialties, the target will be defined by the maximum value of 311 divided by the number of specialties contributing at least 5 percent for any procedure group code for which that specialty contributes. The target sample size for a specialty will be capped at 25 percent of the eligible practitioners within the specialty. For example, if a specialty contributed to two procedure group codes, one of which had four contributing specialties and the other had three contributing specialties, the specialty of interest would have a target of 104 reporting practitioners (which is driven by the procedure group code that is tied to three specialties). These guidelines will target at least 311 reporting practitioners for each procedure group code, and result in a total target sample size of 4,872 providers. A smaller sample size would reduce the precision of estimates from the survey and more importantly risk missing important differences in post-operative care for specific specialties or following different types of surgical procedures. We expect a response rate in excess of 50 percent. Given this response rate (and some uncertainty in this response rate estimate), we will need to approach at least 9,722 practitioners for our target of 4,872 practitioners. Should the response rate be lower than expected, we will continue to sample in waves until we reach the target of approximately 4,872 practitioners. Non-response bias will be assessed by comparing available characteristics of non-respondents (for example, practice type, geography, procedure volume etc.) to those of respondents.

We did not propose that respondents report on the entire period of post-operative care for individual patients, as a 90-day follow-up window (for surgeries currently with a 90-day global period) is too long to implement practically in this study setting and would be more burdensome to practitioners. Instead, we proposed to collect information on a range of different post-operative services resulting from surgeries furnished by the in-sample practitioner prior to or during a fixed reporting period.

Practitioners will be asked to describe 20 post-operative visits furnished to Medicare beneficiaries or other patients during the reporting period. The information collected through the survey instrument, which will be developed based upon direct observation and discussions in a small number of pilot sites, will include contextual information to describe the background for the post-operative care, including, for example:

- Procedure codes(s) and date of service for procedure upon which the global period is based.
- Procedure place of service.
- Whether or not there were complications during or after the procedure.
- The number in sequence of the follow-up visit (for example, the first visit after the procedure).

The survey instrument will also collect information on the visit in question including, for example:

- Which level of visit using existing billing codes.
- Specific face-to-face and non-face-to-face activities furnished on the day of the visit.
- The total time spent on face-to-face and non-face-to-face activities on the day of the visit.
- Direct practice expense items used during the visit, for example supplies like surgical dressings and clinical staff time.

Finally, the instrument will ask respondents to report other prior or anticipated care furnished to the patient by the practice outside of the context of a post-operative visit, for example non-face-to-face services.

The survey approach will complement the claims data collection by collecting detailed information on the activities, time, intensity, and resources involved in delivering global services. The resulting visit-level survey data would allow us to explore in detail the variation in activities, time, intensity, and resources associated with global services within and between physicians and procedures, and would help to validate the information gathered through claims. A summary of the work that RAND would be doing is available on the CMS Web site under downloads for the CY 2017 PFS proposed rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/.*

The following is a summary of the comments that we received on our proposal to conduct a survey of practitioners furnishing 10- and 90-day global services to obtain information about the face-to-face activities and other activities included in post-operative care.

Comment: Most commenters were generally supportive of the survey effort and noted that the provider survey will collect useful information on the level of visits, as well as important contextual detail that will not be available from the claims-based reporting. One commenter stated that a limited approach through surveys of physicians and practices looking at a targeted selection of services, and using CPT code 99024 for the claims based component would yield meaningful and actionable data for the agency and stakeholders.

Response: We agree that the survey portion of the data collection approach will provide useful information on level and context. The survey will complement claims-based reporting and will provide us with important information on non-face-to-face activities and other activities that are not reported with CPT code 99024.

Comment: One commenter pointed out challenges in survey response and in estimating time for visits by aggregating practitioner time estimates for specific activities.

Response: While we have not finalized the design of the survey instrument, we are aware of challenges in collecting detailed time estimates for specific activities. We do not intend to sum estimated times for specific activities to arrive at a total duration for the visit. We also recognize the challenges related to survey response rates and are working with our contractor accordingly.

Comment: Several commenters suggested that the survey effort should not target all 4,200 procedure codes.

Response: The survey component of the data collection effort is not designed to collect information on visits following all global procedure codes. Rather, we expect the sample to be stratified by specialty and to result in a sufficient qualitative data to address key procedures in each specialty furnishing procedures with global periods.

Comment: Some commenters believed that the purpose of the direct observation component of the data collection effort was unclear.

Response: The direct observation component will consist of external observers capturing the activities conducted in a sample of post-operative visits at a small number of practices. It is designed to provide additional context to inform future data collection efforts and to gauge where the practitioner survey does or does not capture the full range of activities. It is not a data collection activity per se.

After consideration of the comments, we are finalizing our proposal to conduct a survey of practitioners to gain information on post-operative activities to supplement our claims-based data collection as proposed. We expect that the survey will be in the field mid-2017.

(2) Required Participation in Data Collection

Using the authority we are provided under sections 1848(c)(8) and

1848(c)(2)(M) of the Act, we proposed to require all practitioners who furnish a 10- or 90-day global service to submit a claim(s) providing information on all services furnished within the relevant global service period in the form and manner described in this section of the final rule, beginning with surgical or procedural services furnished on or after January 1, 2017. We also proposed to require participation by practitioners selected for the broad-based survey through which we proposed to gather additional data needed to value surgical services, such as the clinical labor and equipment involved that cannot be efficiently collected on claim (see below).

Given the importance of the proposed survey effort, making sure that we get valid data is critical. By eliminating the bias that would be associated with using only data reported voluntarily, we stated that we expected to get more accurate and representative data. In addition to the potential bias inherent in voluntary surveys, we expressed concern that relying on voluntary data reporting would limit the adequacy of the volume of data we obtain, would require more effort to recruit participants, and may make it impossible to obtain data for valuation for CY 2019 as required by the statute.

Based on our previous experience with requesting voluntary cooperation in data collection activity, voluntary participation poses a significant challenge in collection and use of data. Specifically, the Urban Institute's work (under contract with us) to validate work RVUs by conducting direct observation of the time it took to furnish certain elements of services paid under the physician fee schedule provides evidence of this challenge. (See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-Urban-Interim-Report.pdf* for an interim report that describes challenges in securing participation in voluntary data collection.) Similarly, we routinely request invoices on equipment and supplies that are used in furnishing PFS services and often receive no more than one invoice. These experiences support the idea that mandatory participation in data collection activities is essential if we are to collect valid and unbiased data.

Section 1848(a)(9) of the Act authorizes us, through rulemaking, to withhold payment of up to 5 percent of the payment for services on which the practitioner is required to report under section 1848(c)(8)(B)(i) of the Act until the practitioner has completed the required reporting. Some commenters opposed the imposition of this payment consequence for failure to report, and others stated that it was too large a penalty. While withholding a portion of payment would encourage practitioners to report the required information, we did not propose to implement this option for CY 2017. We stated that requiring physicians to report the information on claims, combined with the incentive to report complete information so that revaluations of payment rates for global services are based on accurate data, would result in compliance with the reporting requirements. However, we noted that if we find that compliance with required claims-based reporting is not acceptable, we would consider in future rulemaking imposing up to a 5 percent payment withhold as authorized by the statute.

Consistent with the requirements of section 1848(c)(2)(M) of the Act, should the data collected under this requirement be used to determine RVUs, we will disclose the information source and discuss the use of such information in such determination of relative values through future notice and comment rulemaking.

The following is a summary of the comments we received on our proposal to require reporting in the claims-based survey and participation in the survey.

Comment: Many commenters objected overall to the administrative burden of our proposal and questioned the need for some of the data we were proposing to collect, primarily through the claims-based reporting, and made many recommendations for less burdensome data collection to achieve our goals. Some objected to any claims-based reporting at this time. A few recommended a different approach that involved collecting information from a small number of practices that agree to participate and that we pay such practices for participation. However, none recommended that we go forward with data collection on a totally voluntary basis. Some indicated concern that practitioners would not provide required information.

Response: We appreciate the many ideas for how to improve our data collection effort, particularly those that provided information on how to collect the information that we need while imposing a lower administrative burden on practitioners.

Comment: A few commenters supported our not proposing to implement the 5 percent withhold until claims on the post-operative care were submitted.

Response: We appreciate the support of commenters.

After considering the comments, we are finalizing our proposal to require participation in the claims-based reporting. It should be noted, however, due to our modifying the requirement to apply only to those identified as part of the geographic sample, on selected procedures, using one code, and exempting those practicing in groups with fewer than 10 practitioners, as discussed above, the impact of the requirement is significantly reduced overall, including for the subset of practitioners who will have to report under the finalized requirements.

We are not implementing the statutory provision that authorizes a 5 percent withhold of payment for the global services until claims are filed for the post-operative care, if required. We reiterate that should we find that compliance with required claims-based reporting limits confidence in the use of the information for improving the accuracy of payments for the global codes, we would consider in future rulemaking imposing up to a 5 percent payment withhold as authorized by the statute.

(3) Data Collection From Accountable Care Organizations (ACOs)

We are particularly interested in knowing whether physicians and practices affiliated with ACOs expend greater time and effort in providing post-operative global services in keeping with their goal of improving care coordination for their assigned beneficiaries. ACOs are organizations in which practitioners and hospitals voluntarily come together to provide high-quality and coordinated care for their patients. Because such organizations share in the savings realized by Medicare, their incentive is to minimize post-operative visits while maintaining high quality post-operative care for patients. In addition, we believe that such organizations offer us the opportunity to gain more in-depth information about delivery of surgical services.

We proposed to collect data on the activities and resources involved in delivering services in and around surgical events in the ACO context by surveying a small number of ACOs (Pioneer and Next Generation ACOs). Similar to the approach of the more general practitioner survey, this effort would begin with an initial phase of primary data collection using a range of methodologies in a small number of ACOs; development, piloting, and validation of an additional survey module specific to ACOs. A survey of practitioners participating in approximately 4 to 6 ACOs using the

survey instrument along with the additional ACO-specific module will be used to collect data from on pre- and post-operative visits.

The following is summary of the comments we received about our proposal for data ACO data collection.

Comment: Several commenters supported a separate survey of practitioners participating in ACOs. One commenter agreed with CMS that this data collection effort may provide a unique and useful perspective on the matter at hand. Several commenters indicated that there are likely differences in pre- and post-operative care between practitioners who do participate in ACOs and those that do not. One commenter cautioned against extrapolating information gathered from ACOs to value global surgery services that are provided outside of the ACO setting because ACOs are structured differently than other practice settings and data from ACOs may, therefore, be skewed [and] that ACO participants typically are larger practices and thus would underrepresent smaller or solo practitioners.

Response: We agree that ACOs may be structured differently than other practice settings and that these differences may contribute to variations in the provision of outpatient care. By separately surveying ACOs we will be able to investigate whether there are differences in pre- and post-operative care in ACO settings compared to non-ACO settings.

After consideration of the comments received, we are finalizing our proposal for data collection in ACOs. We recognize and will continue to consider the concerns raised by commenters as we implement this project.

(6) Re-Valuation Based Upon Collected Data

We recognize that the some of the data collection activities being undertaken vary from how information is currently gathered to support PFS valuations for global surgery services. However, we believe the proposed claims-based data collection is generally consistent with how claims data is reported for other kinds of services paid under the PFS. We believe that the authority and requirements included in the statute through the MACRA and PAMA were intended to expand and enhance data that might be available to enhance the accuracy of PFS payments. In the proposed rule, we indicated that because these are new approaches to collecting data and in an area—global surgery—where very little data has previously been collected, we cannot describe exactly how this information would be used in valuing services. What is clear is that the claims-based data would provide information parallel to the kinds of claims-data used in developing RVUs for other PFS services and that by collecting these data, we would know far more than we do now about how post-operative care is delivered and gain insight to support appropriate packaging and valuation. We would include any revaluation proposals based on these data in subsequent notice and comment rulemaking.

Even though we did not make a proposal regarding how future re-valuations would use the data collected under these proposals, we received several comments on such revaluations. The following is summary of the comments we received regarding use of the data we obtain through this three-pronged data collection activity in future re-valuations.

Comment: Some commenters stated that the RUC process worked well to value services and should continue to be used to value these and other services. Some of these objected to any claims-based data collection for a variety of reasons including that it was unlikely to provide valid and reliable data, that the RUC process worked well and should continue to be used, and the that since other codes would not be valued on the basis of similar data use of this data would harm the fee schedule's relativity. Some suggested that we use the data obtained here to identify misvalued codes and refer them to the RUC for further evaluation under the usual process. Some commenters suggested that we not collect any data until we could describe how it would be used.

Response: We believe that the Congress enacted the two data collection provisions included in the Act to further the accuracy of PFS rates by having additional data available to the RUC as it makes recommendations to us and to us to inform our evaluation of those recommendations. We do not believe this data collection was intended to replace the RUC or the processes that have been established over the last two decades for valuing physician services. We agree with commenters that one way the data might be used is to identify potentially misvalued codes for the RUC to evaluate. However, we also stress that we do not agree that the use of claims data to value services within global surgery packages would be inconsistent with the valuation of other PFS services. On the contrary, very few other PFS services include estimated work RVUs based on face-to-face patient encounters over multiple days or months. Outside of these services, work RVUs are estimated per patient encounter (or in other cases over longer periods of time for non-face-to-face work). Therefore, the outer limit of any misvaluation between the estimated typical and the actual is the overall value for a single face-to-face service. Under the global packages, potential misvaluations can range from the difference between the estimated typical services for a full global period and the actual services furnished for a full global period for a given patient. We are not finalizing any provisions regarding valuation of global surgical services. Instead, such issues will be addressed in future rulemaking after we collect data and analyze data.

E. Improving Payment Accuracy for Primary Care, Care Management and Patient-Centered Services

1. Overview

In recent years, we have undertaken ongoing efforts to support primary care and patient-centered care management within the PFS as part of HHS' broader efforts to achieve better care, smarter spending and healthier people through delivery system reform. We have recognized the need to improve payment accuracy for these services over several years, especially beginning in the CY 2012 PFS proposed rule (76 FR 42793) and continuing in each subsequent year of rulemaking. In the CY 2012 proposed rule, we acknowledged the limitations of the current code set that describes evaluation and management (E/M) services within the PFS. For example, E/M services represent a high proportion of PFS expenditures, but have not been recently revalued to account for significant changes in the disease burden of the Medicare patient population and changes in health care practice that are underway to meet the current population's health care needs. These trends in the Medicare population and health care practice have been widely recognized in the provider community and by health services researchers and policymakers alike.[1] We believe the focus of the

[1] See, for example, *http://content.healthaffairs.org/content/25/5/w378.full*; *http://www.commonwealthfund.org/publications/issue-briefs/2008/feb/how-disease-burden-influences-medication-patterns-for-medicare-beneficiaries—implications-for-polic*; *http://www.hhs.gov/ash/about-ash/multiple-chronic-conditions/index.html*; *http://www.nejm.org/doi/full/10.1056/NEJMp1600999#t=article*; *https://www.pcpcc.org/about*; *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html.*

health care system has shifted to delivery system reforms, such as patient-centered medical homes, clinical practice improvement, and increased investment in primary and comprehensive care management/coordination services for chronic and other conditions. This shift requires more centralized management of patient needs and extensive care coordination among practitioners and providers, often on a non-face-to-face basis across an extended period of time. In contrast, the current CPT code set is designed with an overall orientation to pay for discrete services and procedural care as opposed to ongoing primary care, care management and coordination, and cognitive services. It includes thousands of separately paid, individual codes, most of which describe highly specialized procedures and diagnostic tests, while there are relatively few codes that describe care management and cognitive services. The term ''cognitive services'' refers to the type of work that is usually classified and described under the current code set for E/M services, such as the critical thinking involved in data gathering and analysis, planning, management, decision-making, and exercising judgment in ambiguous or uncertain situations.[2] It is often used to describe PFS services that are not procedural or strictly diagnostic in nature. Further, in the past, we have not recognized as separately payable many existing CPT codes that describe care management and cognitive services, viewing them as bundled and paid as part of other services including the broadly drawn E/M codes that describe face-to-face visits billed by physicians and practitioners in all specialties.

This has resulted in minimal service variation for ongoing primary care, care management and coordination, and cognitive services relative to other PFS services, and in potential misvaluation of E/M services under the PFS (76 FR 42793). Some stakeholders believe that there is substantial misvaluation of physician work within the PFS, and that the current service codes fail to capture the range and intensity of nonprocedural physician activities (E/M services) and the ''cognitive'' work of certain specialties (*http://www.nejm.org/doi/full/10.1056/NEJMp1600999#t=article*).

Recognizing the inverse for specialties that furnish other kinds of services, MedPAC has noted that the PFS allows some specialties to more easily increase the volume of services they provide, and therefore, their revenue from Medicare relative to other specialties, particularly those that spend most of their time providing E/M services. (MedPAC March 2015 Report to the Congress, available at *http://www.medpac.gov/-documents-/reports*). We agree with this analysis, and we recognize that the current set of E/M codes limits Medicare's ability under the PFS to appropriately recognize the relative resource costs of primary care, care management/coordination and cognitive services relative to specialized procedures and diagnostic tests.

In recent years, we have been engaged in an ongoing incremental effort to update and improve the relative value of primary care, care management/coordination, and cognitive services within the PFS by identifying gaps in appropriate payment and coding. These efforts include changes in payment and coding for a broad range of PFS services. This effort is particularly vital in the context of the forthcoming transition to the Quality Payment Program that includes the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) incentives under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015), since MIPS and many APMs will adopt and build on PFS coding, RVUs and PFS payment as their foundation.

In CY 2013, we began by focusing on post-discharge care management and transition of beneficiaries back into the community, establishing new codes to pay separately for transitional care management (TCM) services. Next we finalized new coding and separate payment beginning in CY 2015 for chronic care management (CCM) services provided by clinical staff. In the CY 2016 PFS proposed rule (80 FR 41708 through 41711), we solicited public comments on three additional policy areas of consideration: (1) Improving payment for the professional work of care management services through coding that would more accurately describe and value the work of primary care and other cognitive specialties for complex patients (for example, monthly timed services including care coordination, patient/caregiver education, medication management, assessment and integration of data, care planning); (2) establishing separate payment for collaborative care, particularly, how we might better value and pay for robust inter-professional consultation between primary care physicians and psychiatrists (developing codes to describe and provide payment for the evidence-based psychiatric collaborative care model (CoCM)), and between primary care physicians and other (non-mental health) specialists; and (3) assessing whether current PFS payment for CCM services is adequate and whether we should reduce the administrative burden associated with furnishing and billing these services.

We received substantial feedback on this comment solicitation, which we summarized in the CY 2017 PFS proposed rule and used to develop the following coding and payment proposals for CY 2017 (81 FR 46200 through 46215, and 46263 through 46265):

- Separate payment for existing codes describing prolonged E/M services without direct patient contact by the physician (or other billing practitioner), and increased payment for prolonged E/M services with direct patient contact by the physician (or other billing practitioner) adopting the RUC-recommended values.[3]
- New coding and payment mechanisms for behavioral health integration (BHI) services including substance use disorder treatment, specifically three codes to describe services furnished as part of the psychiatric CoCM and one code to address other BHI care models.
- Separate payment for complex CCM services, reduced administrative burden for CCM, and an add-on code to the visit during which CCM is initiated (the CCM initiating visit) to reflect the work of the billing practitioner in assessing the beneficiary and establishing the CCM care plan.
- A new code for cognition and functional assessment and care planning, for treatment of cognitive impairment.
- An adjustment to payment for routine visits furnished to beneficiaries for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary.

We noted that the development of coding for these and other kinds of services across the PFS is typically an iterative process that responds to changes in medical practice and may be best refined over several years, with PFS rulemaking and the development of CPT codes as important parts of that process. We noted with interest that the CPT Editorial Panel and AMA/RUC restructured the former Chronic Care Coordination Workgroup to establish a

[2] *http://www.nejm.org/doi/full/10.1056/NEJMp1600999#t=article.*

[3] ''Without direct patient contact'' and ''with direct patient contact'' in this sentence are the terms used in the CPT code descriptor or prefatory language for these prolonged E/M services.

new Emerging CPT and RUC Issues Workgroup that we hope will continue to consider the issues raised in this section of our CY 2017 proposed rule. At the time of publication of the proposed rule, we were aware that CPT had approved a code to describe assessment and care planning for treatment of cognitive impairment; however, it would not be ready in time for valuation in CY 2017. Therefore, we proposed to make payment using a G-code (G0505 [4]) for this service in CY 2017. We were also aware that CPT had approved three codes that describe services furnished consistent with the psychiatric CoCM, but that they would also not be ready in time for valuation in CY 2017. We discuss these services in more detail in the next section of this final rule.

To facilitate separate payment for these services furnished to Medicare beneficiaries during CY 2017, we proposed to make payment through the use of three G-codes (G0502, G0503, and G0504—see below) that parallel the new CPT codes, as well as a fourth G-code (G0507—see below) to describe services furnished using other models of BHI in the primary care setting. We intended for these to be temporary codes and would consider whether to adopt and establish values for the new CPT codes under our standard process, potentially for CY 2018. We anticipated continuing the multi-year process of implementing initiatives designed to improve payment for, and recognize long-term investment in, primary care, care management and cognitive services, and patient-centered services. While we recognized that there may be some overlap in the patient populations for the proposed new codes, we noted that time spent by a practitioner or clinical staff could not be counted more than once for any code (or assigned to more than one patient), consistent with PFS coding conventions. We expressed continued consideration of additional codes for CCM services that would describe the time of the physician or other billing practitioner. We also expressed interest in whether there should be changes under the PFS to reflect additional models of inter-professional collaboration for health conditions, in addition to those we proposed for BHI.

We proposed to pay under the PFS for services described by new coding as follows (please note that the descriptions included for G0502, G0503, and G0504 are from *Current Procedural Terminology* (CPT®) Copyright 2016 American Medical Association (and we understand from CPT that they will be effective as part of CPT codes January 1, 2018). All rights reserved):

- G0502: 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.

- G0503: 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.

- G0504: 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 (List separately in addition to code for primary procedure) (Use G0504 in conjunction with G0502, G0503).
- G0507: 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 time, per calendar month.
- G0505: Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, by the physician or other qualified health care professional in office or other outpatient setting or home or domiciliary or rest home.
- G0506: Comprehensive assessment of and care planning by the physician or other qualified health care professional for patients requiring chronic care management services, including assessment during the provision of a face-to-face service (billed separately from monthly care management services) (Add-on code, list separately in addition to primary service).
- G0501: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient evaluation and management visit (Add-on code, list separately in addition to primary procedure).

Regarding the majority of these proposals, the public comments were broadly supportive, some viewing our proposals as a temporary solution to an underlying need to revalue E/M services, especially outpatient E/M. Several commenters recommended that CMS utilize the global surgery data collection effort or another major research initiative to distinguish and revalue different kinds of E/M work.

[4] We note that we used placeholder codes (GPPP1, GPPP2, GPPP3, GPPPX, GPPP6, GPPP7, and GDDD1) in the proposed rule. In order to avoid confusion, we have replaced those codes with those that have been finalized as part of the 2017 HCPCS set, even when describing the language in the proposed rule.

The commenters made recommendations about the scope and definition of the proposed services, what types of individuals should be able to provide them, and potential alignment and overlap. The commenters agreed with the need to increase the relative value of primary care, care management and other cognitive care under the PFS and minimize administrative burden for such services, while ensuring value to the program and beneficiaries. The public comments raise or inform a number of issues around how to define and pay for care that is collaborative, integrative or continuous, and we discuss the comments in greater detail below.

2. Non-Face-to-Face Prolonged Evaluation & Management (E/M) Services

In public comments on the CY 2016 PFS proposed rule, many commenters recommended that CMS should establish separate payment for non-face-to-face prolonged E/M service codes that we currently consider to be ''bundled'' under the PFS (CPT codes 99358, 99359). The CPT descriptors are:

- CPT code 99358 (Prolonged evaluation and management service before and/or after direct patient care, first hour); and
- CPT code 99359 (Prolonged evaluation and management service before and/or after direct patient care, each additional 30 minutes (List separately in addition to code for prolonged service).

Commenters believed that separate payment for these existing CPT codes would provide a means for physicians and other billing practitioners to receive payment that more appropriately accounts for time that they spend providing non-face-to-face care. We agreed that these codes would provide a means to recognize the additional resource costs of physicians and other billing practitioners, when they spend an extraordinary amount of time outside of an E/M visit performing work that is related to that visit and does not involve direct patient contact (such as extensive medical record review, review of diagnostic test results or other ongoing care management work). We also believed that doing so in the context of the ongoing changes in health care practice to meet the current population's health care needs would be beneficial for Medicare beneficiaries and consistent with our overarching goals related to patient-centered care.

These non-face-to-face prolonged service codes are broadly described (although they include only time spent personally by the physician or other billing practitioner) and have a relatively high time threshold (the time counted must be an hour or more beyond the usual service time for the primary or ''companion'' E/M code that is also billed). They are not reported for time spent in care plan oversight services or other non-face-to-face services that have more specific codes and no upper time limit in the CPT code set. We believed this made these codes sufficiently distinct from the other codes we proposed for CY 2017 as part of our primary care/cognitive care/care management initiative described in this section of our final rule. Accordingly, we proposed to recognize CPT codes 99358 and 99359 for separate payment under the PFS beginning in CY 2017. We noted that time could not be counted more than once towards the provision of CPT codes 99358 or 99359 and any other PFS service. We addressed their valuation in the valuation section of the CY 2017 proposed rule.

Through a drafting error, we stated in the proposed rule that we would require these services to be furnished on the same day by the same physician or other billing practitioner as the companion E/M code. We intended to propose conformity with CPT guidance that requires that time counted towards the codes describe services furnished during a single day directly related to a discrete face-to-face service that may be provided on a different day, provided that the services are directly related to those furnished in a face-to-face visit.

We also solicited public comment on our interpretation of existing CPT guidance governing concurrent billing or overlap of CPT codes 99358 and 99359 with complex CCM services (CPT codes 99487 and 99489) and TCM services (CPT codes 99495 and 99496). Specifically CPT provides, ''Do not report 99358, 99359 during the same month with 99487–99489. Do not report 99358, 99359 when performed during the service time of codes 99495 or 99496.'' Complex CCM services and TCM services are similar to the non-face-to-face prolonged services in that they include substantial non-face-to-face work by the billing physician or other practitioner. The TCM and CCM codes similarly focus on a broader episode of patient care that extends beyond a single day, although they have a monthly service period and the prolonged service codes do not. We sought public input on the intersection of the non-face-to-face prolonged service codes with CCM and TCM services, and with the proposed add-on code to the CCM initiating visit G0506 (Comprehensive assessment of and care planning for patients requiring CCM services). We also solicited comment regarding how distinctions could be made between time associated with prolonged services and the time bundled into other E/M services, particularly pre- and post-service times, which would continue to be bundled with the other E/M service codes. For all of these services, we expressed concern that there would potentially be program integrity risks as the same or similar non-face-to-face activities could be undertaken to meet the billing requirements for a number of codes. We solicited public comment to help us identify the full extent of program integrity considerations, as well as options for mitigating program integrity risks.

Comment: Many commenters recommended that we adopt the CPT coding provision for CPT codes 99358 and 99359 that allows the prolonged services to be provided on a different day than the companion E/M code. At the same time, several commenters indicated that they request changes to the codes through the established processes of the CPT Editorial Panel. For example, some commenters suggested that CPT codes 99358 and 99359 should be revised so that they have a limited (calendar month) service period or measure shorter time increments (15 minutes). Some commenters recommended that a given physician should not be allowed to report CPT codes 99358 and 99359 for the same beneficiary during the same time he or she reported CCM, TCM, or G0506. These commenters stated that CCM, TCM, and proposed G0506 encompass non-face-to-face care provided to the beneficiary during a given period of time that would be duplicated if the physician is also allowed to report CPT codes 99358 and 99359 during the same time period. Other commenters stated that it would be unusual for G0506 and non-face-to-face prolonged services (CPT codes 99358 and 99359) to be reported for services on the same day, but that both should be allowed if time thresholds are met. To facilitate determination of whether time thresholds are met for various potential code combinations, some commenters recommended that CMS establish a time for G0506 and publish typical times for the companion codes to the prolonged service codes. This would enable practitioners to determine when they have exceeded ''usual'' or average times for E/M services and may bill prolonged services. Some commenters recommended that CMS provide tables

showing times for E/M visits, CCM, G0506 and prolonged services with specific clinical examples for concurrent billing.

Some commenters believed there might be some overlap between the proposed non-face-to-face prolonged service codes and the post-service work of G0505 (Cognition and functional assessment by the physician or other qualified health care professional in office or other outpatient). Some commenters believed there is a discrepancy between our proposal to allow G0505 to be a companion code to prolonged services, and CPT's intent that G0505 should only be billed on the same day as another E/M visit if they are unrelated.

MedPAC commented that the companion E/M codes should be revalued instead of providing separate payment for prolonged services associated with the companion codes. However, if we finalize as proposed, MedPAC recommended that we clarify what situations the prolonged codes are appropriate for, beyond average times. Another commenter recommended an alternative policy instead of the non-face-to-face prolonged service codes, namely several modifiers and add-on codes to E/M services, associated with increased work RVUs. A typical time for the primary service would not need to be established. This coding schema would focus on visits actively treating patients with four or more chronic conditions; patients with three or more chronic problems introducing an acute problem during their visit; unexpected abnormal studies; and electronic communication after visits with the patient, lab, and other clinicians. One commenter drew a distinction between prolonged service work and care management services, where care management does not include extensive review of medical records, review of diagnostic tests and further discussion with a caregiver.

Response: We appreciate the comments. First, we had intended to propose to adopt the CPT coding provision for CPT codes 99358 and 99359 that allows the prolonged time to be provided on a different day than the companion E/M code, along with the rest of the CPT prefatory language for these codes. Our final policy will adopt the CPT guidance that allows the prolonged time to be reported for time on a different day than the companion E/M code, along with the rest of the CPT prefatory language for CPT codes 99358 and 99359.

Second, the public comments elucidate that it is difficult to assess potential overlap between prolonged services and many other codes because the included services, service periods and timeframes are not aligned. For example, most services paid under the PFS are valued based on assumptions regarding the typical pre-service, intra-service and post-service time, but do not have required thresholds for time spent. It is difficult to distinguish the times associated with these services from the times for codes that include time requirements in their descriptor. It is also difficult to distinguish the time and other work included in codes that generally describe services furnished during one day (prolonged services and E/M visits) with codes that describe time and work over substantially different service periods (such as the calendar month services like CCM or BHI services) or add-on codes with no pre or post-service time (such as G0506). In addition, because portions of many services are likely describing work that is furnished ''incident to'' a physician's or practitioner's services, the time and effort of the billing practitioner may not be the only relevant time and effort to consider. Moreover, the comments reflect a desire and intent on the part of stakeholders to alter the prolonged service codes in the near future, which would, in turn, alter their intersection with the codes proposed in this section of our 2017 rule and many other codes. The public comments also reflect a lack of consensus regarding appropriate medical practice and reporting patterns for prolonged services in relation to the services described by the CCM, TCM, proposed G0505 and proposed G0506 codes.

Having considered this feedback, we have decided to finalize our proposal for separate payment of the non-face-to-face prolonged service codes (CPT 99358, 99359) and adopt the CPT code descriptors and prefatory language for reporting these services. We stress that we intend these codes to be used to report extended non-face-to-face time that is spent by the billing physician or other practitioner (not clinical staff) that is not within the scope of practice of clinical staff, and that is not adequately identified or valued under existing codes or the 2017 finalized new codes. We appreciate the commenters' suggestion to display the typical times associated with relevant services. We have posted a file that notes the times assumed to be typical for purposes of PFS rate-setting. That file is available on our Web site under downloads for the CY 2017 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. We note that while these typical times are not required to bill the displayed codes, we would expect that only time spent in excess of these times would be reported under a non-face-to-face prolonged service code.

Based on our analysis of comments, we do not believe there is significant overlap between CPT codes 99358 and 99359 and the CCM codes (CPT 99487, 99489, 99490) or our finalized BHI service codes (G0502, G0503, G0504, G0507 discussed below). The work of the billing practitioner in the provision of non-complex CCM and the BHI services is related to the direction of ongoing care management and coordination activities of other individuals, compared to the work of 99358 and 99359 which is described as personally performed and directly related to a face-to-face service. On that basis, we do not believe that there is significant overlap in the description of services or the valuation.

The potential intersection of CPT codes 99358 and 99359 with the complex CCM codes is harder to assess because complex CCM explicitly includes medical decision-making of moderate to high complexity by the billing practitioner, which is not performed by clinical staff. The complex CCM codes, however, only measure or count the time of clinical staff. Similarly, TCM includes moderate to high complexity medical decision-making during the service period as well as a level 4 or 5 face-to-face visit, even though clinical staff may perform a number of other aspects of the service. For CY 2017, for administrative simplicity, we are adopting the CPT provision (and finalizing as proposed) that complex CCM cannot be reported during the same month as non-face-to-face prolonged services, CPT codes 99358 and 99359 (by a single practitioner). Similarly, we are adopting the CPT provision that non-face-to-face prolonged services, CPT codes 99358 and 99359 may not be reported when performed during the service time of TCM (CPT codes 99495 and 99496) (by a single practitioner). We interpret the CPT provision to mean that CPT codes 99358 and 99359 cannot be reported during the TCM 30-day service period, by the same practitioner who is reporting the TCM.

Regarding potential intersection of CPT codes 99358 and 99359 with proposed G0505 (Cognition and functional assessment by the physician or other qualified health care professional in office or other outpatient), we are finalizing our proposal that G0505 be designated as a

companion or ''base'' E/M code to non-face-to-face prolonged services (CPT codes 99358 and 99359) (see section II.E.5 for a detailed discussion of G0505). That is, for CY 2017 CPT codes 99358 and 99359 may be reported with G0505 as the associated companion code, whether furnished on the same day or a different day. We believe CPT intended the code on which G0505 is modeled to function like a specific E/M service, and that while the specificity of the service explicitly includes care planning unique to the needs of patients with particular conditions, there may well be circumstances where the pre- or post-time for a particular beneficiary may be prolonged. In their current form, the non-face-to-face prolonged service codes exist for the purpose of providing additional payment to account for the biller's additional time related to E/M visits. Therefore, we believe the non-face-to-face prolonged service codes should be reportable when related to E/M services, including those such as G0505 that describe more specific E/M work. We look forward to continued feedback on this issue, including through potential revisions to CPT guidance.

Regarding intersection of CPT codes 99358 and 99359 with G0506, we note that G0506 is already an add-on code to another E/M service (the CCM initiating visit, which can be the AWV/IPPE or a qualifying face-to-face E/M visit). We are providing in section II.E.4.a that at this time (beginning in CY 2017), G0506 will be a code that is only billable one time, at the outset of CCM services. We agree with commenters that it would be unusual for physicians to spend enough time with a given beneficiary on a given day to warrant reporting all three codes (the initiating visit code, G0506, and a prolonged service code). We also believe that a simpler approach is preferable at this time (two related codes for CCM initiation, instead of possibly three). Therefore our final policy for CY 2017 is that prolonged services (whether face-to-face or non-face-to-face) cannot be reported in addition to G0506 in association with a companion E/M code that also qualifies as the CCM initiating visit. In association with the CCM initiating visit, a billing practitioner may choose to report either prolonged services or G0506 (if requirements to bill both prolonged services and G0506 are met), but cannot report both a prolonged service code and G0506.

3. Establishing Separate Payment for Behavioral Health Integration (BHI)

In the CY 2016 PFS final rule with comment period (80 FR 70920), we stated that we believe the care and management for Medicare beneficiaries with behavioral health conditions often requires extensive discussion, information-sharing and planning between a primary care physician and a specialist. In CY 2016 rulemaking, we described that in recent years, many randomized controlled trials have established an evidence base for an approach to caring for patients with behavioral health conditions called the psychiatric Collaborative Care Model (CoCM). We sought information to assist us in considering refinements to coding and payment to address this model in particular. The psychiatric CoCM is one of many models for behavioral health integration or BHI, a term that refers broadly to collaborative care that integrates behavioral health services principally with primary care, but that may also integrate behavioral health care with inpatient and other clinical care. BHI is a team-based approach to care that focuses on integrative treatment of patients with medical and mental or behavioral health conditions. In the CY 2017 proposed rule (81 FR 46203 through 46205), we proposed four new G-codes for BHI services: Three describing the psychiatric CoCM specifically, and one generally describing related models of care.

a. Psychiatric Collaborative Care Model (CoCM)

A specific model for BHI, psychiatric CoCM typically is provided by a primary care team consisting of a primary care provider and a care manager who works in collaboration with a psychiatric consultant, such as a psychiatrist. Care is directed by the primary care team and includes structured care management with regular assessments of clinical status using validated tools and modification of treatment as appropriate. The psychiatric consultant provides regular consultations to the primary care team to review the clinical status and care of patients and to make recommendations. As we previously noted, several resources have been published that describe the psychiatric CoCM in greater detail and assess the impact of the model, including pieces from the University of Washington (*http://aims.uw.edu/*), the Institute for Clinical and Economic Review (*http://icer-review.org/announcements/icer-report-presents-evidence-based-guidance-to-support-integration-of-behavioral-health-into-primary-care/*), and the Cochrane Collaboration (*http://www.cochrane.org/CD006525/DEPRESSN_collaborative-care-forpeople-with-depression-and-anxiety*). Because this particular kind of collaborative care model has been tested and documented in medical literature, in the CY 2016 proposed rule we expressed particular interest in how coding used to describe PFS services might facilitate appropriate valuation of the services furnished under this model. We solicited public comments to assist us in considering refinements to coding and payment to address this model in particular relative to current coding and payment policies, as well as information related to various requirements and aspects of these services.

After consideration of the comments, we proposed in the CY 2017 PFS proposed rule to begin making separate payment for services furnished using the psychiatric CoCM, beginning January 1, 2017. We were aware that the CPT Editorial Panel, recognizing the need for new coding for services under this model of care, had approved three codes to describe the psychiatric collaborative care that is consistent with this model, but the codes would not be ready in time for valuation in CY 2017. Current CPT coding does not accurately describe or facilitate appropriate payment for the treatment of Medicare beneficiaries under this model of care. For example, under current Medicare payment policy, there is no payment made specifically for regular monitoring of patients using validated clinical rating scales or for regular psychiatric caseload review and consultation that does not involve face-to-face contact with the patient. We believed that these resources are directly involved in furnishing ongoing care management services to specific patients with specific needs, but they are not appropriately recognized under current coding and payment mechanisms. Because PFS valuation is based on the relative resource costs of the PFS services furnished to Medicare beneficiaries, we believed that appropriate coding for these services for CY 2017 will facilitate accurate payment for these and other PFS services. Therefore, we proposed separate payment for services under the psychiatric CoCM using three new G-codes, as detailed below: G0502, G0503, and G0504, which would parallel the CPT codes that are being created to report these services.

The proposed code descriptors were as follows (from *Current Procedural Terminology* (CPT®) Copyright 2016 American Medical Association (and we understand from CPT that they will be effective as part of CPT codes January 1, 2018). All rights reserved):

- G0502: 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.

• G0503: 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.

• G0504: 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 (List separately in addition to code for primary procedure) (Use G0504 in conjunction with G0502, G0503).

We stated that we intend these to be temporary codes and would consider whether to adopt and establish values for the associated new CPT codes under our standard process once those codes are active.

We proposed that these services would be furnished under the direction of a treating physician or other qualified health care professional during a calendar month. These services would be furnished when a patient has a diagnosed psychiatric disorder that requires a behavioral health care assessment; establishing, implementing, revising, or monitoring a care plan; and provision of brief interventions. The diagnosis could be either pre-existing or made by the billing practitioner. These services would be reported by the treating physician or other qualified health care professional and include the services of the treating physician or other qualified health care professional, the behavioral health care manager (see description below) who would furnish services incident to services of the treating physician or other qualified health care professional, and the psychiatric consultant (see description below) whose consultative services would be furnished incident to services of the treating physician or other qualified health care professional. We proposed that beneficiaries who are appropriate candidates for care reported using the psychiatric CoCM codes could have newly diagnosed conditions, need help in engaging in treatment, have not responded to standard care delivered in a non-psychiatric setting, or require further assessment and engagement prior to consideration of referral to a psychiatric care setting. Beneficiaries would be treated for an episode of care, defined as beginning when the behavioral health care manager engages in care of the beneficiary under the appropriate supervision of the billing practitioner and ending with:

• The attainment of targeted treatment goals, which typically results in the discontinuation of care management services and continuation of usual follow-up with the treating physician or other qualified healthcare professional; or

• Failure to attain targeted treatment goals culminating in referral to a psychiatric care provider for ongoing treatment; or

• Lack of continued engagement with no psychiatric collaborative care management services provided over a consecutive 6-month calendar period (break in episode).

A new episode of care would start after a break in episode of 6 calendar months or more.

The treating physician or other qualified health care professional would direct the behavioral health care manager and continue to oversee the beneficiary's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed. Medically necessary E/M and other services could be reported separately by the treating physician or other qualified health care professional, or other physicians or practitioners, during the same calendar month. Time spent by the treating physician or other qualified health care professional on activities for services reported separately could not be included in the services reported using G0502, G0503, and G0504. We proposed that the behavioral health care manager would be a member of the treating physician or other qualified health care professional's clinical staff with formal education or specialized training in behavioral health (which could include a range of disciplines, for example, social work, nursing, and psychology) who provides care management services, as well as an assessment of needs, including the administration of validated rating scales,[5] the development of a care plan, provision of brief interventions, ongoing collaboration with the treating physician or other qualified health care professional, maintenance of a registry,[6] all in consultation with a psychiatric consultant. The behavioral health care manager would furnish these services both face-to-face and non-face-to-face, and consult with the psychiatric consultant minimally on a weekly basis. We proposed that the behavioral health care manager would be on-site at the location where the treating physician or other qualified health care professional furnishes services to the beneficiary.

We proposed that the behavioral health care manager may or may not be a professional who meets all the requirements to independently furnish and report services to Medicare. If otherwise eligible, then that individual

[5] For example, see *https://aims.uw.edu/resource-library/measurement-based-treatment-target.*

[6] For example, see *https://aims.uw.edu/collaborative-care/implementation-guide/plan-clinical-practice-change/identify-population-based.*

could report separate services furnished to a beneficiary receiving the services described by G0502, G0503, G0504, and G0507 in the same calendar month. These could include: Psychiatric evaluation (90791, 90792), psychotherapy (90832, 90833, 90834, 90836, 90837, 90838), psychotherapy for crisis (90839, 90840), family psychotherapy (90846, 90847), multiple family group psychotherapy (90849), group psychotherapy (90853), smoking and tobacco use cessation counseling (99406, 90407), and alcohol or substance abuse intervention services (G0396, G0397). Time spent by the behavioral health care manager on activities for services reported separately could not be included in the services reported using time applied to G0502, G0503, and G0504.

The psychiatric consultant involved in the ''incident to'' care furnished under this model would be a medical professional trained in psychiatry and qualified to prescribe the full range of medications. The psychiatric consultant would advise and make recommendations, as needed, for psychiatric and other medical care, including psychiatric and other medical diagnoses, treatment strategies including appropriate therapies, medication management, medical management of complications associated with treatment of psychiatric disorders, and referral for specialty services, that are communicated to the treating physician or other qualified health care professional, typically through the behavioral health care manager. The psychiatric consultant would not typically see the patient or prescribe medications, except in rare circumstances, but could and should facilitate a referral to a psychiatric care provider when clinically indicated.

In the event that the psychiatric consultant furnished services to the beneficiary directly in the calendar month described by other codes, such as E/M services or psychiatric evaluation (CPT codes 90791 and 90792), those services could be reported separately by the psychiatric consultant. Time spent by the psychiatric consultant on activities for services reported separately could not be included in the services reported using G0502, G0503, and G0504.

We also noted that, although the psychiatric CoCM has been studied extensively in the setting of specific behavioral health conditions (for example, depression), we received persuasive comments in response to the CY 2016 proposed rule recommending that we not specify particular diagnoses required for use of the codes for several reasons, including that: There may be overlap in behavioral health conditions; there are concerns that there could be modification of diagnoses to fit within payment rules which could skew the accuracy of submitted diagnosis code data; and for many patients for whom specialty care is not available, or who choose for other reasons to remain in primary care, primary care treatment will be more effective if it is provided within a model of integrated care that includes care management and psychiatric consultation.

Comment: The public comments were very supportive of our creation of the three G-codes for CY 2017 to pay for services furnished using the psychiatric CoCM. The commenters offered a number of recommendations regarding valuation of the codes. Some commenters requested additional codes, sought clarification, or presented statements in favor of including the services of practitioners other than psychiatrists, especially psychologists and social workers, within the proposed codes.

Response: We thank the commenters for their support of coding and valuation for services furnished using the psychiatric CoCM, and for their recommendations regarding appropriate valuation. We address the comments on valuation in section II.L of this final rule. We address the comments regarding payment for services of psychologists and social workers below.

Comment: Several commenters expressed concern that making separate payment for psychiatric CoCM for the treatment of mood disorders might result in neglecting treatment for other mental health conditions. Other commenters expressed support for not designating a limited set of eligible behavioral health diagnoses. One commenter stated that requiring a diagnosed behavioral health condition might mean that subclinical issues or undiagnosed behavioral health conditions would be neglected.

Response: We continue to believe that we should not limit billing and payment for the psychiatric CoCM codes to a limited set of behavioral health conditions. As we understand it, the psychiatric CoCM model of care may be used to treat patients with any behavioral health condition that is being treated by the billing practitioner, including substance use disorders. In the Collaborative Care literature reviewed by the Cochrane Collaboration and others, there is stronger evidence of effectiveness and cost-effectiveness for certain behavioral disorders, particularly mood and anxiety disorders, than for others. However, we continue to receive persuasive comments indicating that the psychiatric CoCM is recommended for broader incorporation into clinical practice, and recommending that we not specify the use of the psychiatric CoCM codes for only particular behavioral health diagnoses. Therefore we are not limiting billing and payment for the psychiatric CoCM codes to a specified set of behavioral health conditions.

In response to the public comment regarding whether we should require a diagnosed psychiatric disorder (as opposed to a subclinical or undiagnosed condition), we are clarifying that as described, the services require that there must be a presenting psychiatric or behavioral health condition(s) that, in the clinical judgment of the treating physician or other qualified health professional, warrants ''referral'' to the behavioral health care manager for further assessment and treatment through provision of psychiatric CoCM services. ''Referral'' is placed in quotes because the behavioral health care manager may be located in the same practice as the treating physician or other qualified health professional, who in any event provides ongoing oversight and continues to treat the beneficiary. However, the referring diagnosis (or diagnoses) may be either pre-existing or made by the treating physician or other qualified health professional, and we are not establishing any specific list of eligible or included diagnoses or conditions. The treating physician or other qualified health professional may not be qualified or able to fully diagnose all relevant psychiatric or behavioral health condition(s) prior to referring the beneficiary for psychiatric CoCM services. If in the course of providing psychiatric CoCM services, it becomes clear that the referring condition(s) or other diagnoses cannot be addressed by psychiatric CoCM services, then we understand that the beneficiary should be referred for other psychiatric treatment or should continue usual follow-up care with the treating practitioner, because the episode of psychiatric CoCM services ends if there is failure to attain targeted treatment goals after or despite changes in treatment, as indicated. Beneficiaries receiving care reported using the psychiatric CoCM codes may, but are not required to have comorbid chronic or other medical condition(s) that are being managed by the treating practitioner.

Comment: Several commenters who supported payment for the proposed codes for psychiatric CoCM services in primary care settings, raised questions about whether these codes could be

used to bill for services furnished in other settings that are not traditional primary care settings, such as inpatient or long-term care, oncology practices, or emergency departments. Some of these commenters recommended additional new codes to pay for services furnished in these other settings.

Response: The psychiatric CoCM trials and real world implementation have mainly included primary care practice that broadly includes pediatrics, obstetrics/gynecology, and geriatrics as well as family practice and general internal medicine. The psychiatric CoCM has also been used in cardiology and oncology practice, and we believe it could be used in various medical specialty settings, as long as the specialist physician or practitioner is managing the beneficiary's behavioral health condition(s) as well as other medical conditions (for example, cancer, status-post acute myocardial infarction and other conditions where co-morbid depression is common). Accordingly, we are not limiting the code to reporting by only ''traditional'' primary care specialties. We believe primary care practitioners will most frequently perform the services described by the new psychiatric CoCM codes, but if other specialist practitioners perform these services and meet all of the requirements to bill the code(s), then they may report the psychiatric CoCM codes. We are interested in receiving additional, more specific information from stakeholders regarding which specialties furnish psychiatric CoCM services. We note that we would generally not expect psychiatrists to bill the psychiatric CoCM codes, because psychiatric work is defined as a sub-component of the psychiatric CoCM codes.

Regarding psychiatric CoCM services furnished to inpatients or beneficiaries in long-term care settings such as nursing or custodial care facilities, we note that the forthcoming CPT codes are not limited to office or other outpatient or domiciliary services. Moreover, our goal is to separately identify and pay for psychiatric CoCM services furnished to beneficiaries in any appropriate setting of care, whether inpatient or outpatient, in recognition of the associated time and service complexity. Care of beneficiaries who are admitted to a facility, are in long-term care, or are transitioning among settings during the month may be more complex than the care of other types of patients. While there is some overlap between psychiatric CoCM and CCM services, they are distinct services with differing patient populations, as discussed elsewhere in this section of our final rule. Therefore, we have valued the psychiatric CoCM services in both facility and non-facility settings (see section II.L on valuation). We are not limiting the time that can be counted towards the monthly time requirement to bill the psychiatric CoCM code(s) to time that is spent in the care of an outpatient or a beneficiary residing in the community. However, we also stress that G0502, G0503 and G0504 can only be reported by a treating physician or other qualified health care professional when he or she has directed the psychiatric CoCM service for the duration of time that he or she is reporting it, and has a qualifying relationship with individuals providing the service under his or her direction and control. Also, time and effort that is spent managing care transitions for CCM or TCM patients and that is counted towards reporting TCM or CCM services, cannot also be counted towards reporting any transitional care management activities reported under a BHI service code(s), either the psychiatric CoCM codes or the code describing other BHI services. We welcome additional input from stakeholders regarding appropriate (or inappropriate) sites of service for G0502, G0503 and G0504.

We note that for CY 2017, the facility PE RVU for psychiatric CoCM services will include the indirect PE allocated based on the work RVUs, but no direct PE (which is explicitly comprised of other labor, equipment and supplies). This is because historically, the PFS facility rate for a given professional service assumes that the billing practitioner is not bearing a significant resource cost in labor by other individuals, equipment or supplies. We generally assume that those costs are instead borne by the facility, and are adequately accounted for in a separate payment made to the facility to account for these costs and other costs incurred by the facility for the beneficiary's facility stay. For BHI services and similar care management services such as CCM, we have been considering whether this approach to PFS valuation is optimal because the PFS service, in significant part, may be provided by the behavioral health care manager, clinical staff, or even other physicians under the employment of the billing practitioner or under contract to the billing practitioner. These individuals may provide much of the PFS service remotely, and are not necessarily employees or staff of the facility. Indeed, the BHI services are defined in terms of activities performed by individual(s) other than the billing practitioner and who may not be affiliated with or located within the facility, even though as we discuss below the billing practitioner must also perform certain work. For this type of PFS service, there may be more direct practice expense borne by the billing practitioner even though the beneficiary is located, for part or all of the month, in a facility receiving institutional payment. We plan to consider these issues further in the future.

Comment: One specialty association supported the proposed psychiatric CoCM codes, noting that although few of their members would use these codes, they set an important precedent to recognize interdisciplinary care that requires significant non-face-to-face work. This commenter anticipated that similar code series may be developed in the future to describe complex management in other specialties including neurology, and supported the adoption of language approved at CPT that carefully defined the roles of multiple professionals. Other commenters similarly expressed support for separate payment for additional collaborative care services, including inter-professional consultation in the treatment of other illnesses such as cancer or multiple sclerosis.

Response: We continue to be interested in new coding that describes integrative, collaborative or consultative care among specialties other than primary care and behavioral health/psychiatry. We are especially interested in new coding that describes such care in sufficient detail that distinguishes it from existing service codes, and that would further the appropriate valuation of cognitive services. We will continue to follow any new coding proposals at CPT relevant for the Medicare population. We note that we have followed CPT's lead in finalizing proposed code G0505 for cognitive impairment assessment and care planning (see section II.E.5) as well as for psychiatric CoCM services. BHI is a unique type of service that we believe until now has not been well identified nor appropriately valued under existing codes. BHI is not comprised of mere consultation among professionals and has a unique evidence base, in addition to being recently addressed by forthcoming CPT coding. In addition, given the shortage of available psychiatric and other mental health professionals in many parts of the country, we believe it is important to identify and make accurate payment for models of care that facilitate access to psychiatric and other behavioral health specialty care through innovations in medical practice, like the ones described by these codes.

Comment: One commenter asked CMS to clarify inclusion of nurse practitioners who are primary care practitioners and, in the specialty of psychiatry, psychiatric nurse practitioners who can perform psychiatric evaluations and treat psychiatric problems.

Response: Nurse practitioners are authorized to independently bill Medicare for their services, and can also bill Medicare for services furnished incident to their services. Therefore, nurse practitioners who furnish the psychiatric CoCM services as described may bill for the psychiatric CoCM codes. Nurse practitioners who meet our final qualifications to serve as the behavioral health care manager may provide the behavioral health care manager services incident to the services of another (billing) practitioner. Nurse practitioners who meet all of our final requirements to serve as the psychiatric consultant may provide the psychiatric consultant services incident to the services of the billing practitioner.

Comment: Regarding the care planning requirements for psychiatric CoCM services, some commenters noted that there is not necessarily value in accumulating or enumerating a number of different types of care plans addressing different aspects of the beneficiary's problems, such as a behavioral or psychiatric care plan, a CCM care plan, and a cognitive impairment care plan (see G0505 in section II.E.5).

Response: While the proposed descriptors for the psychiatric CoCM services referred to an ''individualized treatment plan,'' not a ''care plan,'' we proposed in addition that the behavioral health care manager would ''develop a care plan.'' While any care planning should take into account the whole patient, our intent is that the care planning included in the CCM coding (and G0506, the CCM initiating visit add-on code) will be the most comprehensive in nature, addressing all health issues with particular focus on the multiple chronic conditions being managed by the billing practitioner. In that sense, the CCM care plan is an integrative care plan incorporating more comprehensive health information on all of the beneficiary's health issues, or reconciling care plans of other practitioners. In contrast, the BHI care planning will focus on behavioral health or psychiatric issues, in particular, just as cognitive impairment care planning will focus on cognitive impairment issues, in particular (see section II.E.5). We are not requiring the psychiatric CoCM treating practitioner or behavioral health consultant to perform care planning that incorporates comprehensive health information on all of the beneficiary's health issues or reconciles the care plans of other practitioners, as would be expected for CCM care planning.

We understand that adoption of EHRs may be lower among behavioral health practitioners [7] and note that resources are available to help inform how care plans can support team-based care and BHI.[8] Our understanding from the public comments last year and subsequent discussions with experts on the psychiatric CoCM model of care, is that no specific electronic technology or format is necessary or indispensable to carry out the psychiatric CoCM model of care, or perform the services included in the codes we are creating to describe the services furnished using that model. We believe the format of the behavioral health care plan (or any care plan) is less important than having a process whereby feedback and expertise from all relevant practitioners and providers, whether internal or external to the billing practice, are integrated into the beneficiary's treatment plan and goals; that this plan be regularly assessed and revisited by the practitioner who is assuming an overall care management role for the beneficiary in a given month; that the patient is engaged in the care planning process; and that the care planning be documented in the medical record (as with any required element of any PFS service). We are revising the requirement for care planning by the behavioral health care manager accordingly, that he or she will perform ''behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes.''

Comment: A number of commenters recommended that we should not require the behavioral health care manager for the psychiatric CoCM services to be located on site within the primary care practice. The commenters noted that in some settings, particularly rural areas or smaller practices, this may be especially important. Some commenters assumed that there is also a behavioral health care manager for G0507 (discussed below). These commenters compared BHI services (the psychiatric CoCM services and G0507) to CCM and recommended that CMS adopt the same requirements for all the BHI codes as for CCM, regarding supervision, location of a behavioral health care manager, and third party outsourcing.

Response: For the psychiatric CoCM services, we proposed that the behavioral health care manager would be a member of the treating physician or other qualified health care professional's clinical staff, and would be required to be located on site but able to work under general supervision. In addition, we proposed that the behavioral health care manager provides his or her services both face-to-face and non-face-to-face. We believed that services provided using the psychiatric CoCM model of care commonly involve face-to-face interaction between the behavioral health care manager and the beneficiary on appropriate occasions, such as the outset of services (a ''warm hand-off'' from the treating physician or other qualified health care professional). In addition, whether face-to-face or non-face-to-face, many of the included behavioral health care manager duties could be performed while the treating practitioner is not in the office and could be performed after hours. We note that the behavioral health care manager duties are listed in full above, and include care management services, as well as an assessment of needs, including the administration of validated rating scales, behavioral health care planning, provision of brief interventions, ongoing collaboration with the treating physician or other qualified health care professional, and maintenance of a registry, all in consultation with a psychiatric consultant.

The delivery of the psychiatric CoCM depends, in part, on continuity of care between a given patient and the assigned behavioral health care manager. Also it requires collaboration, integration and ongoing data flow between the behavioral health care manager and the treating practitioner the behavioral health care manager is supporting, as well as with the psychiatric consultant who is usually remotely located under the psychiatric CoCM model of care. As previously discussed, the psychiatric CoCM is an integrative model of care, and in considering our proposal we were concerned that allowing the behavioral health care manager to be located remotely would compromise their ability to collaborate, communicate, and timely treat and share information with the beneficiary and the rest of the care team. We are aware of many care

[7] See for instance *http://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php* and *https://www.thenationalcouncil.org/wp-content/uploads/2012/10/HIT-Survey-Full-Report.pdf.*

[8] For instance, AHRQ has a variety of resources on how shared care plans can support team-based care and behavioral health integration at *https://integrationacademy.ahrq.gov/playbook/develop-shared-care-plan.*

management companies and health information technology companies that may seek to provide remote care management and related services under all of the new BHI codes, as they have for CCM and similar services recently adopted under the PFS. We received public comments from several such stakeholders that indicated an interest in the provision of BHI services and related health information technology. We understand that there have been successful implementations (positive randomized controlled trials) of the psychiatric CoCM using remote call centers; however, in these implementations, call center staff were not randomly rotated among patients and there was ongoing data flow and connectivity between the behavioral health care manager and the other members of the care team, as well as the patient. Moreover, the behavioral health care manager would presumably have to be on site at least some of the time (even if under general supervision), in order to provide some of their services in-person with the beneficiary.

The fact that we proposed and are finalizing general supervision for the psychiatric CoCM codes as we did for CCM services (see section II.E.3.b) does not mean that general supervision alone suffices to meet the requirements of the psychiatric CoCM for continuity, collaboration and integration among the care team members, including the beneficiary. General supervision means that the service is furnished under the overall direction and control of the practitioner billing the service, but without the presence of the practitioner being required during the performance of the service. This definition does not directly govern where individual(s) providing the service on an incident to basis are located, whether on site or remote. Rather, it governs the location and informs the involvement of the billing practitioner.

For payment purposes, we are assigning general supervision to the psychiatric CoCM codes because we do not believe it is clinically necessary that the professionals on the team who provide services other than the treating practitioner (namely, the behavioral health care manager and the psychiatric consultant) must have the billing practitioner immediately available to them at all times, as would be required under a higher level of supervision. However, general supervision sets the minimum standard for supervision and does not, by itself, meet the requirements we are setting for billing new codes G0502, G0503 and G0504. While certain aspects of psychiatric CoCM services might be furnished under general supervision, we do not believe the general supervision requirement adequately describes the nature of the relationship and interactions of the respective team members for services furnished using the psychiatric CoCM or the codes we are creating to describe those services. Moreover it only directly addresses the physical location of the billing practitioner, not the behavioral health care manager, necessarily.

After considering the public comments, we are not finalizing our proposal that the behavioral health care manager must be a member of the treating physician or other qualified health care professional's clinical staff. As some of the psychiatric CoCM services can be contracted out to a third party (subject to rules discussed below), the contracted individuals are not necessarily employees of the treating practitioner.

Regarding the face-to-face provision of services by the behavioral health care manager, we are requiring that the behavioral health care manager must be available to provide services on a face-to-face basis, but not that face-to-face services must be provided. We are not finalizing the proposed requirement that the behavioral health care manager must be located on site, in order to allow for after-hours or appropriate remote provision of services. However, to ensure clinical integration with the treating practitioner and familiarity and continuity with the beneficiary, which are characteristic of services furnished under the psychiatric CoCM model of care, we are requiring that the behavioral health care manager must have a collaborative, integrated relationship with the rest of the care team members, and be able to perform all of the required elements of the psychiatric CoCM services delineated for the behavioral health care manager. The behavioral health care manager must have the ability to engage the beneficiary outside of regular clinic hours as necessary to perform their duties under the CoCM model, and have a continuous relationship with the beneficiary. This does not mean the behavioral health care manager is necessarily an employee of or always physically located within the practice, nor does it require provision of behavioral health care manager services to the beneficiary on site. The behavioral health care manager may provide his or her services from a remote location that is remote from the billing practitioner or remote from the beneficiary, subject to incident to rules and regulations in 42 CFR 410.26, if he or she has a qualifying relationship with the rest of the care team including the beneficiary, and is available to provide services face-to-face.

We will monitor this issue going forward, not just for the psychiatric CoCM but also for the general BHI service code (G0507) we are finalizing, as well as for TCM and CCM services. As we discuss in the final rule section on CCM below, we are continuing to consider whether outsourcing certain aspects of these services to a third party fragments care, leads to insufficient involvement and oversight of the billing practitioner or results in services that do not actually represent or facilitate continuous, seamless transitional care and other required aspects of these services. We will continue to consider how to best define the continuity of care that is required for services furnished and billed under all of these codes, and whether arrangements for remote provision of services whether by a case management company or another entity increases rather than reduces service fragmentation. Advances in health information technology provide opportunities for remote connectivity and interoperability that may assist and be useful, if not necessary, for reducing care fragmentation. However, remote provision of services by entities having only a loose association with the treating practitioner can detract from continuous, patient-centered care, whether or not those entities employ certified or other electronic technology.

We note that while time spent by the treating practitioner is not explicitly counted for in codes G0502, G0503 and G0504, these codes are valued to include work performed directly by the treating practitioner. The treating practitioner directs the behavioral health care manager and continues to oversee the patient's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed. We are finalizing as proposed that some of these services may be separately billable. However, we wish to emphasize that the treating practitioner must remain involved in ongoing oversight, management, collaboration and reassessment as appropriate to bill the psychiatric CoCM codes.

Comment: We received a number of comments requesting that we allow or recognize pharmacists, especially neurologic or psychiatric pharmacists, or doctoral-level clinical psychologists to serve as the psychiatric consultant. Some commenters were concerned that CMS is advocating pharmacotherapy over psychotherapy by requiring a psychiatric consultant who can prescribe medication.

Response: We agree with the commenters that there are multiple types of indicated treatment for behavioral health conditions, including psychotherapy and other psychosocial interventions as well as pharmacotherapy that are available and should be offered to beneficiaries receiving psychiatric CoCM services. Our intent is not to inappropriately steer beneficiaries into medication-based treatment, but rather that the psychiatric consultant be able to present and recommend the full range of treatment options including but not limited to medications, and to advise regarding any medications the beneficiary chooses to take. Under the psychiatric CoCM, the psychiatric consultant must be able to prescribe medication. As we discuss in section II.L on valuation of G0502, G0503 and G0504, we agree with the commenters who stated that the role of the psychiatric consultant under these codes is primarily evaluation and management, which is not within the scope of pharmacists or clinical psychologists under Medicare rules. Therefore, we are finalizing the role and qualifications of the psychiatric consultant as proposed. The general BHI code (G0507), which we are finalizing, was intended and may be used to report other models of care, where the beneficiary may not receive E/M services from the consultant and the consultant may only be authorized to provide psychotherapy or consultation regarding medications (see section II.E.3.b).

Comment: We received a number of comments recommending various types of professionals as qualified to serve as the behavioral health care manager, such as licensed clinical social workers (LCSWs) and psychologists.

Response: Unlike CCM and the general BHI service (code G0507), the psychiatric CoCM codes are used to report time that is spent in specified activities performed by a behavioral health care manager having formal education or specialized training in those activities, whether or not the behavioral health care manager is eligible to directly bill Medicare for other services. The behavioral health care manager may or may not be a professional who meets all the requirements to independently furnish and report services to Medicare. The behavioral health care manager must also meet any applicable licensure and state law requirements, which is required under 42 CFR 410.26 for all services provided under the PFS. LCSWs would meet these requirements, as would qualified registered nurses, clinical psychologists and other qualified clinical staff. Time spent by administrative or clerical staff cannot be counted towards the time required to bill G0502, G0503 or G0504.

Evaluation and management services (such as face-to-face E/M visits) may be separately billed during the service period or on the same day as the psychiatric CoCM services, provided time is not counted twice towards the same code.

b. General Behavioral Health Integration (BHI)

We recognize that the psychiatric CoCM is prescriptive and that much of its demonstrated success may be attributable to adherence to a set of elements and guidelines of care. We are finalizing the code set discussed above to pay accurately for care furnished using this specific model of care, given its widespread adoption and recognized effectiveness. However, we note that PFS coding, in general, does not dictate how physicians practice medicine and believe that it should, instead, reflect the practice of medicine. We also recognize that there are primary care practices that are incurring, or may incur, resource costs inherent to treatment of patients with similar conditions based on BHI models of care other than the psychiatric CoCM that may benefit beneficiaries with behavioral health conditions (see, for example, the approaches described at *http://www.integration.samhsa.gov/integrated-care-models*). There are a variety of care models ranging from behavioral health professionals embedded within a primary care office for same-day treatment, to remote consultation, to assessment-and-referral (see, for example, *http://www.commonwealthfund.org/publications/newsletters/quality-matters/2014/august-september/profiles*; and *http://www.integration.samhsa.gov/integrated-care-models*). These models of care have tended to arise from clinical practice as opposed to the research environment (*http://psychnews.psychiatryonline.org/doi/full/10.1176/appi.pn.2014.10b25*), and include resource costs that differ in various respects from those associated with the psychiatric CoCM.

To recognize the resource costs associated with furnishing such BHI services to Medicare beneficiaries, we also proposed to make payment using a new G-code that describes care management for beneficiaries with behavioral health conditions under other models of care. We believe that the resources associated with such care are not currently adequately recognized under the PFS. The proposed code was G0507 (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). We noted that we would expect this code to be refined over time as we receive more information about other BHI models being used and how they are implemented.

We sought stakeholder input on whether we should consider different increments of time for this code, such as a base code plus an add-on code comprised of additional 20 minute increments. We recognized that BHI services furnished under the proposed code may range in resource costs. We believed that appropriate payment for these services would further the refinement and implementation of BHI models of care, and that having utilization data would inform future refinement of the proposed code's valuation.

Comment: The commenters were supportive of new coding to support payment for other BHI models of care. They believed G0507 could be used by some smaller or medium sized practices who could not conform to the strict parameters of the psychiatric CoCM but provide very similar services. They also stated that G0507 would be appropriate to report services furnished under other BHI models of care that may not require psychiatric services. We received a few comments describing particular models of care in great detail; a few commenters referenced the Veterans' Administration BHI care models, the Primary Care Behavioral Health/Behavioral Health Consultation (PCBH/BHC) Model, or general models in place within other health care systems. However, there was consensus among the commenters that another code(s) in addition to the psychiatric CoCM codes would be useful to collect information on how other behavioral health care models are being used and implemented.

Many commenters recommended that CMS provide more of a framework or description of included services and provider types without being unduly burdensome. Some commenters recommended service elements similar to the CCM service elements (continuity of care with a designated member of the care team; a written care plan; a comprehensive assessment of behavioral health or psychiatric and other medical conditions as well as any functional and psychosocial needs, updated as necessary; routine evaluation of patient progress using a tracking system; services should be documented in the medical record and available to other treating professionals). These

commenters recommended that eligible patients should have a diagnosed psychiatric or substance use disorder that requires care management services. Several commenters recommended that BHI payments be tied to the use of behavioral health assessment tools for screening and collection of treatment outcomes throughout the sessions of care in primary care. These commenters believed this would better position behavioral health to benefit from the movement toward value-based payment in the future. Some commenters assumed there is a designated behavioral health care manager for the service described by G0507, and recommended that we adopt similar rules for this care manager as apply for clinical staff providing CCM services.

Response: We continue to believe that another code, or set of BHI codes, in addition to the psychiatric CoCM code set would be useful to pay appropriately for BHI services furnished to Medicare beneficiaries. We also believe that such payment could facilitate our ability to identify and collect data regarding similar or related BHI service models. We agree with the commenters that we should provide more specificity around the services eligible for reporting under this other code(s). One way to do this would be to create codes with tiered times. Some commenters supported such an approach, while others believed it would be premature. At this time, we are not creating multiple levels of codes distinguishing levels of general BHI services using time or any other metric, but we may reconsider this in the future (also see section II.L on G0507 valuation).

Regarding included elements of the general BHI service (G0507), we agree with the commenters that we should be more specific in our definition of this service. We wish to provide greater specificity without being overly prescriptive, since a range of activities may be included in BHI models of care other than the psychiatric CoCM. We believe we should include a core set of service elements that are similar to core elements of the psychiatric CoCM, especially a systematic process for initial assessment and routine follow up evaluation, revising the treatment approach or methods for patients who are not progressing or whose status changes; facilitating and coordinating behavioral health expertise and treatment; and designating a member of the care team with whom the beneficiary has a continuous relationship. We may revisit the included services in future years, but for CY 2017 the required service elements for the general BHI service (G0507) will be:

- 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.

Accordingly, the final code descriptor will be, G0507: 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.

We are aware of a number of validated rating scales that are available for use for a number of conditions addressed by BHI models of care, such as those described by the Kennedy Forum (see *http://thekennedyforum-dot-org.s3.amazonaws.com/documents/MBC_supplement.pdf*). We are requiring the use of such scales when applicable to the condition(s) that are being treated. Medication Assisted Treatment (MAT) may be a treatment that is facilitated under the facilitating treatment service element.

Regarding diagnosis, we believe we should specify similar diagnostic criteria for G0507 and the psychiatric CoCM services (G0502, G0503 and G0504). Accordingly we are providing that beneficiaries who are appropriate candidates for services billed under G0507 will have an identified psychiatric or behavioral health condition(s) that requires a behavioral health care assessment, behavioral health care planning, and provision of interventions. Eligible beneficiaries must present with a condition(s) that in the treating practitioner's clinical judgment, warrants the services included in G0507. The presenting condition(s) may be pre-existing or newly diagnosed by the treating practitioner, and may be refined as treatment progresses. Beneficiaries receiving services reported under G0507 may, but are not required to have comorbid chronic or other medical condition(s) that are being managed by the treating practitioner. We are not limiting billing and payment for G0507 to a specified set of behavioral health conditions, because there may be overlap in behavioral health conditions; if we specified only certain diagnoses, practitioners might modify diagnoses to fit within payment rules; and for many beneficiaries for whom specialty care is not available, or who choose for other reasons to remain within primary care, their behavioral health condition(s) can be addressed using a model of integrated care.

Regarding rules for clinical staff, we are clarifying that services included in the code G0507 may be provided directly by the treating practitioner or provided by other qualifying individuals (whom we term ''clinical staff'') under his or her direction, during the calendar month service period. Unlike the psychiatric CoCM codes, for G0507 there is not necessarily a specific individual designated as a ''behavioral health care manager'' with formal or specialized education in providing the services (although there could be). Similarly, there is not necessarily a psychiatric or other behavioral health specialist consultant (although there could be), and we note that G0507 is not valued to explicitly account for such a consultant. We will apply the same definition of the term ''clinical staff'' that we have applied for CCM to G0507, namely, the CPT definition of this term, subject to the incident to rules and regulations and applicable state law, licensure and scope of practice at 42 CFR 410.26. For G0507, then, we note that the term ''clinical staff'' will encompass or include a psychiatric or other behavioral health specialist consultant, if the treating practitioner obtains consultative expertise. Clinical staff that provide included services do not have to be employed by the treating practitioner or located on site, necessarily, and may or may not be a professional who is permitted to independently furnish and report services to Medicare. Time spent by administrative or clerical staff cannot be counted towards the time required to bill G0507.

G0507 is valued to include minimal work by the treating practitioner; the bulk of the valuation is based on clinical staff time (see section II.L on valuation). However, we want to emphasize that the

treating practitioner must direct the service, continue to oversee the beneficiary's care, and perform ongoing management, collaboration and reassessment. If the service (or part thereof) is provided incident to the treating practitioner's services, whether on site or remotely, the clinical staff providing services must have a collaborative, integrated relationship with the treating practitioner. They must also have a continuous relationship with the beneficiary.

Evaluation and management services, such as face-to-face E/M visits, may be separately billed during the service period or on the same day as G0507, provided time is not counted twice towards the same code.

For payment purposes, we are categorizing this service as a designated care management service assigned general supervision for purposes of ''incident to'' billing, because we do not believe it is clinically necessary for the individuals on the team who provide services other than the treating practitioner (namely, clinical staff) to have the treating practitioner immediately available to them at all times, as would be required under a higher level of supervision. However, general supervision sets the minimum standard for supervision and does not, by itself, meet the requirements we are setting for billing new code G0507. While certain aspects of G0507 might be furnished under general supervision, we do not believe the general supervision requirement adequately describes the nature of the relationship and interactions of the respective team members for services furnished using BHI models of care or the codes we are creating to describe those services. Moreover the general supervision requirement only directly addresses the physical location of the treating practitioner, not the location of clinical staff, necessarily.

Comment: Regarding behavioral health care planning, some commenters noted that there is not necessarily value in accumulating or enumerating a number of different types of care plans addressing different aspects of the beneficiary's problems, such as a behavioral or psychiatric care plan, a CCM care plan, and a cognitive impairment care plan (see G0505 in section II.E.5).

Response: While any care planning should take into account the whole patient, our intent is that the care planning included in the CCM coding (and G0506, the CCM initiating visit add-on code) will be the most comprehensive in nature, addressing all health issues with particular focus on the multiple chronic conditions being managed by the treating practitioner. In contrast, the BHI care planning will focus on behavioral health or psychiatric issues, in particular, just as the cognitive impairment care planning will focus on cognitive impairment issues, in particular (see section II.E.5. of this final rule).

However, we understand that adoption of EHRs may be lower among behavioral health practitioners [9] and note that resources are available to help inform how care plans can support team-based care and BHI.[10] While we understand that practitioners, in general, are exploring a wide variety of innovative approaches and tools that facilitate care plan integration across clinical disciplines, at this time, there may not be sufficient adoption of interoperable health IT interoperability among all practitioners and providers treating a given beneficiary to necessarily have a single, master care plan that adequately addresses the progress of the beneficiary in relation to all of these issues. In general, practitioners are encouraged to pursue approaches that integrate health information from multiple sources into a single care plan, but we understand that practitioners may need to create separate documents or the relevant care planning may be documented in another format within the medical record.

We believe the format of the care plan(s) is less important than having a process whereby feedback and expertise from all relevant practitioners and providers, whether internal or external to the billing practice, are integrated into the beneficiary's treatment plan and goals; that this plan be regularly assessed and revisited by the practitioner who is assuming an overall care management role for the beneficiary in a given month; that the patient is engaged in the care planning process; and that the care planning be documented in the medical record (as with any required element of any PFS service). We have framed the care planning service element for G0507 accordingly, ''Behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes.''

Comment: We received a few comments recommending codes in addition to the psychiatric CoCM codes that would pay for similar services to inpatients, or for behavioral health services by psychologists to psychologically and medically complex patients in skilled nursing facilities (SNF) and nursing homes. Some of these commenters stated that in SNF and long-term care settings, psychologists work closely with primary care physicians, psychiatrists, nurses, and other consultants to improve outcomes by reducing inappropriate use or dosing of psychotropic medications, improving activities of daily living, and preventing avoidable admissions/falls. These commenters stated that many health systems employ psychologists as BHI team leaders or coordinators, and sought clarification on how psychologist-led teams would operationalize the new BHI codes. These commenters believe that psychology training provides unique skills in facilitating interdisciplinary teams. While they acknowledged that psychologists are not qualified to perform the full range of BHI services and interventions, they believed psychologists should be able to separately report and bill for care coordination and BHI initiation activities.

We received similar comments supporting the addition of psychiatric collaborative care services to the PFS, and other evidence-based models in a variety of primary care-based treatment settings. However, these commenters supported the inclusion of social workers at all levels of licensures as reimbursable providers of these services.

Response: We appreciate the commenters' descriptions of some particular working models of care, and we welcome additional information in this regard. We continue to believe it would be appropriate to have new coding for a range of BHI care models applicable to inpatient as well as outpatient and facility settings. Our goal in separately identifying and paying for BHI services is to prioritize accurate payment for these services, in recognition of the associated time and complexity of the services. We agree that beneficiaries who are admitted to a facility, are in long-term care, or are transitioning among settings during the month are likely to be more complex than other types of patients, and to warrant more- not less- BHI services. Therefore, we have valued G0507 in both facility and non-facility settings (see section II.L on valuation). We are not limiting the time that can be counted towards the monthly time

[9] See for instance *http://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php* and *https://www.thenationalcouncil.org/wp-content/uploads/2012/10/HIT-Survey-Full-Report.pdf.*

[10] For instance, AHRQ has a variety of resources on how shared care plans can support team-based care and behavioral health integration at *https://integrationacademy.ahrq.gov/playbook/develop-shared-care-plan.*

requirement to bill G0507 to time that is spent in the care of an outpatient or a beneficiary residing in the community. As we provide for the psychiatric CoCM services, G0507 may be reported by specialties that are not ''traditional'' primary care specialties, if such specialists furnish the included services. However, we stress that G0507 can only be reported by a treating physician or other qualified health care professional when he or she has directed the BHI service for the duration of time that he or she is reporting it, and has a qualifying relationship with individuals providing the service under his or her direction and control. Also, time and effort that is spent managing care transitions for CCM or TCM patients and that is counted towards reporting TCM or CCM services, cannot also be counted towards reporting any transitional care management activities reported under a BHI service code(s). We welcome additional input from stakeholders regarding appropriate (or inappropriate) settings of service for G0507.

Since the BHI initiating visit that is required to bill G0507 is not within the scope of practice of a psychologist or social worker (see below), psychologists and social workers will not be able to report G0507 directly (although a psychiatrist may be able to do so). Psychologists and social workers may provide care management services included in G0507 incident to the services of another (billing) practitioner. They may also provide services that are separately billable during the service period. We appreciate the commenters' support for team-based care, and we recognize the substantial role of various types of mental health professionals within a primary care team. We are interested in receiving additional input from stakeholders as to whether and why behavioral health care management services by a social worker, psychologist or similarly qualified professional should be reportable in its own right, rather than incident to the services of a practitioner authorized to bill Medicare for a BHI initiating visit. Consistent with our recent approaches to making proposals under PFS notice and comment rulemaking, we could consider adopting new coding under a different construct that was not defined as BHI, if stakeholders provided sufficient input on how to design, define and value the services. We would also consider such changes if adopted by the CPT Editorial Panel, per our usual process. BHI integrates behavioral health expertise into evaluation and management care. Therefore G0507 is designed to include services that require the oversight and involvement of a practitioner who can perform evaluation and management services, including facilitation of any needed pharmacotherapy, referral for specialty care, and overall management of the beneficiary's treatment in relation to primary care treatment. We note that G0507 would not be independently billed by psychologists or social workers, though from our understanding of various models of BHI, these professionals seem likely to be participants in team-based care for beneficiaries receiving these services.

c. BHI Initiating Visit

Similar to CCM services (see section II.E.4), we proposed to require an initiating visit for all of the BHI codes (G0502, G0503, G0504 and G0507) that would be billable separate from the BHI services themselves. We proposed that the same services that can serve as the initiating visit for CCM services (see section II.E.4.a. of this final rule) could serve as the initiating visit for the proposed BHI codes. The initiating visit would establish the beneficiary's relationship with the billing practitioner (most aspects of the BHI services would be furnished incident to the billing practitioner's professional services), ensure the billing practitioner assesses the beneficiary prior to initiating care management processes, and provide an opportunity to obtain beneficiary consent (discussed below). We solicited public comment on the types of services that are appropriate for an initiating visit for the BHI codes, and within what timeframe the initiating visit should be conducted prior to furnishing BHI services.

Comment: The commenters were largely supportive of our proposal to allow the same services to qualify for the initiating visit to CCM as for the initiating visit to BHI services. We received a few comments stating that in addition to the qualifying E/M services (or an AWV or IPPE), initiating services should include in-depth psychological evaluations delivered by a psychologist including CPT codes 90791, 96116 or 96118 which, in turn, include care plan development. These commenters agreed that psychologists cannot personally furnish all BHI services (for example, medication reconciliation), but believe psychologists effectively coordinate care and perform other aspects of BHI services as part of a team under current practice models. They believe this approach would be particularly effective for reducing inappropriate use or dosing of psychotropic medications in elderly and complex patients, improving activities of daily living, and preventing avoidable admissions and falls.

Response: We appreciate the commenters' feedback. We agree that psychologists would be qualified to perform care coordination that is included in the psychiatric CoCM codes (G0502, G0503 and G0504) and the general BHI code (G0507) under the direction of a physician or other qualified health care professional. In addition, beneficiaries receiving BHI services under any of those codes may be referred to psychologists for psychotherapy or other services that are separately billable and within the scope of practice of psychologists, as discussed elsewhere in this section of our final rule. However many commenters acknowledged, and we agree, that a BHI initiating visit is necessary. The initiating visit is not, in its entirety, within the scope of psychologist practice. Therefore, we are finalizing our proposal that the same services that qualify as the initiating visit for CCM will also qualify as initiating services for BHI, and they do not include in-depth psychological evaluation by a psychologist. Also, we will require an initiating visit for BHI only for new patients or beneficiaries not seen within a year of commencement of BHI services (the same requirement we are finalizing for CCM, see section II.E.4.a). As more experience is gained with the psychiatric CoCM services and other models of BHI care, we may reassess these provisions.

As discussed above, we are interested in receiving input from stakeholders regarding circumstances other than BHI in which behavioral health care management services by a psychologist, social worker or similarly qualified professional should be reportable in its own right, rather than incident to the services of a practitioner authorized to bill Medicare for a BHI initiating visit.

Comment: Some commenters recommended that CMS establish an add-on code to the initiating visit for BHI services, parallel to G0506 (the proposed add-on code for the CCM initiating visit).

Response: We do not believe we have enough information about practice patterns at this time to create an add-on code to the BHI initiating visit, and we did not propose such a code. We may re-examine this issue in the future.

d. Beneficiary Consent for BHI Services

Commenters to the CY 2016 PFS proposed rule indicated that they did not believe a specific patient consent for BHI services is necessary and indicated that requiring special informed consent

for these services may reduce access due to stigma associated with behavioral health conditions. Instead, the commenters recommended requiring a more general consent prior to initiating these services whereby the beneficiary gives the initiating physician or practitioner permission to consult with relevant specialists, which would include conferring with a psychiatric consultant. Accordingly, we proposed to require a general beneficiary consent to consult with relevant specialists prior to initiating these services, recognizing that applicable rules continue to apply regarding privacy. The proposed general consent would encompass conferring with a psychiatric consultant when furnishing the psychiatric CoCM codes (G0502, G0503, and G0504) or the proposed broader BHI code (G0507). Similar to the proposed beneficiary consent process for CCM services, we proposed that the billing practitioner must document in the beneficiary's medical record that the beneficiary's consent was obtained to consult with relevant specialists including a psychiatric consultant, and that, as part of the consent, the beneficiary is informed that there is beneficiary cost-sharing, including potential deductible and coinsurance amounts, for both in-person and non-face-to-face services that are provided. We solicited stakeholder comments on this proposal.

We recognized that special informed consent could also be helpful in cases when a particular service is limited to being billed by a single practitioner for a particular beneficiary. We did not believe that there are circumstances where it would reasonable for multiple practitioners to be reporting these codes during the same month. However, we did not propose a formal limit at this time. We solicited comment on whether such a limitation would be beneficial or whether there are circumstances under which a beneficiary might reasonably receive BHI services from more than one practitioner during a given month.

Comment: The commenters were largely supportive of our proposal regarding BHI consent, some noting that physician-to-physician communication as well as communication within treatment teams happens routinely, without an extra layer of formal written consent, for other medical conditions. A few commenters intimated that CMS might pursue a single broad consent that could be used across care management services; for example, applying for both CCM and BHI. We did not receive any public comments delineating the circumstances under which it would be appropriate to bill for services furnished using more than one BHI service model per month, or appropriate for more than one practitioner (whether in the same practice or different practices) to bill for services furnished in a BHI care model per month.

Response: We agree with the commenters that physician-to-physician communication as well as communication within treatment teams happens routinely, without an extra layer of formal written consent, for other medical conditions. However there are particular privacy concerns addressed by other rules and regulations for some behavioral health or substance use care. Also we are concerned that beneficiaries should not incur unexpected expenses for care that is largely, or in significant part, non-face-to-face in nature. Finally, there are issues to consider, that we considered for CCM, regarding prevention of duplicative practitioner billing, and whether BHI services can actually be furnished under the direction and control of any given practitioner if for a given service period, more than one practitioner is furnishing BHI services and billing them.

The public comments were supportive of our proposal for a broad consent that could be verbally obtained but must be documented in the medical record, and we are finalizing as proposed. At this time, we do not believe a single consent process for both BHI and CCM is advisable. It is not clear how frequently BHI and CCM would or should be furnished concurrently. BHI and CCM are distinct, separate services, having significant differences in time thresholds, the nature of the services, types of individuals providing the services, and payment and cost sharing amounts. Therefore, at this time, we are maintaining separate consent processes for CCM and BHI, as provided in the respective sections of this final rule. Also, as discussed in section II.E.4 on CCM, CCM and BHI may be billed during the same service period.

It remains unclear whether it would be reasonable and necessary for more than one practitioner (whether in the same practice or different practices) to bill BHI services for a given beneficiary for a given service period, given the lack of public response and input on this issue. It may depend on the conditions(s) being treated and whether specialty care, other than psychiatric or behavioral health specialty care, and primary care are both involved. We are not proposing a formal limit at this time, but we stress that BHI services can only be reported by a treating physician or other qualified health care professional when he or she has obtained the required beneficiary consent, directed the BHI services he or she reports for the duration of time reported, and has a qualifying relationship with individuals providing the reported services under his or her direction and control. We would not expect a single practitioner to furnish care to a given beneficiary under more than one BHI model of care during a given month. Therefore a single practitioner must choose whether to report psychiatric CoCM code(s) (G0502, G0503, and G0504 as applicable) or the general BHI code (G0507) for a given month for a given beneficiary. We remind stakeholders that time cannot be counted more than once towards any code(s), all services must be medically reasonable and necessary, and that beneficiary cost sharing and advance consent apply. We will be monitoring the claims data and studying the utilization patterns. We will continue to assess appropriate reporting patterns, and we expect that potential coding changes by the CPT Editorial Panel may inform this issue.

Comment: We received a number of comments recommending that cost sharing be removed for all care management services, whether through legislative change, demonstration, waiver safe harbor, or designation as preventive services.

Response: We appreciate commenters' concerns and recognize many of the challenges associated with patient cost-sharing for these kinds of services. At this time, we do not have authority to waive cost sharing for the BHI or other care management services. We appreciate the commenters' acknowledgement of our current limitations and we will continue to consider this issue.

e. Summary of Final BHI Policies

Beginning in CY 2017, we are providing separate payment for a range of BHI services. Specifically, we are providing payment for psychiatric CoCM services under the following codes:

- G0502: 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.

• G0503: 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.

• G0504: 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 (List separately in addition to code for primary procedure) (Use G0504 in conjunction with G0502, G0503).

These psychiatric CoCM services are reported by the treating physician or other qualified health care professional for services furnished during a calendar month service period. These services may be furnished when a beneficiary has a psychiatric or behavioral health condition(s) that in the treating physician or other qualified health care professional's clinical judgment, requires a behavioral health care assessment; establishing, implementing, revising, or monitoring a care plan; and provision of brief interventions. The diagnosis or diagnoses may be pre-existing or made by the treating physician or other qualified health care professional, and may be refined over time. The psychiatric CoCM services may be furnished to beneficiaries with any psychiatric or behavioral health condition(s) that is being treated by the physician or other qualified health care professional, including substance use disorders. Beneficiaries receiving psychiatric CoCM services may, but are not required to have comorbid chronic or other medical condition(s) that are being managed by the treating practitioner.

Psychiatric CoCM services include the services of the treating physician or other qualified health care professional, the behavioral health care manager (see description below) who provides services incident to services of the treating physician or other qualified health care professional, and the psychiatric consultant (see description below) whose consultative services are furnished incident to services of the treating physician or other qualified health care professional. Time spent by administrative or clerical staff cannot be counted towards the time required to bill the psychiatric CoCM service codes.

Beneficiaries receiving psychiatric CoCM services may have newly diagnosed conditions, need help in engaging in treatment, have not responded to standard care delivered in a non-psychiatric setting, or require further assessment and engagement prior to consideration of referral to a psychiatric care setting. Beneficiaries are treated for an episode of care, defined as beginning when the behavioral health care manager engages in care of the beneficiary under the appropriate supervision of the billing practitioner and ending with:

• The attainment of targeted treatment goals, which typically results in the discontinuation of care management services and continuation of usual follow-up with the treating physician or other qualified healthcare professional; or

• Failure to attain targeted treatment goals culminating in referral to a psychiatric care provider for ongoing treatment; or

• Lack of continued engagement with no psychiatric collaborative care management services provided over a consecutive 6-month calendar period (break in episode).

A new episode of care will start after a break in episode of 6 calendar months or more.

The treating physician or other qualified health care professional directs the behavioral health care manager and continues to oversee the beneficiary's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed. The treating physician or other qualified health care professional must remain involved in ongoing oversight, management, collaboration and reassessment as appropriate to bill the psychiatric CoCM codes.

The behavioral health care manager has formal education or specialized training in behavioral health (which could include a range of disciplines, for example, social work, nursing, and psychology). The behavioral health care manager provides care management services, as well as an assessment of needs, including the administration of validated rating scales; [11] 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 interventions; ongoing collaboration with the treating physician or other qualified health care professional; maintenance of a registry; [12] all in consultation with the psychiatric consultant. The behavioral health care manager is available to provide these services face-to-face and non-face-to-face, and consults with the psychiatric consultant minimally on a weekly basis.

The behavioral health care manager must have a collaborative, integrated relationship with the rest of the care team members, and be able to perform all of the required elements of the service delineated for the behavioral health care manager. The behavioral health care manager must have the ability to engage the beneficiary outside of regular clinic hours as necessary to perform the behavioral health care manager's duties under the psychiatric CoCM model, and must have a continuous relationship with the beneficiary. The behavioral health care manager may or may not be a

[11] For example, see *https://aims.uw.edu/resource-library/measurement-based-treatment-target.*

[12] For example, see *https://aims.uw.edu/collaborative-care/implementation-guide/plan-clinical-practice-change/identify-population-based.*

professional who meets all the requirements to independently furnish and report services to Medicare. The behavioral health care manager is subject to the incident to rules and regulations and applicable state law, licensure and scope of practice (see 42 CFR 410.26).

The psychiatric consultant is a medical professional trained in psychiatry and qualified to prescribe the full range of medications. The psychiatric consultant advises and makes recommendations, as needed, for psychiatric and other medical care, including psychiatric and other medical diagnoses, treatment strategies including appropriate therapies, medication management, medical management of complications associated with treatment of psychiatric disorders, and referral for specialty services, that are communicated to the treating physician or other qualified health care professional, typically through the behavioral health care manager. The psychiatric consultant does not typically see the beneficiary or prescribe medications, except in rare circumstances, but can and should facilitate referral for direct provision of psychiatric care when clinically indicated. The psychiatric consultant is subject to the incident to rules and regulations and applicable state law, licensure and scope of practice (see 42 CFR 410.26).

Beginning in CY 2017, we are providing separate payment for BHI services furnished under models of care other than the psychiatric CoCM model, under HCPCS code G0507: 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.

G0507 is reported by the treating physician or other qualified health care professional for services furnished during a calendar month service period. This service may be furnished when the beneficiary has a psychiatric or behavioral health condition(s) that in the treating physician or other qualified health care professional's clinical judgment, requires a behavioral health care assessment, behavioral health care planning, and provision of interventions. The presenting condition(s) may be pre-existing or newly diagnosed by the treating physician or other qualified health care professional, and may be refined over time. Beneficiaries receiving services reported under G0507 may have any psychiatric or behavioral health condition(s) that is being treated by the physician or other qualified health care professional, including substance use disorders. Beneficiaries receiving services reported under G0507 may, but are not required to have comorbid chronic or other medical condition(s) that are being managed by the treating practitioner.

Services reported under G0507 may be provided directly by the treating physician or other qualified health care professional, or provided by clinical staff under his or her direction, during a calendar month service period. For G0507, there is not necessarily a specific individual designated as a ''behavioral health care manager'' with formal or specialized education in providing the services (although there could be). Similarly, there is not necessarily a psychiatric or other behavioral health specialist consultant (although there could be) and we note that G0507 is not valued to explicitly account for expert consultation. For G0507, the term ''clinical staff'' means the CPT definition of this term, subject to the incident to rules and regulations and applicable state law, licensure and scope of practice at 42 CFR 410.26. For G0507, then, we note that the term ''clinical staff'' will encompass or include any psychiatric or other behavioral health specialist consultant that may provide consultative services. Clinical staff providing services are not required to be employed by the treating practitioner or located on site, and these individuals may or may not be a professional permitted to independently furnish and report services to Medicare. Time spent by administrative or clerical staff cannot be counted towards the time required to report G0507. We emphasize that the physician or other qualified health care professional must direct the service, continue to oversee the beneficiary's care, and perform ongoing management, collaboration and reassessment. If the service (or part thereof) is provided incident to services of the treating practitioner, whether on site or remotely, the clinical staff providing services must have a collaborative, integrated relationship with the treating practitioner. They must also have a continuous relationship with the beneficiary.

For all of the BHI service codes (G0502, G0503, G0504 and G0507), we are requiring an initiating visit that is billable separate from the BHI services themselves. The same services that qualify as initiating visits for CCM services can serve as the initiating visit for BHI services (certain face-to-face E/M services including the face-to-face visit required for TCM services, and the AWV or IPPE). The BHI initiating visit establishes the beneficiary's relationship with the treating practitioner (BHI services may be furnished incident to the treating practitioner's professional services); ensures that the treating practitioner assesses the beneficiary prior to initiating care management processes; and provides an opportunity to obtain beneficiary consent (consent may also be obtained outside of the BHI initiating visit, as long as it is obtained prior to commencement of BHI services).

For all of the BHI service codes, we are also requiring prior beneficiary consent, recognizing that applicable rules continue to apply regarding privacy. The consent will include permission to consult with relevant specialists including a psychiatric consultant, and inform the beneficiary that cost sharing will apply to in-person and non-face-to-face services provided. Consent may be verbal (written consent is not required) but must be documented in the medical record.

For payment purposes, we are assigning general supervision to all of the BHI service codes (G0502, G0503, G0504 and G0507). However we note that general supervision does not, by itself, comprise a qualifying relationship between the treating practitioner and other individuals providing BHI services under the incident to relationship. Also we note that we valued BHI services in both facility and non-facility settings. BHI services may be furnished to beneficiaries in any setting of care. Time that is spent furnishing BHI services to a beneficiary who is an inpatient or in any other facility setting during service provision or for any part of the service period may be counted towards reporting a BHI code(s). We refer the reader to our discussion above on this matter, as well as reporting by specialty, intersection with other services, and potential reporting by more than one practitioner for a given beneficiary within a service period. A single practitioner must choose whether to report psychiatric CoCM code(s) (G0502, G0503, and

G0504 as applicable) or the general BHI code (G0507) for a given month (service period) for a given beneficiary.

4. Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) Services

Beginning in CY 2015, we implemented separate payment for CCM services under CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health professional, per calendar month, with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;
- Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;
- Comprehensive care plan established, implemented, revised, or monitored).

In the CY 2015 final rule with comment period, we finalized a proposal to make separate payment for CCM services as one initiative in a series of initiatives designed to improve payment for, and encourage long-term investment in, care management services (79 FR 67715). In particular, we sought to address an issue raised to us by the physician community, which stated that the care management included in many of the existing E/M services, such as office visits, does not adequately describe the typical non-face-to-face care management work required by certain categories of beneficiaries (78 FR 43337). We began to re-examine how Medicare should pay under the PFS for non-face-to-face care management services that were bundled into the PFS payment for face-to-face E/M visits, being included in the pre- and post-encounter work (78 FR 43337). In proposing separate payment for CCM, we acknowledged that, even though we had previously considered non-face-to-face care management services as bundled into the payment for face-to-face E/M visits, the E/M office/outpatient visit CPT codes may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries. We stated that we believed that the resources required to furnish complex chronic care management services to beneficiaries with multiple (that is, two or more) chronic conditions were not adequately reflected in the existing E/M codes. Medical practice and patient complexity required physicians, other practitioners and their clinical staff to spend increasing amounts of time and effort managing the care of comorbid beneficiaries outside of face-to-face E/M visits, for example, complex and multidisciplinary care modalities that involve regular physician development and/or revision of care plans; subsequent report of patient status; review of laboratory and other studies; communication with other health care professionals not employed in the same practice who are involved in the patient's care; integration of new information into the care plan; and/or adjustments of medical therapy.

Therefore, in the CY 2014 PFS final rule with comment period, we established a separate payment under the PFS for CPT code 99490 (78 FR 43341 through 43342). We sought to include a relatively broad eligible patient population within the code descriptor, established a moderate payment amount, and established bundled payment for concurrently new CPT codes that were reserved for beneficiaries requiring ''complex'' CCM services (base CPT code 99487 and its add-on code 99489) (79 FR 67716 through 67719). We stated that we would evaluate the services reported under CPT code 99490 to assess whether the service is targeted to the right population and whether the payment amount is appropriate (79 FR 67719). We remind stakeholders that CMS did not limit the eligible population to any particular list of chronic conditions other than the language in the CPT code descriptor. Accordingly, one or more of the chronic conditions being managed through CCM services could be chronic mental health or behavioral health conditions or chronic cognitive disorders, as long as the chronic conditions meet the eligibility language in the CPT code descriptor for CCM services and the billing practitioner meets all of Medicare's requirements to bill the code including comprehensive, patient-centered care planning for all health conditions.

In finalizing separate payment for CPT code 99490, we considered whether we should develop standards to ensure that physicians and other practitioners billing the service would have the capability to fully furnish the service (79 FR 67721). We sought to make certain that the newly payable PFS code(s) would provide beneficiary access to appropriate care management services that are characteristic of advanced primary care, such as continuity of care; patient support for chronic diseases to achieve health goals; 24/7 patient access to care and health information; receipt of preventive care; patient, family and caregiver engagement; and timely coordination of care through electronic health information exchange. Accordingly, we established a set of scope of service elements and payment rules in addition to or in lieu of those established in CPT guidance (in the CPT code descriptor and CPT prefatory language), that the physician or nonphysician practitioner must satisfy to fully furnish CCM services and report CPT code 99490 (78 FR 74414 through 74427, 79 FR 67715 through 67730, and 80 FR 14854). We established requirements to furnish a preceding qualifying visit, obtain advance written beneficiary consent, use certified electronic health record (EHR) technology to furnish certain elements of the service, share the care plan and clinical summaries electronically, document specified activities, and other items summarized in Table 11 of our CY 2017 proposed rule. For the CCM service elements for which we required use of a certified EHR, the billing practitioner must use, at a minimum, technology meeting the edition(s) of certification criteria that is acceptable for purposes of the EHR Incentive Programs as of December 31st of the calendar year preceding each PFS payment year. (For the CY 2017 PFS payment year, this would mean technology meeting the 2014 edition of certification criteria).

These elements and requirements for separately payable CCM services are extensive and generally exceed those required for payment of codes describing procedures, diagnostic tests, or other E/M services under the PFS. In addition, both CPT guidance and Medicare rules specify that only a single practitioner who assumes the care management role for a given beneficiary can bill CPT code 99490 per service period (calendar month). Because the new CCM service closely overlapped with several Medicare demonstration models of advanced primary care (the Multi-Payer Advanced Primary Care Practice (MAPCP) demonstration and the Comprehensive Primary Care Initiative (CPCI)), we provided that practitioners participating in one of these two initiatives could not be paid for CCM services furnished to a beneficiary attributed by the initiative to their practice (79 FR 67729).

Given the non-face-to-face nature of CCM services, we also sought to ensure that beneficiaries would receive advance notice that Part B cost sharing applies since we currently have no legislative authority to ''waive'' cost sharing for this service. Also since only one practitioner can bill for CCM each service period, we believed the

beneficiary notice requirement would help prevent duplicate payment to multiple practitioners.

Since the establishment of CPT code 99490 for separate payment of CCM services, in a number of forums and in public comments to the CY 2016 PFS final rule (80 FR 70921), many practitioners have stated that the service elements and billing requirements are burdensome, redundant and prevent them from being able to provide the services to beneficiaries who could benefit from them. Stakeholders have stated that CPT code 99490 is underutilized because it is underpaid relative to the resources involved in furnishing the services, especially given the extensive Medicare rules for payment, and they have suggested a number of potential changes to our current payment rules. Stakeholders continue to believe that many of the CCM payment rules are duplicative, and to recommend that we reduce the rules and expand CCM coding and payment to distinguish among different levels of patient complexity. We also note that section 103 of the MACRA requires CMS to assess and report to Congress (no later than December 31, 2017) on access to CCM services by underserved rural and racial and ethnic minority populations and to conduct an outreach/education campaign that is underway.

The professional claims data for CPT code 99490 show that utilization is steadily increasing but may remain low considering the number of eligible Medicare beneficiaries. To date, approximately 513,000 unique Medicare beneficiaries received the service an average of four times each, totaling $93 million in total payments. Since CPT code 99490 describes a minimum of 20 minutes of clinical staff time spent furnishing CCM services during a month and does not have an upper time limit, and since we currently do not separately pay the other codes in the CCM family of CPT codes (which would provide us with utilization data on the number of patients requiring longer service times during a billing period), we do not know how often beneficiaries required more than 20 minutes of CCM services per month. We also do not know their complexity relative to one another, other than meeting the acuity criteria in the CPT code descriptor. Initial information from practitioner interviews conducted as part of our CCM evaluation efforts indicates that practitioners overwhelmingly meet and exceed the 20-minute threshold time for billing CCM. Typically, these practitioners reported spending between 45 minutes and an hour per month on CCM services for each patient, with times ranging between 20 minutes and several hours per month. CCM beneficiaries tend to exhibit a higher disease burden, are more likely to be dually eligible for Medicare and Medicaid, and are older than the general Medicare fee-for-service population.[13] However, absent multiple levels of CCM coding, we do not have comprehensive data on the relative complexity of the CCM services furnished to beneficiaries.

In light of this stakeholder feedback and our mandate under MACRA section 103 to encourage and report on access to CCM services, we proposed several changes in the payment rules for CCM services. Our primary goal, and our statutory mandate, is to pay as accurately as possible for services furnished to Medicare beneficiaries based on the relative resources required to furnish PFS services, including CCM services. In so doing, we also expect to facilitate beneficiaries' access to reasonable and necessary CCM services that improve health outcomes. First, for CY 2017 we proposed to more appropriately recognize and pay for the other codes in the CPT family of CCM services (CPT codes 99487 and 99489 describing complex CCM), consistent with our general practice to price services according to their relative ranking within a given family of services. We direct the reader to section II.L of this final rule for a discussion of valuation for base CPT code 99487 and its add-on CPT code 99489. The CPT code descriptors are:

- CPT code 99487—Complex chronic care management services, with the following required elements:

++ Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;

++ Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;

++ Establishment or substantial revision of a comprehensive care plan;

++ Moderate or high complexity medical decision making;

++ 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.

- CPT code 99489—Each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure).

As CPT provides, less than 60 minutes of clinical staff time in the service period could not be reported separately, and similarly, less than 30 minutes in addition to the first 60 minutes of complex CCM in a service period could not be reported. We would require 60 minutes of services for reporting CPT code 99487 and 30 additional minutes for each unit of CPT code 99489.

We proposed to adopt the CPT provision that CPT codes 99487, 99489 and 99490 may only be reported once per service period (calendar month) and only by the single practitioner who assumes the care management role with a particular beneficiary for the service period. That is, a given beneficiary would be classified as eligible to receive either complex or non-complex CCM during a given service period, not both, and only one professional claim could be submitted to the PFS for CCM for that service period by one practitioner.

Comment: Several commenters were supportive of separate payment for complex CCM services.

Response: We thank the commenters for their support and are finalizing separate payment for CPT codes 99487 and 99489 as proposed. As finalized, these separate payments for complex CCM services will support care management for the most complex and time-consuming cases of beneficiaries with multiple chronic conditions.

Except for differences in the CPT code descriptors, we proposed to require the same CCM service elements for CPT codes 99487, 99489 and 99490. In other words, all the requirements in Table 11 of our proposed rule would apply, whether the code being billed for the service period is CPT code 99487 (plus CPT code 99489, if applicable) or CPT code 99490. These three codes would differ in the amount of clinical staff service time provided; the complexity of medical decision-making as defined in the E/M 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). Billing practitioners could consider identifying beneficiaries who require complex CCM services using criteria suggested in CPT guidance (such as number of illnesses, number of medications or repeat admissions or emergency department visits) or the profile of typical patients in the CPT

[13] Schurrer, John, and Rena Rudavsky. ''Evaluation of the Diffusion and Impact of the Chronic Care Management (CCM) Fees: Third Quarterly Report.'' Report submitted to the Center for Medicare and Medicaid Innovation. Washington, DC: Mathematica Policy Research, May 6, 2016.

prefatory language, but these would not comprise Medicare conditions of eligibility for complex CCM.

We proposed several changes to our current scope of service elements for CCM, and proposed that the same scope of service elements, as amended, would apply to all codes used to report CCM services beginning in 2017 (*i.e.,* CPT codes 99487, 99489 and 99490). In particular, we proposed changes in the requirements for the initiating visit, 24/7 access to care and continuity of care, format and sharing of the care plan and clinical summaries, beneficiary receipt of the care plan, beneficiary consent and documentation.

Comment: Commenters were broadly supportive of these proposals. We received several comments recommending changes to the scope of service for non-complex CCM that might improve the distinction between non-complex and complex CCM and inform which ''level'' of service a given beneficiary is eligible for. For example, these commenters suggested changes to the time included in the code descriptor to reflect two or more time increments for CPT code 99490 using add-on codes, or retaining the current low time threshold while allowing practitioners to choose among certain service elements. Some commenters do not believe CPT code 99490 is intended for beneficiaries who require all the current service elements in a given month, and that only a more limited set of elements is medically necessary for the non-complex population.

Response: We appreciate the commenters' recommendations about how we might better distinguish complex CCM services from non-complex CCM services. The CPT Editorial Panel currently maintains the coding for CCM services. Further changes in codes and/or descriptors may be appropriately addressed by CPT and in subsequent PFS rulemaking.

a. CCM Initiating Visit & Add-On Code (G0506)

As provided in the CY 2014 PFS final rule with comment period (78 FR 74425) and subregulatory guidance (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Payment_for_CCM_Services_FAQ.pdf*), CCM must be initiated by the billing practitioner during a ''comprehensive'' E/M visit, AWV or IPPE. This face-to-face, initiating visit is not part of the CCM service and can be separately billed to the PFS, but is required before CCM services can be provided directly or under other arrangements. The billing practitioner must discuss CCM with the patient at this visit. While informed patient consent does not have to be obtained during this visit, the visit is an opportunity to obtain the required consent. The face-to-face visit included in transitional care management (TCM) services (CPT codes 99495 and 99496) qualifies as a ''comprehensive'' visit for CCM initiation. Levels 2 through 5 E/M visits (CPT codes 99212 through 99215) also qualify; CMS does not require the practice to initiate CCM during a level 4 or 5 E/M visit. However, CPT codes that do not involve a face-to-face visit by the billing practitioner or are not separately payable by Medicare (such as CPT code 99211, anticoagulant management, online services, telephone and other E/M services) do not qualify as initiating visits. If the practitioner furnishes a ''comprehensive'' E/M, AWV, or IPPE and does not discuss CCM with the patient at that visit, that visit cannot count as the initiating visit for CCM.

We continued to believe that we should require an initiating visit in advance of furnishing CCM services, separate from the services themselves, because a face-to-face visit establishes the beneficiary's relationship with the billing practitioner and most aspects of the CCM services are furnished incident to the billing practitioner's professional services. The initiating visit also ensures collection of comprehensive health information to inform the care plan. We continued to believe that the types of face-to-face services that qualify as an initiating visit for CCM are appropriate. We did not propose to change the kinds of visits that can qualify as initiating CCM visits. However, we proposed to require the initiating visit only for new patients or patients not seen within one year instead of for all beneficiaries receiving CCM services. We believed this would allow practitioners with existing relationships with patients who have been seen relatively recently to initiate CCM services without furnishing a potentially unnecessary E/M visit. We solicited public comment on whether a period of time shorter than one year would be more appropriate.

Comment: The commenters were generally supportive of requiring the CCM initiating visit only for beneficiaries who are new patients or have not been seen in a year. A few commenters suggested a 6-month timeframe, or adopting one year and reconsidering as we gain more experience with CCM. Some commenters misinterpreted our proposal as requiring face-to-face visits every year to periodically reassess the beneficiary or the appropriateness of CCM services. Some recommended a similar coding structure for specialists managing a single condition, in place of prolonged services, or for BHI services.

Response: Our intent was to revise the timeframe for the single CCM initiating visit that is required at the outset of services. We did not propose subsequent ''re-initiation'' of CCM services or face-to-face reassessment within a given timeframe. We discuss further below that we have some concerns about how to ensure that the billing practitioner remains involved in the beneficiary's care and continually reassesses the beneficiary's care, but at this time we do not believe we should require subsequent face-to-face visits within certain timeframes to address those concerns.

We believe that the proposed one-year timeframe for the single, CCM initiating visit is appropriate for CY 2017, so we are finalizing as proposed. We will require the CCM initiating visit only for new patients or patients not seen within the year prior to commencement of CCM (instead of for all beneficiaries receiving CCM services). We will continue to consider in future years whether a different timeframe is warranted. The goal of our final policy is to allow practitioners with existing relationships with beneficiaries who have been seen relatively recently to initiate CCM services (for the first time) without furnishing a potentially unnecessary E/M visit. Regarding subsequent visits (after CCM services begin), practitioners are already permitted to furnish and separately bill subsequent E/M visits (or AWVs) for beneficiaries receiving CCM services. If a face-to-face reassessment is reasonable and necessary and furnished by the billing practitioner, then he or she may bill an appropriate code describing the face-to-face assessment of a beneficiary to whom they have previously furnished CCM services.

We also proposed for CY 2017 to create a new add-on G-code that would improve payment for services that qualify as initiating visits for CCM services. The code would be billable for beneficiaries who require extensive face-to-face assessment and care planning by the billing practitioner (as opposed to clinical staff), through an add-on code to the initiating visit, G0506 (Comprehensive assessment of and care planning by the physician or other qualified health care professional for patients requiring chronic care management services (billed separately from monthly care management services) (Add-on code, list separately in addition to primary service)).

We proposed that when the billing practitioner initiating CCM personally

performs extensive assessment and care planning outside of the usual effort described by the billed E/M code (or AWV or IPPE code), the practitioner could bill G0506 in addition to the E/M code for the initiating visit (or in addition to the AWV or IPPE), and in addition to the CCM CPT code 99490 (or proposed 99487 and 99489) if all requirements to bill for CCM services are also met. We proposed valuation for G0506 in a separate section of our proposed rule.

The code G0506 would account specifically for additional work of the billing practitioner in personally performing a face-to-face assessment of a beneficiary requiring CCM services, and personally performing CCM care planning (the care planning could be face-to-face and/or non-face-to-face) that is not already reflected in the initiating visit itself (nor in the monthly CCM service code). We believed G0506 might be particularly appropriate to bill when the initiating visit is a less complex visit (such as a level 2 or 3 E/M visit), although G0506 could be billed along with higher level visits if the billing practitioner's effort and time exceeded the usual effort described by the initiating visit code. It could also be appropriate to bill G0506 when the initiating visit addresses problems unrelated to CCM, and the billing practitioner does not consider the CCM-related work he or she performs in determining what level of initiating visit to bill. We believed that this proposal would more appropriately recognize the relative resource costs for the work of the billing practitioner in initiating CCM services, specifically for extensive work assessing the beneficiary and establishing the CCM care plan that is reasonable and necessary, and that is not accounted for in the billed initiating visit or in the unit of the CCM service itself that is billed for a given service period. In addition, we believed this proposal would help ensure that the billing practitioner personally performs and meaningfully contributes to the establishment of the CCM care plan when the patient's complexity warrants it.

Comment: Several commenters were supportive of the add-on code (G0506) to the CCM initiating visit to describe physician assessment and care planning for patients requiring CCM services. Some commenters raised questions about whether G0506 should be a one-time service or could also be billed as an add-on code to subsequent reassessments by the billing practitioner (whether E/M visits or subsequent AWVs).

Response: At this time, we do not believe we should permit billing of G0506 more than once by the billing practitioner for a given beneficiary. G0506 was proposed as an add-on code to the single initiating visit, to help ensure the billing practitioner's assessment and involvement at the outset of CCM services. At this time there are no requirements for the billing practitioner to ''re-initiate'' CCM services; therefore we do not believe we should create an add-on code for a CCM ''re-initiation'' service. We would have to define ''re-initiation'' and develop rules regarding when subsequent E/M visits or AWVs are related to the performance of CCM. We do not believe beneficiaries would understand why they are incurring additional cost sharing for an add-on code to a ''re-initiation'' visit that has not been required or defined by CMS.

As we stated in the CY 2017 proposed rule, we were very interested in coding that was presented to the CPT Editorial Panel, but not adopted, to create code(s) that would separately identify and account for monthly CCM work by the billing practitioner. Such coding may be a better means of separately identifying and valuing the subsequent work of the billing practitioner after CCM is initiated. We want to establish policies that help ensure that the billing practitioner is not merely handing the beneficiary off to a remote care manager under general supervision while no longer remaining involved in their care. We believe that the practitioner billing CCM services should be actively re-assessing the beneficiary's chronic conditions, reviewing whether treatment goals are being met, updating the care plan, performing any medical decision-making that is not within the scope of practice of clinical staff, performing any necessary face-to-face care, and performing other related work. However, it would be more straightforward to separately identify this CCM-related work under code(s) that in their own right describe it, instead of add-on codes to very broadly drawn E/M codes where it becomes difficult to assess the relationship between the two services. Also for beneficiaries receiving complex CCM, some of this work is explicitly included in the complex CCM service codes (*i.e.,* medical decision-making of moderate to high complexity). Therefore, at this time, G0506 will only serve as an add-on code to describe work performed by the billing practitioner once, in conjunction with the start or initiation of CCM services.

We note that despite the role of the billing practitioner in the initiation and provision of CCM services provided by clinical staff, non-complex CCM (CPT code 99490) is described based on the time spent by clinical staff. Complex CCM (CPT codes 99487 and 99489) similarly counts only clinical staff time, although it also includes complex medical decision-making by the billing practitioner. This raises issues regarding appropriate valuation in the facility setting that we will continue to consider in future rulemaking. The facility PE RVU for CCM includes indirect PE (which is an allocation based on physician work), but no direct PE (which would be comprised of other labor, supplies and equipment). This is because historically, the PFS facility rate assumes that the billing practitioner is not bearing a significant resource cost in labor by other individuals, equipment or supplies. Medicare assumes that those costs are instead borne by the facility and adequately accounted for in a separate payment made to the facility. The PFS non-facility rate generally does include such costs, assuming that the billing practitioner bears the resource costs in clinical and other staff labor, supplies and equipment.

For CCM, we have been considering whether this approach to valuation remains appropriate, because the service, in whole or in significant part, is provided by clinical staff under the direction of the billing practitioner. These individuals may provide the service or part thereof remotely, and are not necessarily employees or staff of the facility. Under this construct, there may be more direct practice expense borne by the billing practitioner that should be separately identified and valued over and above any institutional payment to the facility for its staff and infrastructure. We plan to explore these issues in future rulemaking and consider other approaches to valuation that would recognize the accurate relative resource costs to the billing practitioner for CCM and similar services furnished to beneficiaries who remain or reside in a facility setting during some or all of the service period.

Consistent with general coding guidance, we proposed that the work that is reported under G0506 (including time) could not also be reported under or counted towards the reporting of any other billed code, including any of the monthly CCM services codes. The care plan that the practitioner must create to bill G0506 would be subject to the same requirements as the care plan included in the monthly CCM services, namely, it must be an electronic patient-centered care plan based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an

inventory of resources and supports; a comprehensive care plan for all health issues. This would distinguish it from the more limited care planning included in the BHI codes G0502, G0503, G0504 or G0507 which focus on behavioral health issues, or the care planning included in G0505 which focuses on cognitive status. We sought public input on potential overlap among these codes and further clinical input as to how the assessments and care planning that is included in them would differ.

We received a number of comments regarding the relationship between proposed G0506, G0505 (Cognition and functional assessment by the physician or other qualified health care professional in office or other outpatient), prolonged non-face-to-face services, and BHI. We address these comments in the sections of this final rule regarding G0505, prolonged non-face-to-face services and BHI services (sections II.E.5, II.E.2 and II.E.3). In brief, we are not allowing G0506 and G0505 to be billed the same day (by a single practitioner). G0506 will not be an add-on code for the BHI initiating visit or BHI services. G0506 will be a one-time service code for CCM initiation, and the billing practitioner must choose whether to report either G0506 or prolonged services in association with CCM initiation (if requirements to bill both are met).

The CCM and BHI service codes differ substantially in potential diagnosis and comorbidity, the expected duration of the condition(s) being treated, the kind of care planning performed (comprehensive care planning versus care planning focused on behavioral/mental health issues), service elements and who performs them, and the interventions the beneficiary needs and receives apart from the CCM and BHI services themselves. The BHI codes include a more focused process than CCM for the clinical integration of primary care and behavioral health/psychiatric care, and for continual reassessment and treatment progression to a target or goal outcome that is specific to mental and behavioral health or substance abuse issues. However there is no explicit BHI service element for managing care transitions or systematic assessment of receipt of preventive services; there is no requirement to perform comprehensive care planning for all health issues (not just behavioral health issues); and there are different emphases on medication management or medication reconciliation, if applicable. In deciding which code(s) to report for services furnished to a beneficiary who is eligible for both CCM and BHI services, practitioners should consider which service elements were furnished during the service period, who provided them, how much time was spent, and should select the code(s) that most accurately and specifically identifies the services furnished without duplicative time counting. Practitioners should generally select the more specific code(s) when an alternative code(s) potentially includes the services provided. We are not precluding use of the CCM codes to report, or count, behavioral health care management if it is provided as part of a broader CCM service by a practitioner who is comprehensively overseeing all of the beneficiary's health issues, even if there are no imminent non-behavioral health needs. However, such behavioral care management activities could not also be counted towards reporting a BHI code(s). If a BHI service code more specifically describes the service furnished (service time and other relevant aspects of the service being equal), or if there is no focus on the health of the beneficiary outside of a narrower set of behavioral health issues, then it is more appropriate to report the BHI code(s) than the CCM code(s). Similarly, it may be more appropriate for certain specialists to bill BHI services than CCM services, since specialists are more likely to be managing the beneficiary's behavioral health needs in relation to a narrow subset of medical condition(s). CCM and BHI services can only be billed the same month for the same beneficiary if all the requirements to bill each service are separately met. We will monitor the claims data, and we welcome further stakeholder input to inform appropriate reporting rules.

b. 24/7 Access to Care, Continuity of Care, Care Plan and Managing Transitions

We proposed several revisions to the scope of service elements of 24/7 Access to Care, Continuity of Care, Care Plan and Managing Transitions. We continued to believe these elements are important aspects of CCM services, but that we should reduce the requirements for the use of specified electronic health information technology (IT) in their provision. In sum, we proposed to retain a core requirement to use a certified electronic health record (EHR), but allow fax to count for electronic transmission of clinical summaries and the care plan; no longer require access to the electronic care plan outside of normal business hours to those providing CCM services; and remove standards for clinical summaries in managing care transitions.

We sought to improve alignment with CPT provisions by removing the requirement for the care plan to be available remotely to individuals providing CCM services after hours. Studies have shown that after-hours care is best implemented as part of a larger practice approach to access and continuity (see for example, the peer-review article available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/*). There is substantial local variation in how 24/7 access and continuity of care are achieved, depending on the contractual relationships among practitioners and providers in a particular geographic area and other factors. Care models include various contractual relationships between physician practices and after-hours clinics, urgent care centers and emergency departments; extended primary care office hours; physician call-sharing; telephone triage systems; and health information technology such as shared EHRs and systematic notification procedures (*http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/*). Some or all of these may be used to provide access to urgent care on a 24/7 basis while maintaining information continuity between providers.

We recognized that some models of care require more significant investment in practice infrastructure than others, for example resources in staffing or health information technology. In addition, we believed there is room to reduce the administrative complexity of our current payment rules for CCM services to accommodate a range of potential care models. In re-examining what should be included in the CCM scope of service elements for 24/7 Access to Care and Continuity of Care, we believed the CPT language adequately and more appropriately describes the services that should, at a minimum, be included in these service elements. Therefore, we proposed to adopt the CPT language for these two elements. For 24/7 Access to Care, the scope of service element would be to provide 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. We believed the CPT language more accurately reflects the potential role of clinical staff or call-sharing services in addressing after-hours care needs than our current language does. In addition, the 24/7 access would be for ''urgent'' needs

rather than ''urgent chronic care needs,'' because we believed after-hours services typically would and should address any urgent needs and not only those explicitly related to the beneficiary's chronic conditions.

We recognized that health information systems that include remote access to the care plan or the full EHR after hours, or a feedback loop that communicates back to the primary care physician and others involved in the beneficiary's care regarding after-hours care or advice provided, are extremely helpful (*http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/#CR25*). They help ensure that the beneficiary receives necessary follow up, particularly if he or she is referred to the emergency department, and follow up after an emergency department visit is required under the CCM element of Management of Care Transitions. Accordingly, we continued to support and encourage the use of interoperable EHRs or remote access to the care plan in providing the CCM service elements of 24/7 Access to Care, Continuity of Care, and Management of Care Transitions. However, adoption of such technology would be optimal not only for CCM services, but also for a number of other PFS services and procedures (including various other care management services), and we have not required adoption of any certified or non-certified health information technology as a condition of payment for any other PFS service. We noted that there are incentives under other Medicare programs to adopt such information technology, and were concerned that imposing too many EHR-related requirements at the service level as a condition of PFS payment could create disparities between these services and others under the fee schedule. Lastly, we recognized that not all after-hours care warrants follow-up or a feedback loop with the practitioner managing the beneficiary's care overall, and that under particular circumstances feedback loops can be achieved through oral, telephone or other less sophisticated communication methods. Therefore, we proposed to remove the requirement that the individuals providing CCM after hours must have access to the electronic care plan.

This proposal reflected our understanding that flexibility in how practices can provide the requisite 24/7 access to care, as well as continuity of care and management of care transitions, for their CCM patients could facilitate appropriate access to these services for Medicare beneficiaries. This proposal was not intended to undermine the significance of standardized communication methods as part of effective care. Instead, we recognized that other CMS initiatives (such as MIPS and APMs under the Quality Payment Program) may be better mechanisms to incentivize increased interoperability of health information systems than conditions of payment assigned to particular services under the PFS. We also anticipated that improved accuracy of payment for care management services and reduced administrative burden associated with billing for them would contribute to practitioners' capacity to invest in the best tools for managing the care of Medicare beneficiaries.

For Continuity of Care, we currently require the ability to obtain successive routine appointments ''with the practitioner or a designated member of the care team,'' while CPT only references successive routine appointments ''with a designated member of the care team.'' We do not believe there is any practical difference between these two phrases and therefore proposed to omit the words ''practitioner or'' from our requirement. The billing practitioner is a member of the CCM care team, so the CPT language already allows for successive routine appointments either with the billing practitioner or another appropriate member of the CCM care team.

Based on review of extensive public comment and stakeholder feedback, we had also come to believe that we should not require individuals providing the beneficiary with the required 24/7 access to care for urgent needs to have access to the care plan as a condition of CCM payment. As discussed above, we believed that in general, provision of effective after-hours care of the beneficiary would require access to the care plan, if not the full EHR. However, we have heard from rural and other practices that remote access to the care plan is not always necessary or possible because urgent care needs after-hours are often referred to a practitioner or care team member who established the care plan or is familiar with the beneficiary. In some instances, the care plan does not need to be available to address urgent patient needs after business hours. In addition, we have not required the use of any certified or non-certified health information technology in the provision of any other PFS services (including various other care management services). We were concerned that imposing EHR-related requirements at the service level as a condition of PFS payment could distort the relative valuation of services priced under the fee schedule. Therefore, we proposed to change the CCM service element to require timely electronic sharing of care plan information within and outside the billing practice, but not necessarily on a 24/7 basis, and to allow transmission of the care plan by fax.

We acknowledged that it is best for practitioners and providers to have access to care plan information any time they are providing services to beneficiaries who require CCM services. This proposal was not intended to undermine the significance of electronic communication methods other than fax transmission in providing effective, continuous care. On the contrary, we believed that fax transmission, while commonly used, is much less efficient and secure than other methods of communicating patient health information, and we encouraged practitioners to adopt and use electronic technologies other than fax for transmission and exchange of the CCM care plan. We continued to believe the best means of exchange of all relevant patient health information is through standardized electronic means. However, we recognized that other CMS initiatives (such as MIPS and APMs under the Quality Payment Program) may be better mechanisms to incentivize increased interoperability of health information systems than conditions of payment assigned to particular services under the PFS. We believed our proposal would still allow timely availability of health information within and outside the practice for purposes of providing CCM, and would simplify the rules governing provision of the service and improve access to the service. The proposed revisions would better align the service with appropriate CPT prefatory language, which may reduce unnecessary administrative complexity for practitioners in navigating the differences between CPT guidance and Medicare rules.

The CCM scope of service element Management of Care Transitions includes a requirement for the creation and electronic transmission and exchange of continuity of care documents referred to as ''clinical summaries'' (see Table 11 of the CY 2017 PFS proposed rule). We patterned our requirements regarding clinical summaries after the EHR Incentive Program requirement that an eligible professional who transitions their patient to another setting of care or provider of care, or refers their patient to another provider of care, should provide a summary care record for each transition of care or referral. This clinical summary includes demographics, the medication list, medication allergy list, problem list, and a number of other data elements if the

practitioner knows them. As a condition of CCM payment, we required standardized content for clinical summaries (that they must be created/formatted according to certified EHR technology). For the exchange/transport function, we did not require the use of a specific tool or service to exchange/transmit clinical summaries, as long as they are transmitted electronically (this can include fax only when the receiving practitioner or provider can only receive by fax).

Based on review of extensive public comment and stakeholder feedback, we had come to believe that we should not require the use of any specific electronic technology in managing a beneficiary's care transitions as a condition of payment for CCM services. Instead, we proposed more simply to require the billing practitioner to create and exchange/transmit continuity of care document(s) timely with other practitioners and providers. To avoid confusion with the requirements of the EHR Incentive Programs, and since we would no longer require standardized content for the CCM continuity of care document(s), we would refer to them as continuity of care documents instead of clinical summaries. We would no longer specify how the billing practitioner must transport or exchange these document(s), as long as it is done timely and consistent with the Care Transitions Management scope of service element. We welcomed public input on how we should refer to these document(s), noting that CPT does not provide model language specific to CCM services. The proposed term ''continuity of care document(s)'' draws on CPT prefatory language for TCM services, which CPT provides may include ''obtaining and reviewing the discharge information (for example, discharge summary, as available, or continuity of care document).''

Again, this proposal was not intended to undermine the significance of a standardized, electronic format and means of exchange (other than fax) of all relevant patient health information, for achieving timely, seamless care across settings especially after discharge from a facility. On the contrary, we believed that fax transmission, while commonly used, is much less efficient and secure than other methods of communicating patient health information, and we encourage practitioners to adopt and use electronic technologies other than fax for transmission and exchange of continuity of care documents in providing CCM services. We continued to believe the best means of exchange of all relevant patient health information is through standardized electronic means. However, as we discussed above regarding the CCM care plan, we have not applied similar requirements to other PFS services specifically (including various other care management services) and had concerns about how doing so may create disparities between these services and others under the PFS. We also recognized that other CMS initiatives (such as MIPS and APMs under the Quality Payment Program) may be better mechanisms to incentivize increased interoperability of health information systems than conditions of payment assigned to particular services under the PFS.

Comment: Most of the commenters supported our proposed revisions to the health IT use requirements for billing the CCM code. They shared CMS' goal of interoperability but believed the changes were necessary to improve CCM uptake. Some commenters favored hardship exceptions or rural or small practice exceptions instead of changes to the current requirements that would apply to all practitioners alike. Some commenters expressed particular concern about relaxing the current rules in instances where CCM outsourcing reduces clinical integration. These commenters noted that CCM is commonly outsourced to third party companies that provide remote care management services (including after hours) via telephone and online contact only, using staff who have no established relationship with the beneficiary or other members of the care team and have no interaction with the office staff and physicians other than electronic communication. These commenters were concerned that our proposed changes to the health IT requirements for CCM payment would result in little to no oversight or guidance of the third party, and recommended that CMS make the proposed changes cautiously. One of these commenters recommended in addition that CMS should seek to increase access to CCM services and reduce administrative burden by pursuing alignment between the provision of CCM and other programs and incentives, such as the Quality Payment Program. Other commenters recommended further reduction in payment rules, such as removing all requirements to use a certified EHR, or movement away from timed codes that require documentation in short time increments and disrupt workflow.

Response: We continue to believe that other Medicare initiatives and programs (such as MIPS and APMs under the Quality Payment Program) are better suited to advance use of interoperable health IT systems than establishing code-level conditions of payment, unique to CCM or other primary care or cognitive services. We also believe that a hardship, rural or small practice exception would greatly increase rather than decrease administrative complexity for practitioners and CMS, and CCM uptake has been relatively high among solo practices. We believe that reducing code-level conditions of payment is necessary to improve beneficiary access to appropriate CCM services. Therefore, we are finalizing revisions to the CCM scope of service elements as proposed.

However, we appreciate the commenters' feedback that relaxing the health IT use requirements may be of particular concern in situations where CCM is outsourced to a third party, reducing clinical integration. As we discuss in the section of this final rule on BHI services (section II.E.3.b), health IT holds significant promise for remote connectivity and interoperability that may assist and be useful (if not necessary) for reducing care fragmentation. However, we agree that remote provision of services by entities having only a loose association with the treating practitioner can detract from continuous, patient-centered care, whether or not those entities employ certified or other electronic technology. We will continue to consider the potential impacts of remote provision of CCM and similar types of services by third parties. We wish to emphasize for CCM, as we did for BHI services, that while the CCM codes do not explicitly count time spent by the billing practitioner, they are valued to include work performed by the billing practitioner, especially complex CCM. We emphasize that the practitioner billing for CCM must remain involved in ongoing oversight, management, collaboration and reassessment as appropriate to bill CCM services. If there is little oversight by the billing practitioner or a lack of clinical integration between a third party providing CCM and the billing practitioner, we do not believe that the CCM service elements are actually being furnished and therefore, in such cases, the practitioner should not bill for CCM.

Finally, we note that activities undertaken as part of participation in MIPS or an APM under the Quality Payment Program may support the ability of a practitioner to meet our final requirements for the continuity of care document(s) and the electronic care plan.

Comment: Several commenters recommended that we define the proposed term ''timely'' for the creation and transmission of care plan and care

transitions health information. Several commenters believed that ''timely'' implies a time period of 30 to 90 days, or believed some third party vendors would interpret the term in this manner.

Response: Our proposal of the term ''timely'' originated from the use of this term in the CPT prefatory language for Care Management services, which includes, for example, ''provide timely access and management for follow-up after an emergency department visit'' and ''timely access to clinical information.'' We do not believe we should specify a timeframe, because it would vary for individual patients and CCM service elements, we are not aware of any clinical standards referencing specific times, and we are seeking to allow appropriate flexibility in how CCM is furnished. We note that dictionary meanings of the term ''timely'' include quickly; soon; promptly; occurring at a suitable time; done or occurring at a favorable or useful time; opportune. ''Timely'' does not necessarily imply speed, and means doing something at the most appropriate moment. Therefore we believe ''timely'' is an appropriate term to use to govern how quickly the health information in question is transmitted or available. We note that even the current requirements for use of specific electronic technology do not necessarily impact how quickly the health information in question is used to inform care, and addition of the word ''timely'' implies more regarding actual use of the information. We are monitoring CCM uptake and diffusion through claims analysis and are pursuing claims-based outcomes analyses, to help inform whether the service is being provided as intended and improving health outcomes. We believe these evaluation activities will help us assess moving forward whether health information is being shared or made available timely enough under our revised CCM payment policies.

As we stated in the CY 2017 proposed rule, the policy changes for CCM health IT use are not intended to undermine the importance of interoperability or electronic data exchange. These changes are driven by concerns that we have not applied similar requirements to other PFS services specifically, including various other care management services, and that such requirements create disparities between CCM services and other PFS services. We believe that other CMS initiatives may be better mechanisms to incentivize increased use and interoperability of health information systems than conditions of payment assigned to particular services under the PFS. We anticipate that these CCM policy changes will improve practitioners' capacity to invest in the best tools for managing the care of Medicare beneficiaries.

c. Beneficiary Receipt of Care Plan

We proposed to simplify the current requirement to provide the beneficiary with a written or electronic copy of the care plan, by instead adopting the CPT language specifying more simply that a copy of the care plan must be given to the patient or caregiver. While we believe beneficiaries should and must be provided a copy of the care plan, and that practitioners may choose to provide the care plan in hard copy or electronic form in accordance with patient preferences, we do not believe it is necessary to specify the format of the care plan that must be provided as a condition of CCM payment. Additionally, we recognize that there may be times that sharing the care plan with the caregiver (in a manner consistent with applicable privacy and security rules and regulations) may be appropriate.

Comment: The commenters who provided comments on this particular proposal were supportive of it. In particular, several commenters expressed appreciation for appropriate inclusion of caregivers.

Response: We thank the commenters for their support and are finalizing as proposed.

d. Beneficiary Consent

We continue to believe that obtaining advance beneficiary consent to receive CCM services is important to ensure the beneficiary is informed, educated about CCM services, and is aware of applicable cost sharing. We also believe that querying the beneficiary about whether another practitioner is already providing CCM services helps to reduce the potential for duplicate provision or billing of the services. However, we believe the consent process could be simplified, and that it should be left to the practitioner and the beneficiary to decide the best way to establish consent. Therefore, we proposed to continue to require billing practitioners to inform the beneficiary of the currently required information (that is, inform the beneficiary of the availability of CCM services; inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month; and inform the beneficiary of the right to stop the CCM services at any time (effective at the end of the calendar month)). However, we proposed to specify that the practitioner could document in the beneficiary's medical record that this information was explained and note whether the beneficiary accepted or declined CCM services instead of obtaining a written agreement.

We also proposed to remove the language requiring beneficiary authorization for the electronic communication of his or her medical information with other treating providers as a condition of payment for CCM services, because under federal regulations that implement the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 164.506), a covered entity is permitted to use or disclose protected health information for purposes of treatment without patient authorization. Moreover, if such disclosure is electronic, the HIPAA Security Rule requires secure transmission (45 CFR 164.312(e)). In previous regulations we have reminded practitioners that for all electronic sharing of beneficiary information in the provision of CCM services, HIPAA Privacy and Security Rule standards apply in the usual manner (79 FR 67728).

Comment: The commenters were largely supportive of our proposed policy changes. The commenters were supportive of verbal instead of written beneficiary consent if a clear requirement remains to transparently inform the beneficiary about the nature and benefit of the services, applicable cost sharing, and document that this information was conveyed; current written agreements qualify; and practitioners can elect to obtain written consent. Some commenters believed that obtaining written consent might be preferable as a means of resolving who is eligible for payment, if more than one practitioner bills. A few commenters suggested CMS require written educational materials about CCM, or conduct beneficiary outreach and education.

Response: We appreciate the commenters' support and recommendations. We are finalizing changes to the beneficiary consent requirements as proposed and clarifying that a clear requirement remains to transparently inform the beneficiary about the nature and benefit of the services, applicable cost sharing, and to document that this information was conveyed. The final beneficiary consent requirements do not affect any written agreements that are already in place for CCM services, and we note that practitioners can still elect to obtain written consent rather than verbal consent.

e. Documentation

We have heard from practitioners that the requirements to document certain

information in a certified EHR format are redundant because the CCM billing rules already require documentation of core clinical information in a certified EHR format. Specifically, we already require structured recording of demographics, problems, medications and medication allergies, and the creation of a clinical summary record, using a qualifying certified EHR; and that a full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care. Therefore, we proposed to no longer specify the use of a qualifying certified EHR to document communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits and to document beneficiary consent. We would continue to require documentation in the medical record of beneficiary consent (discussed above) and of communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits.

Comment: Many commenters were supportive of these proposals.

Response: We thank the commenters for their support and are finalizing changes to the documentation requirements as proposed. We continue to encourage practitioners to utilize health IT solutions for obtaining and documenting health information from sources external to their practice, noting that the 2015 edition of ONC certification criteria (see 80 FR 62601) includes criteria which specifically relate to obtaining information from non-clinical sources and the capture of structured data relating to social, psychological, and behavioral attributes.

f. Summary of Final CCM Policies

We are finalizing changes to the CCM scope of service elements discussed above that will apply for both complex and non-complex CCM services beginning in CY 2017. The final CY 2017 service elements for CCM are summarized in Table 11. We believe these changes 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. For payment of complex CCM services beginning in CY 2017, we are adopting the CPT code descriptors for CPT codes 99487 and 99489 as well as the service elements in Table 11. We are providing separate payment for complex CCM (CPT 99487, 99489) using the RUC-recommended payment inputs for those services. We may reconsider the role of health information technology in CCM service provision in future years. We anticipate that improved accuracy of payment for CCM services, and reduced administrative burden associated with billing CCM services, will contribute to practitioners' capacity to invest in the best tools for managing the care of Medicare beneficiaries.

TABLE 11—SUMMARY OF CY 2017 CHRONIC CARE MANAGEMENT SERVICE ELEMENTS AND BILLING REQUIREMENTS

Initiating Visit—Initiation during an AWV, IPPE, or face-to-face E/M visit (Level 4 or 5 visit not required), for new patients or patients not seen within 1 year prior to the commencement of chronic care management (CCM) services.

Structured Recording of Patient Information Using Certified EHR Technology—Structured recording of demographics, problems, medications and medication allergies using certified EHR technology. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.

24/7 Access & Continuity of Care:

- Provide 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.
- Continuity of care with a designated member of the care team with whom the beneficiary is able to schedule successive routine appointments.

Comprehensive Care Management—Care management for chronic conditions including systematic assessment of the beneficiary's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of beneficiary self-management of medications.

Comprehensive Care Plan:

- Creation, revision and/or monitoring (as per code descriptors) of an electronic patient-centered care plan based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues.
- Must at least electronically capture care plan information, and make this information available timely within and outside the billing practice as appropriate. Share care plan information electronically (can include fax) and timely within and outside the billing practice to individuals involved in the beneficiary's care.
- A copy of the plan of care must be given to the patient and/or caregiver.

Management of Care Transitions:

- 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.
- Create and exchange/transmit continuity of care document(s) timely with other practitioners and providers.

Home- and Community-Based Care Coordination:

- Coordination with home and community based clinical service providers.
- Communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits must be documented in the patient's medical record.

Enhanced Communication Opportunities—Enhanced opportunities for the beneficiary and any caregiver to communicate with the practitioner regarding the beneficiary's care through not only telephone access, but also through the use of secure messaging, Internet, or other asynchronous non-face-to-face consultation methods.

Beneficiary Consent:

- Inform the beneficiary of the availability of CCM services; that only one practitioner can furnish and be paid for these services during a calendar month; and of their right to stop the CCM services at any time (effective at the end of the calendar month).
- Document in the beneficiary's medical record that the required information was explained and whether the beneficiary accepted or declined the services.

Medical Decision-Making—Complex CCM services require and include medical decision-making of moderate to high complexity (by the physician or other billing practitioner).

5. Assessment and Care Planning for Patients with Cognitive Impairment (GPPP6)

For CY 2017 we proposed a G-code that would provide separate payment to recognize the work of a physician (or other appropriate billing practitioner) in assessing and creating a care plan for beneficiaries with cognitive impairment, such as from Alzheimer's disease or dementia, at any stage of impairment, G0505 (Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home). We understand that a similar code was recently approved by the CPT Editorial Panel and is scheduled to be included in the CY 2018 CPT code set. We intended for G0505 to be a temporary code, perhaps for only one year, to be replaced by the CPT code in CT 2018. We will consider whether to adopt and establish relative value units for the new CPT code under our standard process, presumably for CY 2018.

We reviewed the list of service elements that were considered by the CPT Editorial Panel, and proposed the following as required service elements of G0505:

- Cognition-focused evaluation including a pertinent history and examination.
- Medical decision making of moderate or high complexity (defined by the E/M guidelines).
- Functional assessment (for example, Basic and Instrumental Activities of Daily Living), including decision-making capacity.
- Use of standardized instruments to stage dementia.
- Medication reconciliation and review for high-risk medications, if applicable.
- Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized instrument(s).
- Evaluation of safety (for example, home), including motor vehicle operation, if applicable.
- Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks.
- Advance care planning and addressing palliative care needs, if applicable and consistent with beneficiary preference.
- Creation of a care plan, including initial plans to address any neuropsychiatric symptoms and referral to community resources as needed (for example, adult day programs, support groups); care plan shared with the patient and/or caregiver with initial education and support.

The proposed valuation of G0505 (discussed in section II.E.1) assumed that this code would include services that are personally performed by the physician (or other appropriate billing practitioner, such as a nurse practitioner or physician assistant) and would significantly overlap with services described by certain E/M visit codes, advance care planning services, and certain psychological or psychiatric service codes that are currently separately payable under the PFS. Accordingly, we proposed that G0505 must be furnished by the physician (or other appropriate billing practitioner) and could not be billed on the same date of service as CPT codes 90785 (Psytx complex interactive), 90791 (Psych diagnostic evaluation), 90792 (Psych diag eval w/med srvcs), 96103 (Psycho testing admin by comp), 96120 (Neuropsych tst admin w/comp), 96127 (Brief emotional/behav assmt), 99201–99215 (Office/outpatient visits new), 99324–99337 (Domicil/r-home visits new pat), 99341–99350 (Home visits new patient), 99366–99368 (Team conf w/pat by hc prof), 99497 (Advncd care plan 30 min), 99498 (Advncd care plan addl 30 min)), since these codes all reflect face-to-face services furnished by the physician or other billing practitioner for related separately billable services that overlap substantially with G0505. In addition, we proposed to prohibit billing of G0505 with other care planning services, such as care plan oversight services (CPT code 99374), home health care and hospice supervision (G0181, G0182), or our proposed add-on code for comprehensive assessment and care planning by the billing practitioner for patients requiring CCM services (GPPP7). We solicited comment on whether there are circumstances where multiple care planning codes could be furnished without significant overlap. We proposed to specify that G0505 may serve as a companion or primary E/M code to the prolonged service codes (those that are currently separately paid, and those we proposed to separately pay beginning in 2017), but were interested in public input on whether there is any overlap among these services. We solicited comment on how to best delineate the post-service work for G0505 from the work necessary to provide the prolonged services code.

We did not believe the services described by G0505 would significantly overlap with proposed or current medically necessary CCM services (CPT codes 99487, 99489, 99490); TCM services (CPT codes 99495, 99496); or the proposed behavioral health integration service codes (HCPCS codes GPPP1, GPPP2, GPPP3, GPPPX). Therefore, we proposed that G0505 could be billed on the same date-of-service or within the same service period as these codes (CPT codes 99487, 99489, 99490, 99495, 99496, and HCPCS codes GPPP1, GPPP2, GPPP3, and GPPPX). There may be overlap in the patient population eligible to receive these services and the population eligible to receive the services described by G0505, but we believed there would be sufficient differences in the nature and extent of the assessments, interventions and care planning, as well as the qualifications of individuals providing the services, to allow concurrent billing for services that are medically reasonable and necessary. We solicited public comment on potential overlap between G0505 and other codes currently paid under the PFS, as well as the other primary care/cognitive services addressed in this section of the final rule.

Comment: Many commenters were supportive of the proposal, including the provisions regarding scope of service elements, conditions of payment, and overlap with other services under the PFS.

Response: We thank commenters for their support of the proposed scope of service, conditions of payment, and overlap with other services under the PFS for G0505. We believe that by improving payment accuracy by paying separately for this service, practitioners will be able to accurately assess patients for cognitive impairment, particularly in early stages.

Comment: We received numerous comments stating that assessment and staging for dementia is very sensitive and should only be conducted by neuropsychologists, who would be unable to bill G0505. Commenters were concerned that untrained professionals conducting assessments for dementia would lead to errors in diagnosis and inappropriate treatment. Commenters encouraged CMS to not finalize this code and maintain the current coding for psychological and neuropsychological assessment or suggested that CMS remove the bullet points associated with medication management or medical decision making so that G0505 could be billed by psychologists.

Response: While we acknowledge and support the work of psychologists and neuropsychologists in the care of Medicare beneficiaries, we continue to

believe that this code describes a distinct PFS service that may be reasonable and necessary in the diagnosis and treatment of a beneficiary's illness. We remind interested stakeholders that we routinely examine the valuation and coding for existing services under the potentially misvalued code initiative, and that there is a the process for public nomination of particular codes. If stakeholders have information to suggest that the current coding for neuropsychological and psychological testing is inaccurate, we welcome nominations under the established process.

Comment: A few commenters encouraged CMS to avoid adopting scope of service elements that are exhaustive as these may create barriers to utilization, while other commenters made the following recommendations regarding the scope of service provisions:

- Expand scope of service elements related to medication management.
- Include occupational therapy in the scope of service element pertaining to community resources.
- Rewrite ''Creation of a care plan, including initial plans to address any neuropsychiatric symptoms and referral to community resources as needed (for example, adult day programs, support groups); care plan shared with the patient and/or caregiver with initial education and support'' to include ''identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness and availability of caregiver to voluntarily take on caregiving tasks.''
- Make sure that non-paid or informal caregivers are included in care planning and provide resources and support for care givers so as to improve care givers ability to provide care for the beneficiary.
- Require the inclusion of caregiver names in care plan and patients medical record, require that caregivers be assessed for stress and depressive symptoms, as well as care giver skill and education needs.
- State that consultations with the caregiver are permissible under HIPAA and that such conversations may be necessary in the development of a care plan.
- Specify that any advance care planning is consistent with beneficiary preference and addresses any palliative care needs of the patient, and include establishment of durable power of attorney.
- Clarify that diagnosis of dementia is not part of the scope of service by deleting ''cognition focused evaluation including pertinent history'' from the scope of service.
- Clarify that ''functional assessment'' is separate from decision making assessments, and that this is a non-legal assessment of competency.
- Stipulate that other decision makers should be identified.
- Consider deleting ''use of standardized instruments to stage dementia'' because the care plan is the most important aspect of the service and many standardized instruments are not very effective at staging.
- Clarify that the care plan address both medical and non-medical issues, and includes follow-up scheduling for monitoring and evaluation.
- Provide a copy of the written care plan to the patient.
- Refer to the care plan as a ''person-centered care plan.''
- Include evaluation of medical problems including review of lab or imaging tests, review of co-morbidities, especially those which are dependent on self-care, evaluation the risk of falls and recommendations for fall prevention, evaluation of possible elder abuse, and documentation of financial issues, as part of the scope of service.

Response: We appreciate the information provided by commenters on the best practices associated with furnishing this service and would encourage stakeholders to adopt any or all of these scope of service provisions, such as the inclusion of caregivers in care planning. The scope of service for assessment and care planning service for patients with cognitive impairment does not prohibit stakeholders from adopting any additional scope of service provisions which may be beneficial for the treatment of the patient. However, we do not believe that the ability to fully furnish this service and establish an appropriate value for it is contingent on meeting such conditions. Therefore, we do not believe they should be added to the scope of service. We concur with commenters on the necessity of avoiding the imposition of overly burdensome restrictions within the scope of service.

Comment: Some commenters requested that CMS clarify that not all elements in the scope of service need to be provided by the billing practitioner and many can be provided by others incident to the billing practitioner's services. One commenter stated that there are circumstances where the best practitioner to provide a specific service element does not work in the same practice as the billing practitioner, and therefore the billing practitioner should be able to contract out for provision of some aspects, provided that the billing practitioner remain in oversight. Other commenters stated that CMS should make G0505 billable by other practitioners, such as occupational therapists, or community based entities.

Response: G0505 is a service that includes central elements, which must be performed by the billing practitioner subject to established E/M guidelines. Only those practitioners eligible to report E/M services should report this service. Outside of the specified elements, the regular incident-to rules apply consistent with other E/M services. We believe that physicians and eligible non-physician practitioners, such as a nurse practitioners and physician assistants should exclusively bill for this code.

Comment: Many commenters suggested that CMS expand HCPCS code G0505 or pay separately for similar services furnished to patients with other advanced or life threatening illnesses.

Response: We appreciate the comments on other conditions that could benefit from assessment and care planning and will consider these for future rulemaking. We are finalizing the G0505 code to pay separately for the assessment and care plan creation for beneficiaries with cognitive impairment, such as from Alzheimer's disease or dementia, at any stage of impairment.

Comment: Commenters provided many examples of how CMS could develop appropriate quality and outreach measures to ensure appropriate utilization of G0505. Commenters encouraged CMS to closely monitor use of G0505 for a few years following implementation, so as to ascertain whether patient eligibility is an issue in uptake for the code.

Response: We appreciate the information on quality and outreach measures. CMS is engaged in the use of measures to improve quality and access to care. CMS intends to monitor utilization and will consider how conditions of payment align with best practices and quality measures.

Comment: One commenter urged CMS to make the proposed coding and payment changes available to physicians in total cost of care models, such as ACOs and bundled payment programs.

Response: Our proposal relates only to payment for services under the Medicare PFS. We note that the codes and payment amounts that we finalize for services will be available for billing and payment under the PFS for CY 2017. In general, we do not address in this final rule, and instead defer to the policies regarding billing and payment for these services that are applicable within individual Center for Medicare &

Medicaid Innovation models and other programs. However, as our policies regarding payment for new primary care codes are applicable beginning in CY 2017, we note that models may need to update their policies to prevent potential duplication of payment between the PFS and the models. For example, where CCM services have been excluded from separate payment under existing models, newly established care management services (including complex CCM, psychiatric CoCM, and BHI) may likewise be excluded.

Comment: One commenter stated that many small practices do not have the infrastructure to support a multi-disciplinary team of practitioners and urged CMS to allow flexibility for solo and small group practices to share resources. The commenter also suggested that CMS offer a one-time incentive for practices to integrate service elements into workflow.

Response: In general, the coding under the PFS is intended to describe services as they are furnished and are valued using typical resource costs. We appreciate the concern of commenters regarding access, and we are eager to hear from stakeholders regarding concerns related to access for these and other PFS services.

6. Improving Payment Accuracy for Care of People With Disabilities (GDDD1)

We estimate that about 7 percent of all Medicare beneficiaries have a potentially disabling mobility-related diagnosis (the Medicare-only prevalence is 5.5 percent and the prevalence for Medicare-Medicaid dual eligible beneficiaries is 11 percent), using 2010 Medicare (and for dual eligible beneficiaries, Medicaid) claims data.

When a beneficiary with a mobility-related disability goes to a physician or other practitioner's office for an E/M visit, the resources associated with providing the visit can exceed the resources required for the typical E/M visit. An E/M visit for a patient with a mobility-related disability can require more physician and clinical staff time to provide appropriate care because the patient may require skilled assistance throughout the visit to carefully move and adjust his/her body. Furthermore, an E/M visit for a patient with a mobility-related disability commonly requires specialized equipment such as a wheel chair accessible scale, floor and overhead lifts, a movable exam table, padded leg supports, a stretcher and transfer board. The current E/M visit payment rates, based on an assumption of ''typical'' resources involved in furnishing an E/M visit to a ''typical'' patient, do not accurately reflect these additional resources associated with furnishing appropriate care to many beneficiaries with mobility-related disabilities.

When furnishing E/M services to beneficiaries with mobility-related disabilities, practitioners face difficult choices in deciding whether to take the extra time necessary and invest in the required specialized equipment for these visits even though the payment rate for the service does not account for either expense; potentially providing less than optimal care for a beneficiary whose needs exceed the standard appointment block of time in the standard equipped exam room reflected in the current E/M visit payment rate; or declining to accept appointments altogether for beneficiaries who require additional time and specialized equipment.

Each of these scenarios is potentially problematic. The first two scenarios suggest that the quality of care for this beneficiary population might be compromised by assumptions under the PFS regarding relative resource costs in furnishing services to this population. The third scenario reflects an obvious access problem for these beneficiaries. To improve payment accuracy and help ameliorate potential disparity in access and quality for beneficiaries with mobility-related disabilities, we proposed to create a new add-on G-code, effective for CY 2017, to describe the additional services furnished in conjunction with E/M services to beneficiaries with disabilities that impair their mobility:

G0501: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient evaluation and management service visit (Add-on code, list separately in addition to primary procedure).

Effective January 1, 2017, we proposed that this add-on code could be billed with new and established patient office/outpatient E/M codes (CPT codes 99201 through 99205, and 99212 through 99215), as well as transitional care management codes (CPT codes 99495 and 99496), when the additional resources described by the code are medically necessary and used in the provision of care. In addition to seeking comment on this proposal, we are also sought comment on other HCPCS codes that may be appropriate base codes for this proposed add-on code, including those describing preventive visits and services. We reminded potential commenters that the rationale for this proposal is based in large part on the broad use and lack of granularity in coding for E/M services relative to other PFS services in conjunction with the additional resources used.

We received many thoughtful comments on this proposal and thank commenters for their input. Comments received are summarized below.

Comment: Most commenters agreed with the proposed rule's statement of disability disparities and discussed a variety challenges that individuals with disabilities face in accessing the health care system. Several of these commenters cited evidence of existing challenges for individuals with mobility-related disabilities, including a lack of physically accessible equipment within physician offices, barriers to communication, and a lack of existing tools to recognize, track, and consistently meet specialized needs. Commenters applauded CMS for offering a concrete proposal with significant funding to meaningfully address this problem and noted that 26 years after passage of the Americans with Disabilities Act, it is alarming that physical and communication barriers in physicians' and other health care professionals' offices still exist across the country. However, some commenters suggested that the root cause and scope of these issues are not well characterized, and suggested that CMS work with stakeholders to conduct additional studies and gain information as to the underlying reasons for barriers to access to care and lower quality scores on certain measures.

Generally, commenters noted that they appreciate CMS' efforts to address health disparities based on disability, and some then supported this proposal as a first step in providing medically necessary services to patients with disabilities, while others recommended that CMS not finalize the proposal and raised legal, access, and equity concerns.

Response: We agree with commenters that individuals with disabilities face additional barriers to access health care, an issue that contributes to widespread disparities in outcomes. We also agree with commenters that the underlying reasons for these disparities are multifaceted and can include payment challenges, physical accessibility and communication barriers, a lack of awareness among health care providers in assessing and fully addressing the needs and preferences of people with disabilities, and others issues. As a result of all these factors, individuals with disabilities can face challenges in scheduling appointments, and in

finding and maintaining a primary care provider, an essential foundation for accessing the health system.

Although there was near universal agreement among commenters regarding problems in health care disparities and barriers to access among individuals with disabilities, there was disagreement about whether establishing payment for code G0501 as proposed was a good solution to help solve these problems. While we believe that improving the payment accuracy of physicians' services is necessary and appropriate, and can help to address the underlying access issues for individuals with disabilities, we also acknowledge that implementation of new or revised payments can result in unanticipated, and potentially undesirable, consequences. Before implementing payment for code G0501, we plan to further analyze and address the concerns raised by commenters. As such, we are not finalizing payment for code G0501 at this time. We appreciate commenters' insights, and our commitment to promoting better primary care for people with disabilities remains strong. Over the next 6 months we will engage with interested beneficiaries, advocates, and practitioners to continue to explore improvements in payment accuracy for care of people with disabilities. We intend to discuss this issue again in future rulemaking.

While we are not finalizing separate payment for code G0501 for CY 2017, we are including the code in the CY 2017 code set as G0501. The HCPCS code G0501 will not be payable under the Medicare PFS for CY 2017, though practitioners will be able to report the code, should they be inclined to do so.

a. Soliciting Comment on Other Coding Changes To Improve Payment Accuracy for Care of People With Disabilities

When furnishing care to a beneficiary with a mobility-related disability, the current E/M visit payment rates may not fully reflect the associated resource costs that are being incurred by practitioners. We recognize that there are other populations for which payment adjustment may be appropriate. Our proposal regarding beneficiaries with mobility-related disabilities reflected the discrete nature of the additional resource costs for this population, the clear lack of differentiation in resource costs regarding particular kinds of frequently-furnished services, and the broad recognition of access problems. We recognize that some physician practices may frequently furnish services to particular populations for which the relative resource costs are similarly systemically undervalued and we sought comment regarding other circumstances where these dynamics can be discretely observed.

Comment: Multiple commenters suggested additional coding changes to improve payment accuracy for services for people with disabilities. Several commenters requested that CMS broaden the scope of G0501 and the codes with which it may be billed, for example by allowing G0501 to be billed with preventive services, such as the Initial Preventive Physical Examination (IPPE) or ''Welcome to Medicare Visit'', the Annual Wellness Visit, or other preventive services including those that have been assigned a grade of A or B by the United States Preventive Services Task Force. One commenter suggested that CMS also establish payment for a lower-level, lower payment add-on code for use with patients with a mobility-related disability that may not require the use of specialized equipment. Commenters also suggested that CMS establish certain forms of physician payment incentives, which might more effectively address the accessibility needs of individuals with disabilities and ultimately reduce healthcare disparities. Specifically, one commenter suggested CMS incentivize physicians to establish record-keeping to inquire into patients' accessibility and accommodation needs, record the needs of their patients, and take action to meet those needs over time.

Response: We thank commenters for their thoughtful responses. We reiterate our commitment to addressing disparities for individuals with disabilities and advancing health equity, and will continue to explore and revisit potential solutions for overcoming these significant challenges, including the appropriate changes in payment.

7. Regulation Text

Our current regulations in 42 CFR 410.26(b) provide for an exception to assign general supervision to CCM services (and similarly, for the non-face-to-face portion of TCM services), because these are generally non-face-to-face care management/care coordination services that would commonly be provided by clinical staff when the billing practitioner (who is also the supervising practitioner) is not physically present; and the CPT codes are comprised solely (or in significant part) of non-face-to-face services provided by clinical staff. A number of codes that we proposed to establish for separate payment in CY 2017 under our initiative to improve payment accuracy for primary care and care management are similar to CCM services, in that a critical element of the services is non-face-to-face care management/care coordination services provided by clinical staff or other qualified individuals when the billing practitioner may not be physically present. Accordingly, we proposed to amend 42 CFR 410.26(a)(3) and 410.26(b) to better define general supervision and to assign general supervision not only to CCM services and the non-face-to-face portion of TCM services, but also to proposed codes G0502, G0503, G0504, G0507, CPT code 99487, and CPT code 99489. Instead of adding each of these proposed codes assigned general supervision to the regulation text on an individual basis, we proposed to revise our regulation under 42 CFR 410.26(b)(1) to assign general supervision to the non-face-to-face portion of designated care management services, and we would designate the applicable services through notice and comment rulemaking.

We did not receive any public comments on our proposed regulation text. However we received a number of comments regarding a related proposal to require behavioral health care managers to be located on site. Also for psychiatric CoCM services (G0502, G0503 and G0504), we are finalizing a requirement that the behavioral health care manager is available to perform his or her duties face-to-face and non-face-to-face with the beneficiary. We address these issues at length in the BHI section of this final rule (section II.E.3). Since we are assigning general supervision to psychiatric CoCM behavioral health care manager services that may be provided face-to-face with the beneficiary, we are omitting the phrase ''non-face-to-face portion of'' in ''the non-face-to-face portion of designated care management services.'' Accordingly, the final amended regulation text in 42 CFR 410.26(b) assigns general supervision to ''designated care management services'' that we will designate through notice and comment rulemaking. The services that we are newly designating (finalizing) for general supervision in this final rule are G0502, G0503, G0504, G0507, CPT code 99487 and CPT code 99489. We had initially proposed adding a cross-reference to the existing definition of ''general supervision'' in current regulations at § 410.32(b)(3)(i), but to better describe general supervision in the context of these services, we are specifying at § 410.26(a)(3) that general supervision means the service is furnished under the physician's (or other practitioner's)

overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service. At § 410.26(b)(5), we specify that, in general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Designated care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services.

8. CCM Requirements for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).

RHCs and FQHCs have been authorized to bill for CCM services since January 1, 2016, and are paid based on the Medicare PFS national average non-facility payment rate when CPT code 99490 is billed alone or with other payable services on a RHC or FQHC claim. The RHC and FQHC requirements for billing CCM services have generally followed the requirements for practitioners billing under the PFS, with some adaptations based on the RHC and FQHC payment methodologies.

To assure that CCM requirements for RHCs and FQHCs are not more burdensome than those for practitioners billing under the PFS, we proposed revisions for CCM services furnished by RHCs and FQHCs similar to the revisions proposed under the section above entitled, ''Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) Services'' for RHCs and FQHCs. Specifically, we proposed to:

- Require that CCM be initiated during an AWV, IPPE, or comprehensive E/M visit only for new patients or patients not seen within one year. This would replace the requirement that CCM could only be initiated during an AWV, IPPE, or comprehensive E/M visit where CCM services were discussed.
- Require 24/7 access to a RHC or FQHC practitioner or auxiliary personnel with a means to make contact with a RHC or FQHC practitioner to address urgent health care needs regardless of the time of day or day of week. This would replace the requirement that CCM services be available 24/7 with health care practitioners in the RHC or FQHC who have access to the patient's electronic care plan to address his or her urgent chronic care needs, regardless of the time of day or day of the week.
- Require timely electronic sharing of care plan information within and outside the RHC or FQHC, but not necessarily on a 24/7 basis, and expands the circumstances under which transmission of the care plan by fax is allowed. This would replace the requirement that the electronic care plan be available on a 24/7 basis to all practitioners within the RHC or FQHC whose time counts towards the time requirement for the practice to bill the CCM code, and removes the restriction on allowing the care plan to be faxed only when the receiving practitioner or provider can only receive clinical summaries by fax.
- Require that in managing care transitions, the RHC or FQHC creates, exchanges, and transmits continuity of care document(s) in a timely manner with other practitioners and providers. This would replace the requirements that clinical summaries must be created and formatted according to certified EHR technology, and the requirement for electronic exchange of clinical summaries by a means other than fax.
- Require that a copy of the care plan be given to the patient or caregiver. This would remove the description of the format (written or electronic) and allows the care plan to be provided to the caregiver when appropriate (and in a manner consistent with applicable privacy and security rules and regulations).
- Require that the RHC or FQHC practitioner documents in the beneficiary's medical record that all the elements of beneficiary consent (for example, that the beneficiary was informed of the availability of CCM services; only one practitioner can furnish and be paid for these services during a calendar month; the beneficiary may stop the CCM services at any time, effective at the end of the calendar month, etc.) were provided, and whether the beneficiary accepted or declined CCM services. This would replace the requirement that RHCs and FQHCs obtain a written agreement that these elements were discussed, and removes the requirement that the beneficiary provide authorization for the electronic communication of his or her medical information with other treating providers as a condition of payment for CCM services.
- Require that communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits be documented in the patient's medical record. This would replace the requirement to document this patient health information in a certified EHR format.

We noted that we did not propose an additional payment adjustment for patients who require extensive assessment and care planning as part of the initiating visit, as payments for RHC and FQHC services are not adjusted for length or complexity of the visit.

We stated that we believe these proposed changes would keep the CCM requirements for RHCs and FQHCs consistent with the CCM requirements for practitioners billing under the PFS, simplify the provision of CCM services by RHCs and FQHCs, and improve access to these services without compromising quality of care, beneficiary privacy, or advance notice and consent.

We received 31 comments on the proposed revisions to the CCM requirements for RHCs and FQHCs. The following is a summary of the comments we received:

Comment: Commenters stated that they support CMS's efforts to ensure that CCM requirements for RHCs and FQHCs are not more burdensome than those for practitioners billing under the Medicare PFS.

Response: We appreciate the support of the commenters.

Comment: One commenter sought clarification on the requirements for initiating CCM with patients that have been seen in the RHC within the past year. The commenter asked if CCM could be initiated if the patient had any type of visit within the past year, or if the visit within the past year had to be an AWV, IPPE, or comprehensive E/M visit.

Response: To initiate CCM with a patient that has been seen in the RHC or FQHC within the past year, an AWV, IPPE, or comprehensive E/M visit must have taken place within the past year in the RHC or FQHC that is billing for the CCM service. No other type of visit would meet the requirement for initiating CCM services.

Comment: A few commenters were concerned that RHCs and FQHCs were charging beneficiaries for coinsurance for non-face-to-face services, and recommended that the copayment be waived or that CMS pursue waivers of cost-sharing for care coordination codes. One of these commenters stated that patients are often unwilling to pay the patient share of the CCM services since rural providers often have already been

providing similar services without additional cost to the patients.

Response: As previously stated, we do not have the authority to waive the copayment requirements for CCM services. While many practitioners, including those in rural areas, have always provided some care management services, we believe that payment for CCM services will enable many RHCs and FQHCs to furnish comprehensive and systematic care coordination services that were previously unavailable or only sporadically offered.

Comment: A commenter asked for clarification on how claims for patients in RHCs and FQHCs with pre-existing care management plans should be handled, and suggested that CMS permit claims for services for these patients.

Response: We are not entirely clear what this commenter is suggesting. RHCs and FQHCs that bill for CCM services must develop a comprehensive care plan that includes all the elements previously described and also listed in Table 11. When all the requirements for furnishing CCM services are met, including the development of the comprehensive care plan, the RHC or FQHC would submit a claim for CCM payment using CPT code 99490. Only the time spent furnishing CCM services after CCM is initiated with the patient is counted toward the minimum 20 minutes required for CCM billing. There is no additional payment for a pre-existing care plan, and if a comprehensive care plan that meets the CCM requirements was developed before the initiation of CCM services, the time spent developing the plan would not be counted toward the 20 minute minimum requirement.

Comment: A few commenters requested clarification on whether RHCs and FQHCs could bill the new CCM codes for either complex CCM services (CPT 99487 and 99489) or the separately billable comprehensive CCM assessment and care planning (G0506).

Response: As we noted in the proposed rule, we did not propose to adopt codes to provide for an additional payment for patients who require extensive assessment or care planning because payments for RHC and FQHC services are not adjusted for the length or complexity of the visit. Therefore, the codes identified by the commenters are not separately billable by an RHC or FQHC.

Comment: A few commenters recommended that CMS allow RHCs and FQHCs to bill for the new CCM codes, and to allow safety net providers to bill for preventive services in addition to the all-inclusive rate for RHCs and the PPS rate for FQHCs. The commenters stated that the payment structure for RHCs and FQHCs are a disincentive to provide preventative services in addition to E/M services at the same visit.

Response: RHCs and FQHCs are paid for CCM services when CPT code 99490 is billed either alone or with other payable services on a RHC or FQHC claim. The RHC and FQHC payment structures and payment for preventive services is outside the scope of this final rule.

Comment: Several commenters recommended that CMS provide separate payment for psychiatric collaborative care management services furnished in RHCs and FQHCs, including CPT codes G0502, G0503, G0504 and G0507. The commenters stated that allowing RHCs and FQHCs to bill for these services will ensure that their patients who have been diagnosed with a mental health or substance use disorder have access to high-quality care tailored to their individual condition and circumstances.

Response: To be eligible for CCM services, a Medicare beneficiary must have two or more chronic conditions that are 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. While 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 invite 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.

After considering the comments, we are finalizing as proposed the revisions to the requirements for CCM services furnished by RHCs and FQHCs.

F. Improving Payment Accuracy for Services: Diabetes Self-Management Training (DSMT)

Section 1861(s)(2)(S) of the Act specifies that medical and other health services include DSMT services as defined in section 1861(qq) of the Act. DSMT services are intended to educate beneficiaries in the successful self-management of diabetes. DSMT includes, as applicable, instructions in self-monitoring of blood glucose; education about diet and exercise; an insulin treatment plan developed specifically for the patient who is insulin-dependent; and motivation for patients to use the new skills for self-management (see 42 CFR 410.144(a)(5)). DSMT services are reported under HCPCS codes G0108 (Diabetes outpatient self-management training services, individual, per 30 minutes) and G0109 (Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes). The benefit, as specified at 42 CFR 410.141, consists of 1 hour of individual and 9 hours of group training unless special circumstances warrant more individual training or no group session is available within 2 months of the date the training is ordered.

Section 1861(qq) of the Act specifies that DMST services are furnished by a certified provider, defined as a physician or other individual or entity that also provides, in addition to DSMT, other items or services for which payment may be made under Medicare. The physician, individual or entity that furnishes the training also must meet certain quality standards. The physician, individual or entity can meet standards established by us or standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in their establishment, or can be recognized by an organization that represents individuals with diabetes as meeting standards for furnishing the services.

We require that all those who furnish DSMT services be accredited as meeting quality standards by a CMS-approved national accreditation organization (NAO). In accordance with § 410.144, a CMS-approved NAO may accredit an individual, physician or entity to meet one of three sets of DSMT quality standards: CMS quality standards; the National Standards for Diabetes Self-Management Education Programs (National Standards); or the standards of an NAO that represents individuals with diabetes that meet or exceed our quality standards. Currently, we recognize the American Diabetes Association and the American Association of Diabetes Educators as approved NAOs, both of whom follow National Standards. Medicare payment for outpatient DSMT services is made in accordance with 42 CFR 414.63.

An article titled ''Use of Medicare's Diabetes Self-Management Training Benefit'' was published in *Health Education Behavior* on January 23, 2015. The article noted that only 5 percent of Medicare beneficiaries with newly diagnosed diabetes used DSMT services. The article recommended that future research identify barriers to DSMT access.

In the CY 2017 PFS proposed rule (81 FR 45215), we identified issues that the

DSMT community had brought to our attention which may contribute to the low utilization of these services, and indicated that we plan to address and clarify those issues through Medicare program instructions as appropriate. We also solicited public comment as to other access barriers—including whether Medicare payment for these services is accurate—to help us identify and address them. We appreciate the many comments regarding many issues in response to our solicitation.

Comment: Many commenters stated that the payment rates were too low but did not suggest specific changes in the inputs used to develop payment rates under the PFS for particular services (specifically, work RVUs and direct PE inputs). We also received additional comments identifying multiple other possible barriers to access. These commenters' recommendations primarily addressed issues related to regulatory and statutory DSMT requirements, such as: (a) Expanding of the definition of diabetes to include hemoglobin A1C as one of the criteria for diagnosing diabetes; (b) modifying the definition of certified provider to include the certified diabetes educator (CDE) to permit them to bill for DSMT; (c) allowing physicians and NPPs, other than the one treating the beneficiary's diabetes, as required by regulation, to order DSMT services; and, (d) eliminating the copays and deductible for DSMT services.

Response: We appreciate the comments received and will consider changes in valuation of these services and other regulatory issues raised by commenters for future rulemaking. We also appreciate commenters' feedback on several subregulatory guidelines and other operational issues that we will consider addressing outside of rulemaking.

G. Target for Relative Value Adjustments for Misvalued Services

Section 1848(c)(2)(O) of the Act establishes an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. Under section 1848(c)(2)(O)(ii) of the Act, if the estimated net reduction in expenditures for a year as a result of adjustments to the relative values for misvalued codes is equal to or greater than the target for that year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS in accordance with the existing budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. The provision also specifies that the amount by which such reduced expenditures exceeds the target for a given year shall be treated as a net reduction in expenditures for the succeeding year, for purposes of determining whether the target has been met for that subsequent year. Section 1848(c)(2)(O)(iv) of the Act defines a target recapture amount as the difference between the target for the year and the estimated net reduction in expenditures under the PFS resulting from adjustments to RVUs for misvalued codes. Section 1848(c)(2)(O)(iii) of the Act specifies that, if the estimated net reduction in PFS expenditures for the year is less than the target for the year, an amount equal to the target recapture amount shall not be taken into account when applying the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. Under section 1848(c)(2)(O)(v) of the Act, the target that applies to calendar years (CYs) 2017 and 2018 is calculated as 0.5 percent of the estimated amount of expenditures under the PFS for the year.

In CY 2016 PFS rulemaking, we proposed and finalized a methodology to implement this statutory provision.

Because the annual target is calculated by measuring changes from one year to the next, for CY 2016, we considered how to account for changes in values that are best measured over 3 years, instead of 2 years. As we described in the CY 2016 final rule with comment period (80 FR 70932), our general valuation process for potentially misvalued, new, and revised codes was to establish values on an interim final basis for a year in the PFS final rule with comment period. Then, during the 60-day period following the publication of the final rule with comment period, we would accept public comment about those valuations. In the final rule with comment period for the subsequent year, we would consider and respond to public comments received on the interim final values, and make any appropriate adjustments to values based on those comments. Under that process for revaluing new, revised, and misvalued codes, we believe the overall change in valuation for many codes would best be measured across values for 3 years: between the original value in the first year; the interim final value in the second year; and the finalized value in the third year. However, the target calculation for a year would only be comparing changes in RVUs between 2 years and not among 3 years, so the contribution of a particular change towards the target for any single year would be measured against only the preceding year without regard to the overall change that takes place over 3 years.

For recent years, interim final values for misvalued codes (year 2) have generally reflected reductions relative to original values (year 1), and for most codes, the interim final values (year 2) are maintained and finalized (year 3). However, when values for particular codes have changed between the interim final (year 2) and final values (year 3) based on public comment, the general tendency has been that codes increase in the final value (year 3) relative to the interim final value (year 2), even in cases where the final value (year 3) represents a decrease from the original value (year 1). Therefore, for these codes, the year 2 changes compared to year 1 would risk over-representing the overall reduction, while the year 3 to year 2 changes would represent an increase in value. We noted that if there were similar targets in every PFS year, and a similar number of misvalued code changes made on an interim final basis, the incongruence in measuring what is really a 3-year change in 2-year increments might not be particularly problematic since each year's calculation would presumably include a similar number of codes measured between years 1 and 2 and years 2 and 3.

However, including changes that take place over 3 years generated challenges in calculating the target for CY 2016. Because there was no target for CY 2015, any reductions that occurred on an interim final basis for CY 2015 were not counted toward achievement of a target. If we had then included any upward adjustments made to these codes based on public comment as ''misvalued code'' changes for CY 2016, we would effectively be counting the service-level increases for 2016 (year 3) relative to 2015 (year 2) against achievement of the target without any consideration to the service-level changes relative to 2014 (year 1), even in cases where the overall change in valuation was negative.

Therefore, we proposed and finalized the decision to exclude code-level input changes for CY 2015 interim final values from the calculation of the CY 2016 misvalued code target since the misvalued change occurred over multiple years, including years not applicable to the misvalued code target provision.

For the CY 2017 final rule, we will be finalizing values (year 3) for codes that were interim final in CY 2016 (year 2). Unlike codes that were interim final for CY 2015, the codes that are interim final for CY 2016 were included as misvalued codes and will fall within the range of years for which the misvalued code target provision applies. Thus, overall changes in values for these codes would

be measured in the target across 3 full years: The original value in the first year (CY 2015); the interim final value in the second year (CY 2016); and the finalized value in the third year (CY 2017). The changes in valuation for these CY 2016 interim final codes were previously measured and counted towards the target during their initial change in valuation between years 1 and 2.

As such, we proposed to include changes in values of the CY 2016 interim final codes toward the CY 2017 misvalued code target. We believe that this is consistent with the approach that we finalized in the CY 2016 PFS final rule with comment period. The changes in values of CY 2015 interim final codes were not counted towards the misvalued code target in CY 2016 since the valuation change occurred over multiple years, including years not applicable to the misvalued code target provision. However, both of the changes in valuation for the CY 2016 interim final codes, from year 1 to year 2 (CY 2015 to CY 2016) and from year 2 to year 3 (CY 2016 to CY 2017), have taken place during years that occur within the misvalued code target provision. We therefore believe that any adjustments made to these codes based on public comment should be considered towards the achievement of the target for CY 2017, just as any changes in valuation for these same CY 2016 interim final codes previously counted towards the achievement of the target for CY 2016.

We solicited comments regarding this proposal. We also reminded commenters that we revised our process for revaluing new, revised and misvalued codes so that we will be proposing and finalizing values for most of the misvalued codes during a single calendar year. After this year, there will be far fewer instances of interim final codes and changes that are best measured over 3 years.

We refer readers to the regulatory impact analysis section of this final rule for the net reduction in expenditures relative to the 0.5 percent target for CY 2017, and the resulting adjustment required to be made to the conversion factor. Additionally, we refer readers to the public use file that provides a comprehensive description of how the target is calculated, as well as the estimated impact by code family on the CMS Web site under the supporting data files for the CY 2017 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

The following is summary of the comments we received regarding the target for relative value adjustments for misvalued services.

Comment: Several commenters expressed support for the CMS estimate that there would be no target recapture amount by which to reduce payments made under the PFS in CY 2017.

Response: We appreciate the comments. We remind stakeholders that the final determination of the target recapture amount is based on finalized RVUs for the relevant codes. We refer readers to the regulatory impact analysis section of this final rule for the net reduction in expenditures relative to the 0.5 percent target for CY 2017, and the resulting adjustment that is required to be made to the conversion factor.

Comment: One commenter urged CMS to broaden its approach to counting misvalued code payment adjustments in the final rule. The commenter stated that CMS was taking a narrow approach to the misvalued code target.

Response: We finalized our methodology for calculating the estimated net reduction relative to the misvalued code target in the CY 2016 final rule with comment period (80 FR 70921–70927). For CY 2017, we proposed a modification to that methodology that only addressed how changes to interim final codes would be addressed when both first and second year changes could be counted towards a misvalued code target since CY 2017 is the first year for that circumstance. We did not make a proposal on the more general issue of the methodology used to calculate the net reductions for the misvalued code target, which, as noted above, was finalized in the CY 2016 PFS final rule with comment period.

We did not receive any public comments on our proposal to include changes in values of the CY 2016 interim final codes toward the CY 2017 misvalued code target.

After consideration of comments received, we are finalizing our proposal to count any adjustments to interim final codes towards the misvalued code target when both first and second year changes can be counted towards a misvalued codes target.

H. Phase-In of Significant RVU Reductions

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 the CY 2016 PFS rulemaking, we proposed and finalized a methodology to implement this statutory provision. To determine which services are described by new or revised codes for purposes of the phase-in provision, we apply the phase-in to all services that are described by the same, unrevised code in both the current and update year, and exclude codes that describe different services in the current and update year.

Because the phase-in of significant reductions in RVUs falls within the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act, we estimate the total RVUs for a service prior to the budget-neutrality redistributions that result from implementing phase-in values. 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.

The statute provides that the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period when the RVU reduction for a code for a year is estimated to be equal to or greater than 20 percent. Since CY 2016 was the first year in which we applied the phase-in transition, CY 2017 will be the first year in which a single code could be subject to RVU reductions greater than 20 percent for 2 consecutive years.

Under our finalized policy, the only codes that are not subject to the phase-in are those that are new or revised, which we defined as those services that are not described by the same, unrevised code in both the current and update year, or by the same codes that describe different services in the current and update year. Since CY 2016 was the first year for which the phase-in provision applied, we did not address how we would handle codes with values that had been partially phased in during the first year, but that have a remaining phase-in reduction of 20 percent or greater.

The significant majority of codes with reductions in RVUs that are greater than 20 percent in year one would not be likely to meet the 20 percent threshold in a consecutive year. However, in a few cases, significant changes (for example, in the input costs included in the valuation of a service) could produce reductions of 20 percent or greater in consecutive years.

As stated in the CY 2017 PFS proposed rule, we believed that a consistent methodology regarding the phase-in transition should be applied to these cases. We proposed to reconsider

in each year, for all codes that are not new or revised codes and including codes that were assigned a phase-in value in the previous year, whether the total RVUs for the service would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year. Under this proposed policy, the 19 percent reduction in total RVUs would continue to be the maximum one-year reduction for all codes (except those considered new and revised), including those codes with phase-in values in the previous year. In other words, for purposes of the 20 percent threshold, every service is evaluated anew each year, and any applicable phase-in is limited to a decrease of 19 percent. For example, if we were to adopt a 50 percent reduction in total RVUs for an individual service, the reduction in any particular year would be limited to a decrease of 19 percent in total RVUs. Because we do not set rates 2 years in advance, the phase-in transition would continue to apply until the year-to-year reduction for a given code does not meet the 20 percent threshold. We solicited comments regarding this proposal.

The list of codes subject to the phase-in and the associated proposed RVUs that result from this methodology is available on the CMS Web site under downloads for the CY 2017 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

The following is summary of the comments we received regarding the phase-in of significant RVU reductions.

Comment: Many commenters supported the proposal that a 19 percent reduction in total RVUs would continue to be the maximum one-year reduction for all codes that are not new or revised. These commenters urged CMS to finalize the proposal.

Response: We appreciate the support from the commenters.

Comment: Several commenters suggested that CMS should extend the threshold for triggering the phase-in provision, by using a lower single-year maximum reduction (such as 10 percent), at a rate different than what the statute stipulates. The commenters stated that a lower threshold would provide a greater safeguard against payment cuts and disruption of services.

Response: Section 1848(c)(7) of the Act requires the phase-in if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or larger. We do not believe that we have the statutory authority to establish a different threshold value for when the phase-in applies.

Comment: One commenter objected to CMS' decision to exclude from the phase-in codes with a reduction of 20 percent or more that fall within a family with significant coding revisions. The commenter requested that CMS reconsider this policy.

Response: We understand the commenters' concerns. In the CY 2016 final rule with comment period (80 FR 70927–70931), we finalized a policy to identify services that are not subject to the phase-in because they are new or revised codes. As we wrote at the time, 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. We continue to believe that this is the most accurate methodology to use in identifying new and revised codes for the purposes of the phase-in transition. We also note that we did not make a proposal to change how we identify services to which the phase-in does not apply.

Comment: A commenter requested that CMS apply the phase-in policy to services in the PFS with year-to-year reductions of 20 percent or more in payment amount due to the statutory cap that requires payment for the technical component (TC) of certain imaging services furnished in the office setting to be made the lesser of the PFS or OPPS rates. The commenter stated that this application would capture the spirit of the phase-in legislation in dampening the impact of significant payment reductions on a year to year basis.

Response: Section 1848(c)(7) of the Act requires the phase-in of reductions of 20 percent or more in the total RVUs for individual services. The OPPS cap, required under section 1848(b)(4)(A) of the Act, specifies that if the PFS payment rate for the TC of certain imaging services exceeds the OPPS payment amount for the services, the OPPS payment amount must be substituted for the PFS TC payment amount. The OPPS cap refers to, and requires substitution of, payment rates for individual imaging services, and not a reduction in the total RVUs for those services. As such, services that are subject to the OPPS cap are not subject to the phase-in on that basis.

Comment: One commenter opposed the phase-in proposal. The commenter stated that the proposal twisted a plain reading of the law to effectively extend the phase-in period well beyond the 2 years prescribed by the statute. The commenter questioned why Medicare beneficiaries should have to pay a higher fee for overvalued services when identified as such, and pointed out that in the budget-neutral environment of the fee schedule, the proposal would delay the benefit of these RVU reductions to the rest of the services listed in the PFS.

Response: We appreciate the concerns raised by the commenter. As we have addressed over several rulemaking cycles, we are concerned about the impact of misvalued services in creating distortions in relativity across the fee schedule. However, we have already finalized through notice and comment rulemaking and continue to believe that limiting reductions to 19 percent as the maximum 1-year decrease for all codes (except those considered new and revised) is the best and most fair way to apply the phase-in. Additionally, because we do not set rates 2 years in advance, we believe there are significant obstacles to implementing an alternative methodology. For example, codes may be reviewed multiple times in a short period of time, and may have further decreases in total RVUs for a subsequent year due to a variety of reasons in addition to any change inputs from the initial year phase-in. These might include supply and equipment price updates in non-reviewed years, significant changes in specialty mix of practitioners reporting the service, or changes in other PFS ratesetting policies which could lead to several consecutive years of RVU reductions. In any such cases, it would be impractical to identify with certainty what portion of reductions in code values are due to input changes established in a prior year versus input or policy changes from the current year. We also note that all of these circumstances are relatively rare since it is unusual for changes in code inputs to result in reductions of greater than 40 percent. Therefore, while we appreciate the importance of improving payment accuracy as soon as can be practicable for the reasons stated by the commenter, we also believe that, on balance, the best and most fair approach to implementing the required phase-in of RVU reductions over multiple years is to re-examine eligible codes for the phase-in on an annual basis, in conjunction with our annual ratesetting.

After consideration of comments received, we are finalizing the policy as proposed.

I. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, PE, and malpractice (MP)). The PFS localities are discussed in section II.E.3. of this final rule. Although the statute requires that the PE and MP GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier states (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provided for a 1.0 floor for the work GPCIs, which was set to expire on March 31, 2015. Section 201 of the MACRA amended the statute to extend the 1.0 floor for the work GPCIs through CY 2017 (that is, for services furnished no later than December 31, 2017).

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be half of the adjustment that otherwise would be made. Therefore, since the previous GPCI update was implemented in CY 2014 and CY 2015, we proposed to phase in 1/2 of the latest GPCI adjustment in CY 2017.

We have completed a review of the GPCIs and proposed new GPCIs in this final rule. We also calculate a geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each area's work, PE and malpractice expense GPCIs using the national GPCI cost share weights. While we do not actually use GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service would deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those of the GAF.

As noted above, section 201 of the MACRA extended the 1.0 work GPCI floor for services furnished through December 31, 2017. Therefore, the proposed CY 2017 work GPCIs and summarized GAFs reflect the 1.0 work floor. Additionally, as required by sections 1848(e)(1)(G) and 1848(e)(1)(I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier states are permanent, and therefore, applicable in CY 2017. See Addenda D and E to this final rule for the CY 2017 GPCIs and summarized GAFs available on the CMS Web site under the supporting documents section of the CY 2017 PFS final rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

2. GPCI Update

The proposed updated GPCI values were calculated by a contractor. There are three GPCIs (work, PE, and MP), and all GPCIs are calculated relative to the national average for each measure. Additionally, each of the three GPCIs relies on its own data source(s) and methodology for calculating its value as described below. Additional information on the CY 2017 GPCI update may be found in our contractor's draft report, ''Draft Report on the CY 2017 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule,'' which is available on our Web site. It is located under the supporting documents section for the CY 2017 PFS final rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

a. Work GPCIs

The work GPCIs are designed to reflect the relative costs of physician labor by Medicare PFS locality. As required by statute, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average.

To calculate the work GPCIs, we use wage data for seven professional specialty occupation categories, adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. That is, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments.

The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. However, for the CY 2011 GPCI update (75 FR 73252), the 2000 data were outdated and wage and earnings data were not available from the more recent Census because the ''long form'' was discontinued. Therefore, we used the median hourly earnings from the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) wage data as a replacement for the 2000 Census data. The BLS OES data meet several criteria that we consider to be important for selecting a data source for purposes of calculating the GPCIs. For example, the BLS OES wage and employment data are derived from a large sample size of approximately 200,000 establishments of varying sizes nationwide from every metropolitan area and can be easily accessible to the public at no cost. Additionally, the BLS OES is updated regularly, and includes a comprehensive set of occupations and industries (for example, 800 occupations in 450 industries). For the CY 2014 GPCI update, we used updated BLS OES data (2009 through 2011) as a replacement for the 2006 through 2008 data to compute the work GPCIs.

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OES data continue to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed in section II.E.2.b the employee wage component and purchased services component of the PE GPCI). Therefore, for the proposed CY 2017 GPCI update, we used updated BLS OES data (2011 through 2014) as a replacement for the 2009 through 2011 data to compute the work GPCIs.

b. Practice Expense GPCIs

The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising practice expenses (not including malpractice expenses) among the PFS localities as compared to the national average of these costs. Whereas the physician work GPCIs (and as discussed later in this section, the MP GPCIs) are comprised of a single index, the PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and

other miscellaneous expenses). The employee wage index component measures geographic variation in the cost of the kinds of skilled and unskilled labor that would be directly employed by a physician practice. Although the employee wage index adjusts for geographic variation in the cost of labor employed directly by physician practices, it does not account for geographic variation in the cost of services that typically would be purchased from other entities, such as law firms, accounting firms, information technology consultants, building service managers, or any other third-party vendor. The purchased services index component of the PE GPCI (which is a separate index from employee wages) measures geographic variation in the cost of contracted services that physician practices would typically buy. (For more information on the development of the purchased service index, we refer readers to the CY 2012 PFS final rule with comment period (76 FR 73084 through 73085)). The office rent index component of the PE GPCI measures relative geographic variation in the cost of typical physician office rents. For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the equipment, supplies and other miscellaneous expense cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

For the previous update to the GPCIs (implemented in CY 2014) we used 2009 through 2011 BLS OES data to calculate the employee wage and purchased services indices for the PE GPCI. As discussed in section II.E.2.a., because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS OES is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the proposed CY 2017 GPCI update, we used updated BLS OES data (2011 through 2014) as a replacement for the 2009 through 2011 data for purposes of calculating the employee wage component and purchased service index component of the PE GPCI.

c. Malpractice Expense (MP) GPCIs

The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million to $3 million mature claims-made policies (policies for claims made rather than services furnished during the policy term). For the CY 2014 GPCI update (seventh update) we used 2011 and 2012 malpractice premium data (78 FR 74382). The proposed CY 2017 MP GPCI update reflects 2014 and 2015 premium data. Additionally, the proposed CY 2017 MP GPCI update reflects several proposed technical refinements to the MP GPCI methodology as discussed later in section 5.

d. GPCI Cost Share Weights

For CY 2017 GPCIs, we proposed to continue to use the current cost share weights for determining the PE GPCI values and locality GAFs. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74382 through 74383), for further discussion regarding the 2006-based MEI cost share weights revised in CY 2014 that were also finalized for use in the CY 2014 (seventh) GPCI update.

The GPCI cost share weights for CY 2017 are displayed in Table 12.

TABLE 12—COST SHARE WEIGHTS FOR CY 2017 GPCI UPDATE

Expense category	Current cost share weight (%)	Proposed CY 2017 cost share weight (%)
Work	50.866	50.866
Practice Expense	44.839	44.839
—Employee Compensation	16.553	16.553
—Office Rent	10.223	10.223
—Purchased Services	8.095	8.095
—Equipment, Supplies, Other	9.968	9.968
Malpractice Insurance	4.295	4.295
Total	100.000	100.000

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in frontier states effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in states determined to be frontier states. In general, a frontier state is one in which at least 50 percent of the counties are ''frontier counties,'' which are those that have a population per square mile of less than 6. For more information on the criteria used to define a frontier state, we refer readers to the FY 2011 Inpatient Prospective Payment System (IPPS) final rule (75 FR 50160 through 50161). There are no changes in the states identified as Frontier States for the CY 2017 final rule. The qualifying states are: Montana, Wyoming, North Dakota, South Dakota, and Nevada. In accordance with statute, we would apply a 1.0 PE GPCI floor for these states in CY 2017.

f. Proposed GPCI Update

As explained above in the background section, the periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the proposed GPCIs are published in the PFS proposed rule to provide an opportunity for public comment and further revisions in response to comments prior to implementation. As discussed later in this section, we are finalizing the GPCIs as proposed (except where we correct technical errors). The final CY 2017 updated GPCIs for the first and second year of the 2-year transition, along with the GAFs, are displayed in Addenda D and E to this final rule available on our Web site under the supporting documents section of the CY 2017 PFS final rule Web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

3. Payment Locality Discussion

a. Background

The current PFS locality structure was developed and implemented in 1997. There are currently 89 total PFS localities; 34 localities are statewide areas (that is, only one locality for the entire state). There are 52 localities in the other 16 states, with 10 states having 2 localities, 2 states having 3 localities, 1 state having 4 localities, and 3 states having 5 or more localities. The combined District of Columbia, Maryland, and Virginia suburbs; Puerto Rico; and the Virgin Islands are the remaining three localities of the total of 89 localities. The development of the current locality structure is described in detail in the CY 1997 PFS final rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494). We note that the localities generally represent a grouping of one or more constituent counties.

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments were based on the charging patterns of physicians. This resulted in large differences in payment for physicians' services among types of services, geographic payment areas, and physician specialties. Recognizing this, the Congress replaced the reasonable

charge system with the Medicare PFS in the Omnibus Budget Reconciliation Act (OBRA) of 1989, and the PFS went into effect January 1, 1992. Payments under the PFS are based on the relative resources involved with furnishing services, and are adjusted to account for geographic variations in resource costs as measured by the GPCIs.

Payment localities originally were established under the reasonable charge system by local Medicare carriers based on their knowledge of local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. Shortly after the PFS took effect, we undertook a study in 1994 that culminated in a comprehensive locality revision that was implemented in 1997 (61 FR 59494).

The revised locality structure reduced the number of localities from 210 to the current 89, and the number of statewide localities increased from 22 to 34. The revised localities were based on locality resource cost differences as reflected by the GPCIs. For a full discussion of the methodology, see the CY 1997 PFS final rule with comment period (61 FR 59494). The current 89 fee schedule areas are defined alternatively by state boundaries (for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), changes to the PFS locality structure would generally result in changes that are budget neutral within a state. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. In recent years, we have also considered more comprehensive changes to locality configuration. In 2008, we issued a draft comprehensive report detailing four different locality configuration options (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/downloads/ReviewOfAltGPCIs.pdf*). We refer readers to the CY 2014 PFS final rule with comment period for further discussion regarding that report, as well as a discussion about the Institute of Medicine's empirical study of the Medicare GAFs established under sections 1848(e) (PFS GPCI) and 1886(d)(3)(E) (IPPS wage index) of the Act.

The following is a summary of the comments we received regarding the proposed CY 2017 GPCI update.

Comment: A few commenters including a major specialty society expressed support for using more current data in calculating all three GPCIs.

Response: We thank the commenters for their support.

Comment: One commenter expressed support for the elimination of all geographic adjustment factors under the PFS, except those designed to achieve a specific public policy goal, such as to encourage physicians to practice in underserved areas. Another commenter opposed any decrease in the GPCI.

Response: As previously discussed, section 1848(e)(1)(A) of the Act requires us to develop separate GPCIs to measure resource cost differences among localities compared to the national average for each of the three GPCI components, and section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years; and based on new data, GPCI values may increase or decrease.

Comment: A few commenters expressed concern regarding payment for rural localities and recommended that CMS monitor how the GPCI calculation changes affect the sustainability of health services in rural communities. One commenter requested that CMS consider the ongoing data issues regarding the GPCIs raised by stakeholders in the Midwest, and establish 1.0 work and PE GPCI values for Wisconsin and Iowa.

Response: As discussed previously in this section, we are required to update the GPCIs at least every 3 years to reflect the relative cost differences of operating a medical practice in each locality compared to the national average costs. Additionally, as previously discussed in this section, sections 1848(e)(1)(G) and 1848(e)(1)(I) of the Act established the permanent 1.5 work GPCI floor for Alaska and the permanent 1.0 PE GPCI floor for frontier States. We do not otherwise have the authority to establish similar GPCI floors or other policies that do not take into consideration the differences in physicians' resource costs among localities.

Comment: One commenter supported the continuation of the 1.0 PE GPCI floor for frontier states.

Response: As previously discussed, beginning January 1, 2011 section 1848(e)(1)(I) of the Act set a permanent 1.0 PE GPCI floor for services furnished in frontier states (as defined in section 1848(e)(1)(I) of the Act).

Comment: Several commenters stated their objection to the use of residential rents as a proxy for physician office space costs, and stated that CMS should collect commercial rent data and use it either as the basis for measuring geographic differences in physician office rents or, if this is not feasible, use it to validate the residential rents as a proxy. A few commenters requested that CMS provide a specific explanation on the barriers to gaining better commercial rent data.

Response: Because Medicare is a national program, and section 1848(e)(1)(A) of the Act requires us to establish GPCIs to measure relative cost differences among localities compared to the national average, we believe it is important to use the best data that is available on a nationwide basis, that is regularly updated, and retains consistency area-to-area, year-to-year. Since there is currently no national data source available for physician office or other comparable commercial rents, we continue to use county-level residential rent data from the American Community Survey (ACS) as a proxy for the relative cost differences in commercial office rents. The ACS is administered by the United States Census Bureau, which is a leading source of national, robust, quality, publicly available data. We agree that a commercial data source for office rent that provided for adequate representation of urban and rural areas nationally would be preferable to a residential rent proxy. We have previously discussed in the CY 2005, CY 2008, and CY 2011 (69 FR 66262, 72 FR 66376, and 75 FR 73257, respectively) final rules that we recognize that apartment rents may not be a perfect proxy for physician office rent. We have also conducted exhaustive searches for reliable commercial rent data sources that are publicly available in the past and have not found any reliable data that meets our accuracy needs, and we continue to conduct such searches. With regards to suggestion that CMS should collect commercial rent data, we note that we discussed this issue in the CY 2012 PFS final rule with comment period (76 FR 73088) and stated with reference to surveying physicians directly to gather data to compute office rent, we note that the development and implementation of a survey could take several years. Additionally, we have historically not sought direct survey data from physicians related to the GPCI to avoid issues of circularity and self-reporting bias. In the CY 2011 PFS final rule with comment period (75 FR 73259), we

solicited public comments regarding the benefits of utilizing physician cost reports to potentially achieve greater precision in measuring the relative cost difference among Medicare localities. We also asked for comments regarding the administrative burden of requiring physicians to routinely complete these cost reports and whether this should be mandatory for physicians' practices. We did not receive any feedback related to that comment solicitation during the open public comment period for the CY 2011 final rule with comment period. We continue to have concerns that physician cost reports could be prohibitively expensive, and as well about the administrative burden this approach would place on physician's office staff. We reiterate that the GPCIs are not an absolute measure of practice costs, rather they are a measure of the relative cost differences for each of the three GPCI components. The U.S. Census Bureau is a federal agency that specializes in data collection, accuracy, and reliability, and we continue to believe that where such a publicly available resource exists that can provide useful data to assess geographic cost differences in office rent, even though it is a proxy for the exact data we seek, that we should utilize that available resource. Therefore, given its national representation, reliability, high response rate and frequent updates, we continue to believe the ACS residential rent data is the most appropriate data source available at this time for the purposes of calculating the rent index of the PE GPCI.

Comment: One commenter stated that it objects to the 8 percent weight that the rent expense category has been given by CMS in calculating the PE GPCI, and stated that office rent should be given a much larger weight to more accurately reflect its impact on physician practice expenses, and CMS should commit resources to update this data since it is based on 10-year old data from the 2006 AMA Physician Practice Information Survey (AMA PPIS).

Response: We would like to clarify that the office rent expense category has a cost share weight of 10.223 percent, not 8 percent as indicated by the commenter. The MEI cost share weights were derived from data collected by the AMA on the AMA PPIS. CMS has previously stated that we believe the AMA PPIS is a reliable data source, however the AMA PPIS is not an ongoing data source that is regularly published. We continued to use the AMA PPIS data source in the CY 2014 revisions to the MEI which have not been further updated since, and therefore, as discussed above, the 2006-based MEI cost share weights finalized for use in the CY 2014 (seventh) GPCI update, were proposed for the CY 2017 (eighth) GPCI update. The AMA is no longer conducting the AMA PPIS survey, and CMS' Office of the Actuary continues to look into viable options for updating the MEI cost share weights going forward. In the CY 2014 PFS final rule with comment period (78 FR 74275), we stated that we continue to investigate possible data sources to use for the purpose of rebasing the MEI in the future.

Comment: A few commenters expressed concern with the use of unrelated proxy data for physician wages in geographic adjustment. The commenters expressed concern about GPCI proxy inputs that result in downward payment adjustments, which they believe do not reflect the actual cost of physician practices. The commenters stated that better data exist for measuring the real physician compensation rates, such as recruitment compensation surveys and wages for physicians employed at federally qualified health centers. The commenters also stated that MedPAC studies have confirmed that the data sources currently relied upon for geographic adjustment bear no correlation to physician earnings. One commenter also stated that CMS has acknowledged that the proxies utilized for the purposes of geographic adjustment have never been validated and there never has been a new data source utilized in the twenty years since the fee schedule was implemented. The commenters urged CMS to undertake the necessary studies to identify reference occupations that will accurately reflect the higher input costs of rural physician earnings, and implement the resulting corrections to the geographic adjustment of the fee schedule as soon as possible.

Response: We appreciate the comments regarding the professional occupations used to determine the relative cost differences in physician earnings for purposes of calculating the work GPCI. In consideration of the ongoing concerns regarding the reference occupations and other proxy data used to calculate the GPCIs, we also note that in the past we received comments suggesting the use of survey data to determine GPCI values, and stated that we would continue to consider the possibility of establishing a physician cost report and requiring a sufficiently large sample of physicians in each locality to report data on actual costs incurred. However we also stated that we believed that a physician cost report could take years to develop and implement, and could be prohibitively expensive (75 FR 73259). We solicited public comment regarding the potential benefits to be gained from establishing a physician cost report and whether this approach is appropriate to achieve potentially greater precision in measuring the relative cost differences in physicians' practices among PFS localities. We also solicited public comments on the potential administrative burden of requiring physicians to routinely complete and submit a cost report. We did not receive any feedback specifically related to that comment solicitation (76 FR 73088). As noted previously in this section, physicians' wages are not included in the occupation categories (reference occupations) used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. We have long maintained that including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to physician wages. In other words, including physicians' wages in the physician work GPCI would, in effect, make the indices, to some extent, dependent upon Medicare payments, which in turn are impacted by the indices. We reiterate that the work GPCI is not an absolute measure of physician earnings; rather it is a measure of the relative wage differences for each locality as compared to the national average; additionally, the work GPCI reflects only one quarter of those relative wage differences consistent with the statutory requirement as discussed previously in this section.

Comment: We received a few comments on the PFS locality structure that were not within the scope of the CY 2017 proposed rule. For example, several commenters requested that Prince William and Loudoun counties in Virginia be changed from the Rest of Virginia locality into the DC + MD/VA Suburbs locality. Another commenter stated that it believes large cuts to rural and rest-of-State areas should be avoided or minimized, but locality boundaries with large payment differences should not be in the middle of urban areas, because they create payment cliffs where payment can change by up to eight percent if an office location is moved across a street or down a block. The commenter stated that CMS should act quickly to create locality definitions that are not constrained by county boundaries, and advocated implementing locality

definition changes based on Metropolitan Statistical Areas.

Response: We appreciate the suggestions for revisions to the PFS locality structure. As discussed above, we did not propose changes to the PFS locality structure; we note that the update to the California Fee Schedule Areas discussed later in this section is the result of a statutory requirement. Additionally, we would like to note that, absent statutory provisions like those that pertain to California, changes to the locality configuration within a state would lead to significant redistributions in payments within that state. It has been our practice, and we have stated in previous rulemaking (72 FR 38139, and 73 FR 38513), that we have not considered making changes to localities without the support of a State medical association(s) to demonstrate consensus for the change among the professionals whose payments would be affected (with some increasing and some decreasing). Also, we would like to clarify that, just as the localities under the Fee Schedule areas used in the PFS are comprised of one or more constituent counties, so are Metropolitan Statistical Areas. Therefore the concept of a payment cliff between neighboring counties as described by the commenter would not necessarily be mitigated by a change from PFS fee schedule areas to Metropolitan Statistical Areas.

After consideration of the public comments received regarding the proposed CY 2017 GPCI data update, we are finalizing as proposed.

b. California Locality Update to the Fee Schedule Areas Used for Payment Under Section 220(h) of the Protecting Access to Medicare Act

(1) General Discussion and Legislative Change

Section 220(h) of the PAMA added a new section 1848(e)(6) to the Act, that modifies the fee schedule areas used for payment purposes in California beginning in CY 2017.

Currently, the fee schedule areas used for payment in California are based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act requires that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act requires that all areas not located in an MSA must be treated as a single rest-of-state fee schedule area. The resulting modifications to California's locality structure would increase its number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure.

However, section 1848(e)(6)(D) of the Act defines transition areas as the fee schedule areas for 2013 that were the rest-of-state locality, and locality 3, which was comprised of Marin County, Napa County, and Solano County. Section 1848(e)(6)(B) of the Act specifies that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2021, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the current PFS locality structure. That is, the GPCI values applicable for these areas during this transition period are a blend of what the GPCI values would have been under the current locality structure, and what the GPCI values would be under the MSA-based locality structure. For example, in the first year, CY 2017, the applicable GPCI values for counties that were previously in rest-of-state or locality 3 and are now in MSAs are a blend of 1/6 of the GPCI value calculated for the year under the MSA-based locality structure, and 5/6 of the GPCI value calculated for the year under the current locality structure. The proportions shift by 1/6 in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas are a blend of 5/6 of the GPCI value for the year under the MSA-based locality structure, and 1/6 of the GPCI value for the year under the current locality structure. Beginning in CY 2022, the applicable GPCI values for counties in transition areas are the values calculated under the new MSA-based locality structure. For the sake of clarity, we reiterate that this incremental phase-in is only applicable to those counties that are in transition areas that are now in MSAs, which are only some of the counties in the 2013 California rest-of state locality and locality 3.

Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless for transition areas beginning with CY 2017 whereby the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the current locality structure. There are a total of 58 counties in California, 50 of which are in transition areas as defined in section 1848(e)(6)(D) of the Act. Therefore, 50 counties in California are subject to the hold harmless provision. The other 8 counties, which are metropolitan counties that are not defined as transition areas, are not held harmless for the impact of the new MSA-based locality structure, and may therefore potentially experience slight decreases in their GPCI values as a result of the provisions in section 1848(e)(6) of the Act, insofar as the locality in which they are located now newly includes data from adjacent counties that decreases their GPCI values relative to those that would have applied had the new data not been incorporated. Therefore, the GPCIs for these eight counties under the MSA-based locality structure may be less than they would have been under the current GPCI structure. The eight counties that are not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties.

We emphasize that while transition areas are held harmless from the impact of the GPCI changes using the new MSA-based locality structure, because we proposed other updates for CY 2017 as part of the eighth GPCI update, including the use of updated data, transition areas would still be subject to impacts resulting from those other updates. Table 13 illustrates using GAFs, for CY 2017, the isolated impact of the MSA-based locality changes and hold-harmless for transition areas required by section 1848(e)(6) of the Act, the impact of the use of updated data for GPCIs, and the combined impact of both of these changes.

TABLE 13—IMPACT ON CALIFORNIA GAFS AS A RESULT OF SECTION 1848(e)(6) OF THE ACT AND UPDATED DATA BY FEE SCHEDULE AREA

[Sorted alphabetically by locality name]

Medicare fee schedule area	Transition area	2016 GAF	2017 GAF w/o 1848(e)(6)	% change due to new GPCI data	2017 GAF w/ 1848(e)(6)	% change due to 1848(e)(6)	Combined impact of PAMA and new GPCI data (%)
Bakersfield	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Chico	1	1.036	1.031	−0.48	1.031	0.00	−0.48
El Centro	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Fresno	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Hanford-Corcoran	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Los Angeles-Long Beach-Anaheim (Los Angeles Cnty)	0	1.092	1.090	−0.18	1.091	0.09	−0.09
Los Angeles-Long Beach-Anaheim (Orange Cnty)	0	1.111	1.104	−0.63	1.101	−0.27	−0.90
Madera	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Merced	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Modesto	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Napa	1	1.137	1.128	−0.79	1.128	0.00	−0.79
Oxnard-Thousand Oaks-Ventura	0	1.089	1.083	−0.55	1.083	0.00	−0.55
Redding	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Rest of California	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Riverside-San Bernardino-Ontario	1	1.036	1.031	−0.48	1.032	0.10	−0.39
Sacramento-Roseville-Arden-Arcade	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Salinas	1	1.036	1.031	−0.48	1.033	0.19	−0.29
San Diego-Carlsbad	1	1.036	1.031	−0.48	1.035	0.39	−0.10
San Francisco-Oakland-Hayward (Alameda/Contra Costa Cnty)	0	1.124	1.125	0.09	1.142	1.51	1.60
San Francisco-Oakland-Hayward (Marin Cnty)	1	1.137	1.128	−0.79	1.129	0.09	−0.70
San Francisco-Oakland-Hayward (San Francisco Cnty)	0	1.191	1.194	0.25	1.175	−1.59	−1.34
San Francisco-Oakland-Hayward (San Mateo Cnty)	0	1.182	1.187	0.42	1.171	−1.35	−0.93
San Jose-Sunnyvale-Santa Clara (San Benito Cnty)	1	1.036	1.031	−0.48	1.053	2.13	1.64
San Jose-Sunnyvale-Santa Clara (Santa Clara Cnty)	0	1.175	1.176	0.09	1.175	−0.09	0.00
San Luis Obispo-Paso Robles-Arroyo Grande	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Santa Cruz-Watsonville	1	1.036	1.031	−0.48	1.042	1.07	0.58
Santa Maria-Santa Barbara	1	1.036	1.031	−0.48	1.036	0.48	0.00
Santa Rosa	1	1.036	1.031	−0.48	1.037	0.58	0.10
Stockton-Lodi	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Vallejo-Fairfield	1	1.137	1.128	−0.79	1.128	0.00	−0.79
Visalia-Porterville	1	1.036	1.031	−0.48	1.031	0.00	−0.48
Yuba City	1	1.036	1.031	−0.48	1.031	0.00	−0.48

Note: the Los Angeles-Long Beach-Anaheim; San Francisco-Oakland-Hayward; and San Jose-Sunnyvale-Santa Clara Medicare localities are represented at a sub-locality level for the purpose of demonstrating the variation of the GAF within the locality. The variation in the Los-Angeles-Long Beach-Anaheim locality exists only in CY 2017 and results from the two-year 50/50 phase in of the GPCI. The GAF variation in San Francisco-Oakland-Hayward and San Jose-Sunnyvale-Santa Clara results from the localities containing both transition area and non-transition area counties. For the remainder of Medicare localities, the GAF is consistent throughout the entire locality.

Additionally, for the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, we proposed to start by calculating the national GPCIs as if the current localities are still applicable nationwide; then for the purposes of payment in California, we override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is implemented for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

(2) Operational Considerations

As discussed above, under section 1848(e)(6) of the Act, counties that were previously in the rest-of-state locality or locality 3 and are now in MSAs would have their GPCI values under the new MSA-based locality structure phased in gradually, in increments of one-sixth over 6 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be 1/2 of the adjustment that otherwise would be made. While section 1848(e)(6)(B) of the Act establishes a blended phase-in for the MSA-based GPCI values, it does not explicitly state whether or how that provision is to be reconciled with the requirement at section 1848(e)(1)(C) of

the Act. We believe that since section 1848(e)(6)(A) of the Act requires that we must make the change to MSA-based fee schedule areas for California GPCIs notwithstanding the preceding provisions of section 1848(e) of the Act, and subject to the succeeding provisions of section 1848(e)(6) of the Act, that applying the two-year phase-in specified by the preceding provisions simultaneously with the six-year phase-in would undermine the incremental 6-year phase-in specified in section 1848(e)(6)(B) of the Act. Therefore, we proposed that the requirement at section 1848(e)(1)(C) of the Act to phase in 1/2 of the adjustment in year 1 of the GPCI update would not apply to counties that were previously in the rest-of-state or locality 3 and are now in MSAs, and therefore, are subject to the blended phase-in as described above. Since section 1848(e)(6)(B) of the Act provides for a gradual phase in of the GPCI values under the new MSA-based locality structure, specifically in one-sixth increments over 6 years, if we were to also apply the requirement to phase in 1/2 of the adjustment in year 1 of the GPCI update then the first year increment would effectively be one-twelfth. We note that this issue is only of concern if more than 1 year has elapsed since the previous GPCI update, and would only be applicable through CY 2021 since, beginning in CY 2022, the GPCI values for such areas in an MSA would be fully based on the values calculated under the new MSA-based locality structure for California.

As previously stated, the resulting modifications to California's locality structure increase its number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure. However, both the current localities and the MSA-based localities are comprised of various component counties, and in some localities only some of the component counties are subject to the blended phase-in and hold harmless provisions required by section 1848(e)(6)(B) and (C) of the Act. Therefore, the application of these provisions may produce differing GPCI values among counties within the same fee schedule area under the MSA-based locality structure. For example, the MSA-based San Jose-Sunnyvale-Santa Clara locality, is comprised of 2 constituent counties—San Benito County, and Santa Clara County. San Benito County is in a transition area (2013 rest-of-state), while Santa Clara County is not. Hence, although the counties are in the same MSA, the requirements of section 1848(e)(6)(B) and (C) of the Act may produce differing GPCI values for each county. To address this issue, we proposed to assign a unique locality number to the counties that would be impacted in the aforementioned manner. As a result, although the modifications to California's locality structure increase the number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure, for purposes of payment, the actual number of localities under the MSA-based locality structure would be 32 to account for instances where unique locality numbers are needed as described above. Additionally, while the fee schedule area names are consistent with the MSAs designated by OMB, we proposed to maintain 2-digit locality numbers to correspond to the existing fee schedule areas. Pursuant to the implementation of the new MSA-based locality structure for California, the total number of PFS localities would increase from 89 to 112. Table 14 displays the current fee schedule areas in California, and Table 15 displays the MSA-based fee schedule areas in California required by section 1848(e)(6) of the Act. Additional information on the California locality update may be found in our contractor's draft report, ''Draft Report on the CY 2017 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule,'' which is available on the CMS Web site. It is located under the supporting documents section of the CY 2017 PFS final rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

TABLE 14—CURRENT FEE SCHEDULE AREAS IN CALIFORNIA

[Sorted alphabetically by locality name]

Locality number	Fee schedule area	Counties
26	Anaheim/Santa Ana.	Orange.
18	Los Angeles	Los Angeles.
03	Marin/Napa/Solano.	Marin, Napa, And Solano.
07	Oakland/Berkley	Alameda and Contra Costa.
05	San Francisco	San Francisco.
06	San Mateo	San Mateo.
09	Santa Clara	Santa Clara.
17	Ventura	Ventura.
99	Rest of State	All Other Counties.

TABLE 15—MSA-BASED FEE SCHEDULE AREAS IN CALIFORNIA

[Sorted alphabetically by locality name]

Current locality number	New locality number	Fee schedule area (MSA name)	Counties	Transition area
99	54	Bakersfield, CA	Kern	YES.
99	55	Chico, CA	Butte	YES.
99	71	El Centro, CA	Imperial	YES.
99	56	Fresno, CA	Fresno	YES.
99	57	Hanford-Corcoran, CA	Kings	YES.
18	18	Los Angeles-Long Beach-Anaheim, CA *(Los Angeles County)*	Los Angeles	NO.
26	26	Los Angeles-Long Beach-Anaheim, CA *(Orange County)*	Orange	NO.
99	58	Madera, CA	Madera	YES.
99	59	Merced, CA	Merced	YES.
99	60	Modesto, CA	Stanislaus	YES.
3	51	Napa, CA	Napa	YES.
17	17	Oxnard-Thousand Oaks-Ventura, CA	Ventura	NO.
99	61	Redding, CA	Shasta	YES.
99	75	Rest of State	All Other Counties	YES.
99	62	Riverside-San Bernardino-Ontario, CA	Riverside, And San Bernardino	YES.
99	63	Sacramento—Roseville—Arden-Arcade, CA	El Dorado, Placer, Sacramento, And Yolo.	YES.
99	64	Salinas, CA	Monterey	YES.
99	72	San Diego-Carlsbad, CA	San Diego	YES.

TABLE 15—MSA-BASED FEE SCHEDULE AREAS IN CALIFORNIA—Continued

[Sorted alphabetically by locality name]

Current locality number	New locality number	Fee schedule area (MSA name)	Counties	Transition area
7	7	San Francisco-Oakland-Hayward, CA *(Alameda County/ Contra Costa County).*	Alameda, Contra Costa	NO.
3	52	San Francisco-Oakland-Hayward, CA *(Marin County)*	Marin	YES.
5	5	San Francisco-Oakland-Hayward, CA *(San Francisco County)*	San Francisco	NO.
6	6	San Francisco-Oakland-Hayward, CA *(San Mateo County)*	San Mateo	NO.
99	65	San Jose-Sunnyvale-Santa Clara, CA *(San Benito County)*	San Benito	YES.
9	9	San Jose-Sunnyvale-Santa Clara, CA *(Santa Clara County)*	Santa Clara	NO.
99	73	San Luis Obispo-Paso Robles-Arroyo Grande, CA	San Luis Obispo	YES.
99	66	Santa Cruz-Watsonville, CA	Santa Cruz	YES.
99	74	Santa Maria-Santa Barbara, CA	Santa Barbara	YES.
99	67	Santa Rosa, CA	Sonoma	YES.
99	73	Stockton-Lodi, CA	San Joaquin	YES.
3	53	Vallejo-Fairfield, CA	Solano	YES.
99	69	Visalia-Porterville, CA	Tulare	YES.
99	70	Yuba City, CA	Sutter, and Yuba	YES.

We received few comments regarding the California locality update to the fee schedule areas used for payment under section 220(h) of PAMA.

Comment: One commenter stated that it supports the proposed California payment locality implementation plan. The commenter stated that based on its analysis the calculations are accurate except for a few errors. Specifically, the commenter stated that the CY 2016 GAFs for 3 fee schedule areas [Los Angeles-Long Beach-Anaheim (Orange County), San Francisco-Oakland-Hayward (Alameda/Contra Costa County), and San Francisco-Oakland-Hayward (San Francisco County)] in Table 13 of the proposed rule (81 FR 46221 through 46222) were incorrect. The commenter also requested that all of the 2016 GAFs in the table be reported to three decimal places to avoid confusion with rounding. Additionally, the commenter indicated that Sierra County in California was missing from the CY 2017 Proposed GPCI County Data File in the CY 2017 Proposed Rule GPCI Public Use Files available on our Web site under the supporting documents section of the CY 2017 PFS proposed rule Web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

Response: We thank the commenter for its support of our proposed California payment locality implementation plan. With regard to the errors noted by the commenter, we thank the commenter for bringing this issue to our attention. We agree that the CY 2016 GAFs for Los Angeles-Long Beach-Anaheim (Orange County), San Francisco-Oakland-Hayward (Alameda/Contra Costa County), and San Francisco-Oakland-Hayward (San Francisco County) were incorrect in Table 13 of the proposed rule, and have been corrected in Table 13 in this final rule. We have also updated all of the 2016 GAFs in Table 13 to reflect 3 decimal places as to avoid confusion with rounding as requested. Additionally, we note that while the GAFs for these 3 fee schedule areas were incorrect in Table 13 of the proposed rule, the GAF values were correct in Addendum D to the proposed rule available on our Web site under the supporting documents section of the CY 2017 PFS Proposed Rule Web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* Moreover, GAF values are an analysis tool, and are not used to determine service level payment. Additionally, we note Sierra County was omitted from the CY 2017 Proposed GPCI County Data File because we removed counties with 0 total RVUs in 2014. However, for the final rule we have revised the file to include all counties, even those with 0 total RVUs in 2014. The updated file can be viewed in the CY 2017 Final GPCI County Data File in the CY 2017 Final Rule GPCI Public use files available on our Web site.

Comment: One commenter requested that CMS implement the California locality update requirement in a manner that does not require the Medicare Administrative Contractor (MAC) for California to make changes to the enrollment process for physician groups in California or changes in the way that physician groups submit claims to the MAC.

Response: While we note that there are several internal administrative burdens that result from the implementation of the California locality update, we do not believe there should be related burden on practitioners, and California practitioners will continue to follow the existing process for submitting claims.

After consideration of the public comments received regarding the proposed California payment locality implementation plan, we are finalizing as proposed.

4. Update to the Methodology for Calculating GPCIs in the U.S. Territories

In calculating GPCIs within U.S. states, we use county-level wage data from the Bureau of Labor Statistics (BLS) Occupational Employment Statistics Survey (OES), county-level residential rent data from the American Community Survey (ACS), and malpractice insurance premium data from state departments of insurance. In calculating GPCIs for the U.S. territories, we currently use three distinct methodologies—one for Puerto Rico, another for the Virgin Islands, and a third for the Pacific Islands (Guam, American Samoa, and Northern Marianas Islands). These three methodologies were adopted at different times based primarily on the data that were available at the time they were adopted. At present, because Puerto Rico is the only territory where county-level BLS OES, county-level ACS, and malpractice premium data are available, it is the only territory for which we use territory-specific data to calculate GPCIs. For the Virgin Islands, because county-level wage and rent data are not available, and insufficient malpractice premium data are available, CMS has set the work, PE, and MP GPCI values for the Virgin Islands payment locality at the national average of 1.0 even though, like Puerto Rico, the Virgin Islands is its

own locality and county-level BLS OES data are available for the Virgin Islands. For the U.S. territories in the Pacific Ocean, we currently crosswalk GPCIs from the Hawaii locality for each of the three GPCIs, and incorporate no local data from these territories into the GPCI calculations even though county-level BLS OES data does exist for Guam, but not for American Samoa or the Northern Mariana Islands.

As noted above, currently Puerto Rico is the only territory for which we calculate GPCIs using the territory-specific information relative to data from the U.S. States. For several years stakeholders in Puerto Rico have raised concerns regarding the applicability of the proxy data in Puerto Rico relative to their applicability in the U.S. states. We believe that these concerns may be consistent across island territories, but lack of available, appropriate data has made it difficult to quantify such variation in costs. For example, some stakeholders previously indicated that shipping and transportation expenses increase the cost of acquiring medical equipment and supplies in islands and territories relative to the mainland. While we have previously attempted to locate data sources specific to geographic variation in such shipping costs, we found no comprehensive national data source for this information (we refer readers to 78 FR 74387 through 74388 for the detailed discussion of this issue). Therefore, we have not been able to quantify variation in costs specific to island territories in the calculation of the GPCIs.

For all the island territories other than Puerto Rico, the lack of comprehensive data about unique costs for island territories has had minimal impact on GPCIs because we have used either the Hawaii GPCIs (for the Pacific territories) or used the unadjusted national averages (for the Virgin Islands). In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the States in accurately accounting for variability of costs for these island territories, we proposed to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner. We proposed to do so by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. We did not propose any changes to the GPCI methodology for the Pacific Island territories (Guam, American Samoa, and Northern Marianas Islands) where we already consistently assign the Hawaii GPCI values for each of the three GPCIs. Additional information on the Proposed Update to the Methodology for Calculating GPCIs in the U.S. Territories may be found in our contractor's draft report, ''Draft Report on the CY 2017 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule,'' which is available on our Web site. It is located under the supporting documents section of the CY 2017 PFS final rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

The following is a summary of the comments we received regarding the proposed update to the methodology for calculating GPCIs in the U.S. territories.

Comment: Several commenters expressed support for CMS' proposal to assign the national average of 1.0 to each GPCI in Puerto Rico, stating that the physicians in Puerto Rico who treat patients enrolled in fee-for-service Medicare will be reimbursed in a manner that more closely aligns with the manner in which physicians in the other U.S. territories are reimbursed, and better reflects the cost of practicing medicine in Puerto Rico. Other commenters supporting the proposal also suggested that there has been a need for revision of Medicare payment in Puerto Rico, and that the territories of the U.S. have not been treated similarly even though the territories are much alike. Another commenter stated that the existing fee schedule for Puerto Rico does not correlate with the cost of caring for patients, and that the proposed policy is long overdue. Some commenters also stated that increasing the GPCI's for Puerto Rico is an important and necessary first step in trying to salvage Puerto Rico's deteriorated health system.

Response: We thank the commenters for their support.

Comment: A few commenters requested that CMS consider raising the GPCI values in Puerto Rico to 1.25.

Response: We proposed assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands, in an effort to provide greater consistency in the calculation of GPCIs among these island territories, given the lack of information on the validity of applying the proxy data used in the States to accurately account for variability of costs in these territories as compared to the national average costs. Ultimately we proposed to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner by assigning the national average of 1.0 to each GPCI index. We do not believe that it would be appropriate to raise the value to 1.25 in the absence of data demonstrating that would be an accurate reflection of costs in those territories relative to national average costs.

Comment: We received several comments that are outside of the scope of the Physician Fee Schedule, requesting that CMS explore every option to determine whether a one-time correction can be made to the Medicare Advantage (MA) regulatory cycle so that the per-person monthly payment to Puerto Rico MA Plans in CY 2017 will reflect the increase to the fee-for-service spending in the territory as a result of the proposed GPCI increase. Some commenters stated that it is imperative that CMS see that the increased physician fees reach the actual providers and are not diverted away from patient care by third parties such as Medicare Advantage Organizations. Some commenters requested that CMS clarify that the new GPCIs will be incorporated into the MA benchmarks in CY 2018.

Response: We appreciate the concerns raised by the commenters. Consistent with the statute, we published the final CY 2017 Rate Announcement for Medicare Advantage on April 4, 2016. Medicare Advantage actuarial bids and benefit packages for 2017 have been approved by CMS and sponsors have begun marketing plan to beneficiaries. Thus, a change in to CY 2017 benchmark would be disruptive to beneficiaries. In future years, including CY 2018, we will follow our normal process for calculating rates. This process incorporates historical Fee for Service expenditures, which would include any updates to Fee for Service payment rates, such as an adjustment to the Puerto Rico GPCI. CMS will not be making any adjustments to CY 2017 Medicare Advantage rates as a result of this final rule. Finally, we note that according to the statute, we are prohibited from interfering or directing the contracting between Medicare Advantage Organizations (MAOs) and contracted providers. As such, we are not permitted to dictate to MAOs how any increase in payment rates can be spent, including on provider rates.

Comment: One commenter suggested that if the MA benchmark cannot be adjusted for CY 2017 that CMS should postpone the applicability of the GPCI change in Puerto Rico until CY 2018 when such an effect is also reflected in the MA benchmarks.

Response: We do not agree that the proposal to update to the methodology for calculating GPCIs in the U.S. territories, which will provide greater consistency in the calculation of GPCIs for these areas, should be delayed based on when the MA benchmarks will

reflect the increases as a result of this policy.

After consideration of the public comments received regarding our proposal to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner, by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands, we are finalizing as proposed.

5. Refinement to the MP GPCI Methodology

In the process of calculating MP GPCIs for the purposes of this final rule, we identified several technical refinements to the methodology that yield improvements over the current method. We also proposed refinements that conform to our proposed methodology for calculating the GPCIs for the U.S. Territories described above. Specifically, we proposed modifications to the methodology to account for missing data used in the calculation of the MP GPCI. Under the methodology used in the CY 2014 GPCI update (78 FR 74380 through 74391), we first calculated the average premiums by insurer and specialty, then imputed premium values for specialties for which we did not have specific data, before adjusting the specialty-specific premium data by market share weights. We proposed to revise our methodology to instead calculate the average premiums for each specialty using issuer market share for only available companies. This proposed methodological improvement would reduce potential bias resulting from large amounts of imputation, an issue that is prevalent for insurers that only write policies for ancillary specialties for which premiums tend to be low. The current method would impute the low premiums for ancillary specialties across the remaining specialties, and generally greater imputation leads to less accuracy. Additional information on the MP GPCI methodology, and the proposed refinement to the MP GPCI methodology may be found in our contractor's draft report, ''Draft Report on the CY 2017 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule,'' which is available on our Web site. It is located under the supporting documents section of the CY 2017 PFS final rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

We did not receive any comments regarding the proposed technical refinements to the MP GPCI methodology, and we are finalizing as proposed.

J. 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, 2016 (Pub. L. 114–113) amended section 1848(b) of the Act by adding new paragraph (b)(9). Effective for services furnished on or after January 1, 2017, section 1848(b)(9)(A) of the Act reduces by 20 percent the payment amounts under the PFS for the technical component (TC) (including the TC portion of a global services) of imaging services that are X-rays taken using film. The reduction is made prior to any other adjustment under this section and without application of this new paragraph.

Section 1848(b)(9) of the Act allows for the implementation of the payment reduction through appropriate mechanisms which may include use of modifiers. In accordance with section 1848(c)(2)(B)(v)(X), the adjustments under section 1848(b)(9)(A) of the Act are exempt from budget neutrality.

To implement this provision, in the CY 2017 PFS proposed rule (81 FR 46224), we proposed to establish a new modifier to be used on claims that include imaging services that are X-rays (including the imaging portion of a service) taken using film. Since the display of the proposed rule, modifier FX has been established for that purpose. Effective January 1, 2017, the modifier must be used on claims for X-rays that are taken using film. The use of this modifier will result in a 20 percent reduction for the X-ray service, as specified under section 1848(b)(9)(A) of the Act.

The proposed rule preamble stated that the applicable HCPCS codes describing imaging services that are X-ray services could be found on the PFS Web site. However, we did not intend this to indicate that we would be developing or displaying an exhaustive list of applicable codes. Instead, we intended to refer to the several lists of PFS imaging codes, including those that describe imaging services that are X-rays.

Comment: Many commenters commented on the merits of the statutory provision. The commenters stated that the reduction of Medicare film-based x-ray payments by 20 percent will have unintended consequences on patient care.

Response: We believe our proposal would implement the required statutory provision and we do not believe that we have the authority to alter the application of the provision based on these comments.

Comment: An overwhelming majority of the commenters requested CMS implement an alternative policy to improve quality of imaging services. The recommended policy would require registered radiologic technicians to perform all Medicare film or digital radiography procedures. Other commenters countered this recommended alternative by stating that it would exclude otherwise qualified professionals who have undergone education to acquire limited scope licenses or certification programs demonstrating As Low As Reasonably Achievable (ALARA) safety practices by either a third party, vendor training, or another didactic course deemed acceptable by any of the four accreditation organizations. One commenter also referenced 35 states that have an entry level certification for X-ray technicians and that throughout the US, there are x-ray technicians and limited scope X-ray machine operators that are also licensed and certified.

Response: We appreciate commenters' interests in standards that might improve quality of care for Medicare beneficiaries, but we did not propose a policy regarding standards for radiologic technicians in the proposed rule. Also, as previously stated, we do not believe we have the authority to implement conditions of payment regarding radiologic technicians as an alternative to the adjustments required by the statutory provision.

Comment: A commenter recommended that a financial incentive be provided for physicians to convert to digital machines as had been done in the case of electronic medical records.

Response: The legislation does not authorize any financial incentive in the form of increased payment, but provides an incentive to use digital images to avoid the 20 percent reduction that applies to imaging services that are X-rays taken using film.

Comment: One commenter requested that in the absence of a meaningful opportunity to comment on the list of codes for which the policy applies, the provision should be limited to traditional diagnostic X-ray procedures only. Two commenters presented separate lists of codes for which the payment reduction should apply. One commenter also provided codes that should be explicitly excluded from the payment reduction, for example, radiographic-fluoroscopic, vascular and mammography X-ray imaging services, radioscopic, radioscopic and radiography services provided in a

single examination. Other commenters also provided a list of procedures that should be excluded. The commenter also requested that we publish the list of applicable codes as soon as possible.

Response: As previously stated, we did not publish an exhaustive list of applicable codes, and previously intended to point to existing lists of PFS imaging services. We believe that physicians and non-physician practitioners are in the best position to determine whether a particular imaging service is an X-ray taken using film.

Comment: One commenter suggested that if at least half of the number of discrete X-ray exposures required for the radiographic exam are captured using a DR detector, then the examination should be considered as digital and the payment differential should not be applied. Another commenter requested that we clarify that the law only applies (and requires use of a modifier) to sites that use X-ray as a single method for image capture. The commenter also seeks clarification that if a site uses both X-ray film and electronic capture of images and maintains digital archives, by a picture archiving communication system or other electronic method, that the site is not required to report the modifier.

Response: At this time, in accordance with the statute, we are requiring the FX modifier to be used whenever an imaging service is an X-ray taken using film. As stated, the statute requires that if an imaging service is an X-ray taken using film, a reduction in payment is to occur. The statutory requirement applies at the service level, not based on where the service is furnished or the method used to store images. There is no provision for an exception to the payment reduction based on the availability of various technologies or the use of certain image archiving technology at a particular site.

After consideration of the public comments we received, we are finalizing the establishment of new modifier ''FX'' to be reported on claims for imaging services that are X-rays that are taken using film.

Beginning January 1, 2017, claims for imaging services that are X-rays taken using film must include the modifier ''FX.''

The use of this modifier will result in a 20 percent reduction for the X-ray service, as specified under section 1848(b)(9)(A) of the Act.

K. Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

Effective January 1, 2012, we implemented an MPPR of 25 percent on the professional component (PC) of advanced imaging services. The reduction applies when multiple imaging procedures are furnished by the same physician (or physician in the same group practice) to the same patient, in the same session, on the same day. Full payment is made for the PC of the highest priced procedure. Payment for the PC of subsequent services is reduced by 25 percent.

Section 502(a)(2)(A) of Division O, Title V of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113, enacted on December 18, 2015) added a new section 1848(b)(10) of the Act which revises the payment reduction from 25 percent to 5 percent, effective January 1, 2017. Section 502(a)(2)(B) added a new subclause at section 1848(c)(2)(B)(v)(XI) which exempts the reduced expenditures attributable to the revised 5 percent MMPR on the PC of imaging from the PFS budget neutrality provision. We proposed to implement these provisions for services furnished on or after January 1, 2017. We refer readers to section VI.C of this final rule regarding the necessary adjustment to the proposed PFS conversion factor to account for the mandated exemption from PFS budget neutrality.

We note that the lists of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 5102(b) of the Deficit Reduction Act (DRA), and therefore, are subject to the OPPS cap, are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2017 are available on our Web site under downloads for the CY 2017 PFS final rule with comment period at *http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html.*

Comment: Commenters supported the proposal to implement the statutory provision.

Response: We our finalizing our CY 2017 proposal to revise the MPPR on the PC of diagnostic imaging services.

L. 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.D.4 of this final 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 proposed rule, the new process is applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 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 proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in this 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 are not aware of any new codes that describe such wholly new services. Therefore, we are not establishing any code values on an interim final basis. However, we remind stakeholders that we continually review stakeholder information regarding the valuation of codes under the potentially misvalued code initiative and, under our existing process, could consider proposing any particular changes as early as CY 2018 rulemaking.

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 review of recommended work RVUs and time inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC (Health Care Professionals Advisory Committee), 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 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. 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 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. The building block methodology is used to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code.

Components used in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could be the CPT codes that make up the bundled code and the inputs associated with those codes. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or 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 refine 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 six preservice time packages for services typically furnished in the facility setting, reflecting the different combinations of straightforward or difficult procedure, straightforward or difficult patient, and without or with sedation/anesthesia. Currently, there are three preservice time packages for services typically furnished in the nonfacility setting, reflecting procedures without and with sedation/anesthesia care.

We have developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. 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 believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time has already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically 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 regarding the time resources involved in furnishing individual services. We are 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. 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 apply various methodologies to identify several potential work values for individual codes. However, we want to reiterate that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services.

We have observed that for many codes reviewed by the RUC, final recommended work RVUs appear to be incongruous with recommended assumptions regarding the resource costs in time. This is 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 begin by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we employ 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 blocks, 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 sometimes use 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 are using the recommended values as a starting reference and then applying one of these several methodologies to account for the reductions in time that we believe have not otherwise been reflected in the RUC-recommended value. When we believe that such changes in time have already been accounted for in the RUC recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We clarify that we are not implying 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 believe 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 has 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 generally use 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 commenters, 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. We received several specific comments regarding this issue in response to the CY 2016 PFS final rule with comment period and those comments are summarized below.

Comment: Several commenters, including the RUC, stated that our methodology for adjusting work RVUs appears to be contrary to the statute.

Response: We disagree with these comments. Since section 1848(c)(1)(A) of the Act explicitly identifies time as one of the two types of resources that encompass the work component of the PFS payment, we do not believe that our use of the aforementioned methodologies to adjust the work RVU to account for the changes in time, which is one of the resources involved, is inconsistent with the statutory requirements related to the maintenance of work RVUs, and we have regularly used these and other methodologies in developing values for PFS services. In selecting which methodological approach will best determine the appropriate value for a service, we consider the current and recommended work and time values, as well as the intensity of the service, all relative to other services. In our review of RUC recommended values, we have observed that the RUC also uses a variety of methodologies to develop work RVUs for individual codes, and subsequently validates the results of these approaches through magnitude estimation or crosswalk to established values for other codes.

Comment: Several commenters, including the RUC, stated that we could not take one element of the services that has changed such as intra-service time, and apply an overall ratio for reduction to the work RVU based on changes to time, as that renders the value no longer resource-based in comparison to the RUC-recommended values.

Response: We disagree with the commenters and continue to believe that the use of time ratios is one of several reasonable methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values do not account for information that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values determines that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case. Furthermore, we reiterate that we use time ratios to identify potential work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. We also disagree with several commenters' implications that a work RVU developed through such estimation methods is only resource-based through the RUC process.

Comment: Several commenters, including the RUC, stated that our inconsistent use of the time ratio methodology has rendered it ineffective for valuation purposes and that by choosing the starting base work value and/or physician time at random, we are essentially reverse engineering the work value we want under the guise of a standard algorithm.

Response: We do not choose a starting base work value and/or physician time at random as suggested by the commenters. We use the RUC recommended values or the existing values as the base values; essentially, we are taking one of those values and applying adjustments to account for the change in time that based on our analysis of the RUC recommendation, we determine has not been properly accounted for to determine an appropriate work RVU. In circumstances where adjustments to time and the corresponding work RVU are relatively congruent or persuasively explained, our tendency has been to use those values as recommended. Where the RUC recommendations do not account for changes in time, we have made changes to RUC-recommended values to account for the changes in time.

Comment: Commenters, including the RUC, also stated that the use of time ratio methodologies distills the valuation of the service into a basic formula with the only variable being either the new total physician time or the new intra-service physician time, and that these methodologies are based

on the incorrect assumption that the per minute physician work intensity established is permanent regardless of when the service was last valued. Other commenters have suggested that previous assumed times are inaccurate.

Response: We agree with commenters that per minute intensity for a given service may change over time. If we believed that the per-minute intensity for a given service were immutable, then a reverse-building block approach to revaluation based on new time data could be appropriate. However, we have not applied such an approach specifically because 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 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.

Regarding the validity of comparing new times to the old times, we, too, hope that time estimates have improved over many years especially when many years have elapsed since the last time the service in question was valued. However, we also believe that our operating assumption regarding the validity of the pre-existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. Pre-existing times are a very important element in the allocation of indirect PE RVUs by specialty, and had the previously recommended times been overestimated, the specialties that furnish such services would be benefitting from these times in the allocation of indirect PE RVUs. As long time observers of the RUC process, we also recognize that the material the RUC uses to develop overall work recommendations includes the data from the surveys about time. We have previously stated concerns regarding the validity of much of the RUC survey data. However, we believe additional kinds of concern would be warranted if the RUC itself were operating under the assumption that its pre-existing data were typically inaccurate.

We understand stakeholders' concerns regarding how best to consider changes in time in improving the accuracy of work RVUs and have considered all of the issues raised by commenters. In conjunction with our review of recommended code values for CY 2017, we conducted a preliminary analysis to identify general tendencies in the relationship between changes in time and changes in work RVUs for CY 2014 and CY 2015. We looked at services for which there were no coding changes to simplify the analysis. The intent of this preliminary analysis was to examine commenters' beliefs that CMS is only considering time when making refinements to RUC recommended work values. For CY 2014, we found that in the aggregate, the average difference between the RUC recommended intraservice time and existing intraservice time was −17 percent, but the average difference between the RUC recommended work RVU and existing work RVU was only −4 percent. However, the average difference between the CMS refined work RVU and existing work RVU was −7 percent. For CY 2015, the average difference between the RUC recommended intraservice time and existing intraservice time was −17 percent, but the average difference between the RUC recommended work RVU and existing work RVU was 1 percent, and the average difference between the CMS refined work RVU and existing work RVU was −6 percent. This preliminary analysis demonstrates that we are not making refinements solely in consideration of time, if that were the case, the changes in the work RVU values that we adopted would be comparable to the changes in the time that we adopted, but that is not the case.

We believe that we should account for efficiencies in time when the recommended work RVU does not account for those efficiencies, otherwise relativity across the PFS can be significantly skewed over periods of time. For example, if when a code is first valued, a physician was previously able to do only 5 procedures per day, but due to new technologies, the same physician can now do 10 procedures per day, resource costs in time have empirically been lessened, and we believe that relative reduction in resources involved in furnishing that service should be accounted for in the assignment of work RVUs for that service, since the statute explicitly identifies time as one of the two components of work. Of course, if more resource intensive technology has allowed for the increased efficiency in furnishing the procedure, then the nonfacility PE RVUs for the service should also be adjusted to account for this change. Additionally, we believe it may be that the intensity per minute of the procedure may have changed with the greater efficiency in time. Again, that is why we do not generally reduce work RVUs in strict proportion to changes in time. We understand that intensity is not entirely linear, and that data related to time as obtained in the RUC survey instrument may improve over time, and that the number of survey respondents may improve over time. However, we also understand time as a tangible resource cost in furnishing PFS services, and a cost that by statute, is one of the two kinds of resources to be considered as part of the work RVU.

Therefore, in the proposed rule, we stated that we were interested in receiving comments on whether, within the statutory confines, there are alternative suggestions as to how changes in time should be accounted for when it is evident that the survey data and/or the RUC recommendation regarding the overall work RVU does not reflect significant changes in the resource costs of time for codes describing PFS services. We solicited comment on potential alternatives, including the application of the reverse building block methodology, to making the adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services.

The following is a summary of the comments we received in response to our solicitation regarding potential alternatives, including the application of the reverse building block methodology, to making the adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services.

Comment: One commenter stated that it continues to support CMS in its efforts to adjust work RVUs commensurate with changes in intra-service and total time, as well as post-operative visits despite RUC recommendations to the contrary. The commenter agreed with our changes and encouraged CMS to continue to identify and address such incongruities. The commenter stated that it is routine to encounter recommended decreases in physician time and/or post-procedure visits combined with RUC recommendations to maintain or increase the work RVUs. The commenter agreed that when physician time decreases, physician work should decrease comparatively, absent a compelling argument that the intensity of the service has increased sufficiently to offset the decrease in physician time. The commenter did not have alternative suggestions for how CMS should make these adjustments, and believes the approaches that CMS has taken are reasonable and defensible.

Another commenter stated that it appreciates that CMS provided

information about how it reviews recommendations for work RVUs that come from the RUC. Additionally, one commenter stated appreciation for the consideration and effort that CMS gives in valuing the work RVUs for a service. The commenter stated that the accuracy of RVU estimates has improved as a result of CMS' various validation processes for collecting data and its consideration of feedback from the RUC and public commenters. The commenter stated that CMS should account for efficiencies in the resource costs of time when the recommended work RVU does not account for emerging efficiencies, such as advances in surgical techniques, and that by considering time in these situations, CMS will be able to effectively adjust both emerging technological trends and their impact on resource costs needed to deliver care to beneficiaries.

Response: We appreciate the commenters' support for our ongoing adjustment of work RVUs based on changes in the best information we have regarding the time resources involved in furnishing individual services. We also agree that CMS should account for efficiencies in the resource costs of time, as indicated by one commenter, and will endeavor to do so when we consider the work RVU and how the effect of advancements such as emerging technology and improvements in surgical techniques impact the resource costs of time.

Comment: A few commenters, including the RUC, stated that all adjustments to work RVUs should be solely based on the resources involved in performing each procedure or service. The commenters stated that all adjustments to work RVUs should either be work neutral to the family or result in budget neutral adjustment to the conversion factor, and that broadly redistributing work RVUs would distort the relative value system and create unintended consequences.

Response: We agree that adjustments to work RVUs should be based on the resources involved with each procedure or service, and consistent with the statute, the work RVUs should reflect the relative resources costs of time and intensity. We also agree with the commenter regarding how changes in work RVUs affect PFS relativity. We have a long-standing practice of making an adjustment to the CF to account for increases or decreases in work RVUs across the PFS instead of scaling the work RVUs to maintain overall relativity. The practical effect of a positive adjustment to the CF is that the value of a single work RVU is greater than it previously had been. In other words, the relative value of the other work RVUs has increased, across the PFS, whenever we apply a positive budget neutrality adjustment to the CF to account for an overall decrease in work RVUs.

Comment: A few commenters, including the RUC, stated that they appreciate CMS agreeing with the RUC's assertion that the usage of time ratios to reduce work RVUs is typically not appropriate, as often a change in physician time coincides with a change in the physician work intensity per minute. The commenters stated that CMS acknowledges that physician work intensity per minute is typically not linear and also that making reductions in RVUs in strict proportion to changes in time is inappropriate.

Response: We do not agree with the commenters' characterization of our statements, and believe it misinterprets our view on this matter. We specifically stated in the CY 2017 proposed rule that we are not implying that the decrease in time as reflected in survey values must necessarily equate to a one-to-one or linear decrease in newly valued work RVUs, given that intensity for any given procedure may change over several years or within the intraservice period. Nevertheless, we believe that since the two components of work are time and intensity, that absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has specifically increased or that the reduction in time is disproportionally from less-intensive portions of the procedure, that significant decreases in time should generally be reflected in decreases to work RVUs.

Comment: A few commenters, including the RUC, stated that they wanted to remind CMS of the Agency's and the RUC's longstanding position that treating all components of physician time as having identical intensity is incorrect, and inconsistently applying this treatment to only certain services under review creates inherent payment disparities in a payment system that is based on relative valuation. The commenters stated that when physician times are updated in the fee schedule, the ratio of intra-service time to total time, the number and level of bundled post-operative visits, the length of pre-service, and the length of immediate post-service time may all potentially change for the same service. These changing components of physician time result in the physician work intensity per minute often changing when physician time also changes, and the commenters recommended that CMS always account for these nuanced variables. A few commenters also stated that the RUC recommendations now explicitly state when physician time has changed and address whether and to what magnitude these changes in time impact the work involved.

Response: We appreciate the commenters' feedback. We understand that not all components of physician time have identical intensity and are mindful of this point when we are determining what the appropriate work RVU values should be. We also agree that the nuanced variables involved in the changing components of physician time must be accounted for, and it is our goal to do so when determining the appropriate valuation. We appreciate when the RUC recommendations provide as much detailed information regarding the recommended valuations as possible, including thorough discussions regarding physician time changes and how the RUC believes such changes should or should not impact the work involved, and we consider that information when conducting our review of each code.

Comment: A few commenters stated that CMS places undue emphasis on time and not enough emphasis on intensity or whether a value is appropriately ranked in the Medicare fee schedule. The commenters stated that CMS ignores compelling evidence that work has changed if the time has not also changed, and that CMS uses codes as supporting references for new lower values that make no clinical sense. The commenters urged CMS to always consider all elements of relative work in every review, including time, relative intensity and relative work.

Response: We disagree with commenters' statement that CMS ignores compelling evidence that work has changed if the time has not also changed. As previously stated, we are not making refinements solely in consideration of time, and if that were the case, changes in work RVU values that we adopted would consistently be comparable to the changes in the time that we adopted, and that is not the case. It is our practice to consider all elements of the relative work when we are reviewing and determining work RVU valuations. Additionally, our review of recommended work RVUs and time inputs generally includes review of various sources such as information provided by the RUC, other public commenters, medical literature, and comparative databases.

Comment: A few commenters, including the RUC, stated that they do not agree with any suggested methodology to use a reverse building block methodology to systematically

reduce work RVUs for services. The commenters stated that any purely formulaic approach should never be used as the primary methodology to value services, and that it is highly inappropriate due to the fact that magnitude estimation was used to establish work RVUs for services.

Response: We note that a formulaic approach is not being used as the primary methodology to value services. Instead, we use various methodologies to identify values to consider relative to other PFS services. We reiterate that we use the RUC-recommended values or the existing values as the base values. We then apply adjustments to the RUC-recommended values where, for example, the RUC's recommendations do not account for changes in time.

Comment: Another commenter stated that the establishment of a time formula or use of reverse building block methodology as the primary method for valuation would completely disregard the possibility that physicians actually get better at what they do in favor of the erroneous conclusion that physicians only find new ways to cut corners. The commenter provided an example to demonstrate why time alone does not create value, and it is instead just one component of valuation. The commenter described an example of two watchmakers that make watches at different rates—one makes two watches per day, the other makes four watches per day. Each watch involves the same number of gears, sprockets, jewels, and escapements. One watchmaker is faster than the other: More focused, more experienced, more agile, and able to accomplish fastidious work more efficiently. At the end of one workday, the first watchmaker has two finished watches on the bench, while the other has four. The commenter questioned that if the watches are identical, why should the faster (better) watchmaker be paid half the price for each watch?

Response: We understand some stakeholders' interest in the maintenance of work RVUs regardless of efficiencies gained. The work RVU is not a measure of our appreciation for the work ethic of the physician. Instead, the work RVU reflects the time and intensity of a particular service relative to others on the PFS. For this reason, we do not agree with the implication that we should ignore efficiencies in time, and instead believe that we are obligated to recognize when efficiencies change the relative resource costs involved in particular procedures. Of course, such efficiencies can occur as physicians become more proficient and can therefore complete a service or procedure in less time. We believe that time is a tangible resource, particularly the time of a physician or other practitioner paid on the PFS, and the statute specifically identifies it as such.

Comment: A few commenters urged CMS to always enlist the assistance of medical officers familiar with procedures under review to examine CMS staff recommendations that reject the RUC recommendation. Similarly, a few commenters also urged CMS to work with the RUC to ensure that the robust discussions and key points that are discussed during RUC meetings are transferred to CMS in a way that is meaningful to staff to develop the proposed relative value recommendations.

Response: We note that the values proposed by CMS are developed through consultation with, and input from CMS staff including medical officers, who often attend RUC meetings as observers, and therefore, have had the opportunity to listen to the discussions that take place and key points that are raised during the RUC meetings.

Comment: One commenter stated that the recent rejections of RUC recommendations by CMS to instead reduce the work RVUs for almost every code, even if only by one or two percent, are illogical.

Response: We do not agree with the suggestion that we reject the RUC-recommended values for most codes. Furthermore, given the numerical specificity of the RUC-recommended values and that so many PFS services reviewed under the misvalued code initiative are high-volume, we do not believe that relatively minor adjustments are unimportant or illogical because a minor adjustment to the work RVU of a high-volume code may have a significant dollar impact. However, we would be interested to know if stakeholders generally agree that the RUC-recommended values represent only rough estimates, and because of that belief, minor refinements would be considered illogical, as indicated by the commenter.

Comment: A few commenters stated that they are concerned with the CMS trend to discredit intensity when assigning work RVUs to procedures. These commenters stated that intensity is a key factor when specialties are making work RVU recommendations and needs to remain an equal force along with time in the relative value system. One commenter stated that it is concerned that CMS is repeatedly ignoring intensity discussions and picking arbitrary crosswalks to justify lowering work RVU values. One commenter stated that by placing the same value on clearly different services that vary both in intensity and in types of patients treated, CMS ignores its statutory requirement to consider time and intensity in the valuation of services. One commenter stated that CMS does not mention how it considers, weights or measures intensity, and there is no validity to the assumption that reduced time equals less work. The commenter stated that it found no published evidence supporting this, and states that if the same amount of work is performed for a shorter period of time, it is logical that the intensity of work per unit of time increases. The commenter stated that CMS must be transparent and demonstrate why current intensity measurements are not appropriate, and if there is a more accurate way to measure intensity, this must be clearly elucidated with evidence for superiority of the alternative proposal.

Response: We disagree that we discredit intensity when we establish work RVUs for procedures. We reiterate that we use RUC-recommended values or existing values, which we understand to incorporate an assessment of intensity, as the base values, and then subsequently apply adjustments as necessary. Additionally, as we have previously stated, we recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work. Additionally, if we were to disregard intensity altogether, the work RVUs for all services would be developed solely based on time values, and that is absolutely not the case. We have previously stated that in cases where the RUC's recommendations do not account for changes in time, but do provide a persuasive explanation regarding why the time has drastically changed but the work RVU value has remained the same, our tendency has been to use those values as recommended. When the RUC's recommendations do not account for changes in time, and provide no explanation as to why this is appropriate, we have made changes to the RUC-recommended values to account for changes in time.

We also disagree that we ignore the statutory requirement to consider time and intensity in the valuation of services. Based on the assessments of CMS medical officers and other reviewers, as well as upon consideration of the survey results, and the rationales in the recommendations, we make determinations about the overall work valuations. We acknowledge that the degree to which intensity varies among different procedures is a relatively subjective assessment, and we understand that sometimes stakeholders

may have a different perspective in cases where the intensities of procedures differ. We recognize that the IWPUT measure is a derived value with specific uses for quantifying intensity. However, the limited way in which that derived value is used under the RUC valuation process, we believe reflects a general consensus that there are not widely accepted metrics for intensity. As a part of recommendations for misvalued codes, we welcome any information from stakeholders for us to more objectively measure intensity.

Comment: A few commenters stated that they are concerned with the current implied methodology that the 25th survey percentile is the ceiling for RUC recommendations, and stated that if codes are continually sent forth for re-survey and the 25th percentile is the ceiling, a built in reduction is applied to all surveyed codes just by the nature of surveying the codes, regardless of other factors.

Response: We disagree with commenters' statement that the 25th survey percentile is the ceiling for RUC recommendations. We note that, as previously stated in the CY 2011 final rule with comment period (75 FR 73328), we had concerns that surveys conducted on existing codes produced predictable results, and upon clinical review of a number of these situations, we were concerned over the validity of the survey results since the survey values often were very close to the current code values. Increasingly, the RUC is choosing to recommend the 25th percentile survey value, potentially responding to the same concern we have identified, rather than recommending the median survey value that had historically been the most commonly used. We reiterate that this does not designate the 25th percentile as the ceiling, rather suggests that in many instances the 25th percentile is the most appropriate since it is more frequently being identified through the RUC process as the recommended value.

Comment: One commenter stated that the time data obtained through the RUC survey process based on subjective physician perceptions of time, may not be the most accurate data available on intraoperative time. The commenter stated that CMS should be open to reviewing additional sources of objective validated time data, and that such sources might include peer reviewed and published studies of comparative surgery times amongst different procedures in the same institution using standardized metrics. Another commenter stated that if CMS seeks specific information to substantiate time and intensity changes associated with services, they should specify these clearly so stakeholders can provide the necessary data detailing changes over time.

Response: As previously discussed, our review of work RVUs and time inputs utilizes information from various resources. It 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 comparison with other codes with the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. Additionally, 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. However, we continue to seek information regarding the best sources of objective, routinely-updated, auditable, and robust data regarding the resource costs of furnishing PFS services.

We thank the commenters for their feedback. We did not receive any comments regarding specific potential alternatives to making the adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services as requested. However, we appreciate the commenters' sharing their concerns and suggestions and will continue to consider them as we continue examining the valuation of services, and as we explore the best way to address these issues.

3. Requests for Refinement Panel

Consistent with the policy finalized in the CY 2016 PFS final rule with comment period, we have retained the Refinement Panel process for use with codes with interim final values where additional input by the panel is likely to add value as a supplement to notice and comment rulemaking. Because there are no codes with interim final values in this final rule, the refinement panel is not necessary for CY 2017. We note that many commenters requested inclusion of codes with proposed values for a refinement panel. While these requests are not consistent with our established process, given the number of requests we received, we are addressing them here. Many commenters appear to believe that that the purpose of the refinement panel process was to serve as a kind of ''appeals'' or reconsideration process outside of notice and comment rulemaking and that we have effectively eliminated a useful appeals process. We understand that the refinement panel has been perceived as an appeals process by many stakeholders. However, as we have previously clarified, the purpose of the refinement panel process was to assist us in reviewing the public comments on CPT codes with interim final work RVUs and to consider more fully the interests of the specialty societies who provide input on RVU work time and intensity with the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services. From our perspective, the objective of the refinement panel has long been to provide a needed venue for stakeholders to present any new clinical information that was not available at the time of the RUC valuation for interim final values in order that we arrive at the most appropriate final valuation, especially since the initial values for such codes were generally established approximately 2 months prior to being used for Medicare payment. In recent years, we have continually observed that the material presented to the refinement panel largely raised and discussed issues and perspective already included as part of the RUC meetings and considered by us.

We believe that our new process, in which we propose the vast majority of code values in the proposed rule for public comment on those proposed values prior to their taking effect, provides stakeholders and the public with several opportunities to present data or information that might affect code valuation. We believe that this is generally consistent with the purpose of the rulemaking process and reflects our efforts to increase transparency and accountability to the public. We also note that we continue to seek new information that is relevant to valuation of particular services, including those with values recently finalized, for use in future rulemaking. We believe that notice and comment rulemaking provides the most appropriate means for valuing services under the PFS. We note that in several instances in this final rule, thoughtful and informative comments have helped us to finalize values for CY 2017 that we believe are improved from those we had proposed. In many cases, these changes reflect the RUC-recommended value. Therefore, we urge commenters to review this information and continue to consider how we might continue to improve the notice and comment rulemaking process rather than establish a process outside of notice and comment rulemaking.

Table 27 contains a list of codes for which we proposed work RVUs; this includes all RUC recommendations received by February 10, 2016, and

codes for which we established interim final values in the CY 2016 PFS final rule with comment period. When the proposed work RVUs vary from those recommended by the RUC or for which we do not have RUC recommendations, we address those codes in the portions of this section that are dedicated to particular codes. The final work RVUs and work time and other payment information for all CY 2017 payable codes are available on the CMS Web site under downloads for the CY 2017 PFS final rule at *http://www.cms.gov/physicianfeesched/downloads/*.

4. 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, 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 28 details our finalized refinements of the RUC's direct PE recommendations at the code-specific level. In this final 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 $0.32 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 28 result in changes under the $0.32 threshold and are unlikely to result in a change to the proposed RVUs.

We also note that the final direct PE inputs for CY 2017 are displayed in the CY 2017 direct PE input database, available on the CMS Web site under the downloads for the CY 2017 final rule at *www.cms.gov/PhysicianFeeSched/*. The inputs displayed there have also been used in developing the final CY 2017 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.

In general, clinical labor tasks fall into one of the categories on the PE worksheets. In cases where tasks cannot be attributed to an existing category, the tasks are labeled ''other clinical activity.'' We believe that continual addition of new and distinct clinical labor tasks each time a code is reviewed under the misvalued code initiative is likely to degrade relativity between newly reviewed services and those with already existing inputs. This is because codes more recently reviewed would be more likely to have a greater number of clinical labor tasks as a result of the general tendency to increase the number of clinical labor tasks. To mitigate the potential negative impact of these additions, we review these tasks to determine whether they are fully distinct from existing clinical labor tasks, typically included for other clinically similar services under the PFS, and thoroughly explained in the recommendation. For those tasks that do not meet these criteria, we do not accept these newly recommended clinical labor tasks.

(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 2017, we received invoices for several new supply and equipment items. Tables 30 and 31 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.A. of this final 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 final 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 30 and 31 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 2017 are available on the CMS Web site under downloads for the CY 2017 PFS final rule at *http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html*.

4. Specialty-Mix Assumptions for Proposed Malpractice RVUs

The final CY 2017 malpractice crosswalk table is displayed in the public use files for the PFS final rule. The public use files for CY 2017 are available on the CMS Web site under downloads for the CY 2017 PFS final rule at *http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html*. The table lists the CY 2017 HCPCS codes and their respective source codes used to set the final CY 2017 MP RVUs where the

source code for this calculation deviates from the source code for the utilization otherwise used for purposes of PFS ratesetting. The MP RVUs for all PFS services and the utilization crosswalk used to identify the source codes for all other codes are reflected in Addendum B on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

5. Valuation of Specific Codes

(1) Anesthesia Services Furnished in Conjunction With Lower Gastrointestinal (GI) Procedures (CPT Codes 00740 and 00810)

CPT codes 00740 and 00810 are used to report anesthesia furnished in conjunction with lower gastrointestinal (GI) procedures. 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 the relative frequency with which anesthesia codes are reported with colonoscopy services, we believed the relative values of the anesthesia services should be reexamined. We proposed to identify CPT codes 00740 and 00810 as potentially misvalued and sought public comment regarding valuation for these services.

The RUC recommended maintaining the base unit value of 5 as an interim base value for both CPT code 00740 and 00810 on an interim basis, due to their concerns about the specialty societies' surveys. The RUC suggested that the typical patient vignettes used in the surveys for both CPT codes 00740 and 00810 were not representative of current typical practice and recommended that the codes be resurveyed with updated vignettes. We stated in the CY 2017 proposed rule that we believed it premature to propose any changes to the valuation of CPT codes 00740 and 00810, continued to believe that these services are potentially misvalued, and sought additional input from stakeholders for consideration during future rulemaking.

Comment: Commenters were supportive of CMS' proposal to maintain the current values for CPT codes 00740 and 00810 for CY 2017. One commenter requested that CMS ensure that reimbursement for anesthesia services remains adequate to compensate providers for the cost of furnishing these services. Commenters also stated that due to greater complexity of furnishing anesthesia services compared to moderate sedation, payment for anesthesia services should not be lower than the values established for moderate sedation.

One commenter stated that CMS' perception that these codes are misvalued is related to the distinction between screening, diagnostic, and therapeutic endoscopies. The commenter further stated that there are no differences in the clinical risk and anesthesia preparation regardless of the indication for these procedures and suggested that the current base unit value of 5 units for CPT codes 00740 and 00810 is appropriate and should be maintained. Another commenter stated that the frequency of use of separate anesthesia services concurrent with colonoscopy procedures is not due to any potential misvaluation, but rather due to changes in Medicare coverage and payment policies that encourage Medicare beneficiaries to undergo screening colonoscopies.

Response: We appreciate the information provided by commenters. We continue to encourage feedback from interested parties and specialty societies, all of which we will take under consideration for future rulemaking.

(2) Soft Tissue Localization (CPT Codes 10035 and 10036)

In the CY 2016 PFS final rule with comment period, we established the RUC-recommended work value as interim final for CPT codes 10035 and 10036. We also made standard refinements to remove duplicative clinical labor and utilize standard equipment time formulas for the PACS workstation proxy (ED050).

Comment on the CY 2016 PFS final rule with comment period: A commenter stated that the clinical labor task ''Review/read X-ray, lab, and pathology reports'' occurs during the preservice period, and it is a separate activity than ''Review examination with interpreting MD'', which occurs during the service period.

Response in the CY 2017 PFS proposed rule: We continued to believe that the clinical labor was duplicative with the clinical labor for ''Review examination with interpreting MD'' because we believed that the two descriptors detailed the same clinical labor activity taking place, rather than two separate and distinct tasks.

In the CY 2017 proposed rule, we proposed to maintain our previous refinement to 0 minutes for this clinical labor task for CPT codes 10035 and 10036. We also proposed to maintain the interim final work RVUs for CPT codes 10035 and 10036.

We did not receive any comments in response to our proposed valuation on CPT codes 10035 and 10036 and we are finalizing the clinical labor task and work RVUs as proposed.

(3) Removal of Nail Plate (CPT Code 11730)

We identified CPT code 11730 through a screen of high expenditures by specialty. The HCPAC recommended a work RVU of 1.10. We believed the recommendation for this service overestimates the work involved in performing this procedure, specifically given the decrease in physician intraservice and total time concurrently recommended by the HCPAC. We believed that a work RVU of 1.05, which corresponds to the 25th percentile of the survey results, more accurately represents the time and intensity of furnishing the service. To further support the validity of the use of the 25th percentile of the survey, we identified two crosswalk codes, CPT code 20606 (Arthrocentesis, aspiration and/or injection, intermediate joint or bursa), with a work RVU of 1.00, and CPT code 50389 (Removal of nephrostomy tube, requiring fluoroscopic guidance), with a work RVU of 1.10, both of which have identical intraservice times, similar total times and similar intensity. We noted that our proposed work RVU of 1.05 for CPT code 11730 falls halfway between the work RVUs for these two crosswalk codes. CPT code 11730 may be reported with add-on CPT code 11732 to report performance of the same procedure for each additional nail plate procedure.

Since CPT code 11732 was not reviewed by the HCPAC for CY 2017, we proposed a new work value to maintain the consistency of this add-on code with the base code, CPT code 11730. We proposed to remove 2 minutes from the physician intraservice time to maintain consistency with the HCPAC-recommended reduction of 2 minutes from the physician intraservice time period for the base code. We are using a crosswalk from the value for CPT code 77001 (Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (List separately in addition to code for primary procedure)), which has similar physician intraservice and total time values; therefore, we proposed a

work RVU of 0.38 for CPT code 11732. As further support for this proposal, we noted that this proposed RVU reduction is similar to the value obtained by subtracting the incremental difference in the current and recommended work RVUs for the base code from the current value of CPT code 11732.

We proposed to use the HCPAC-recommended direct PE inputs for CPT code 11730. We proposed to apply some of the HCPAC-recommended refinements for CPT code 11730 to CPT code 11732, including the removal of the penrose drain (0.25 in × 4 in), lidocaine 1%–2% inj (Xylocaine), applicator (cotton-tipped, sterile) and silver sulfadiazene cream (Silvadene), as well as the reduction of the swab-pad, alcohol from 2 to 1. In addition, we proposed not to include the recommended supply items ''needle, 30g, and syringe, 10–12ml'' since other similar items are present, and we believe inclusion of these additional supply items would be duplicative. For clinical labor, we proposed to assign 8 minutes to ''Assist physician in performing procedure'' to maintain a reduction that is proportionate to that recommended for CPT code 11730. For the supply item ''ethyl chloride spray,'' we believed that the listed input price of $4.40 per ounce overestimates the cost of this supply item, and we solicited comment on the accuracy of this supply item price. Finally, we proposed to add two equipment items as was done in the base code, basic instrument pack and mayo stand, and proposed to adjust the times for all pieces of equipment to eight minutes to reflect the clinical service period time.

Comment: A commenter states that the work for CPT code 11730 has not changed since the previous recommendation, thus maintenance of a work RVU of 1.10 is proper.

Response: We continue to believe that the HCPAC-recommended reduction in intraservice and total time supports a reduction in our estimation of the physician work value of furnishing this service.

Comment: The HCPAC stated that it did not support the proposed decrease in the work RVU for CPT code 11732.

Response: We welcome any additional input as to the appropriate valuation of CPT code 11732. At this time, we continue to believe that a work RVU of 0.38 is appropriate, considering its relationship to CPT code 11730. We proposed values for CPT code 11732 based on its being an add-on code for CPT code 11730. We remind commenters and stakeholders that they may nominate this code family as potentially misvalued if they believe that both codes should be evaluated through the standard process, which would involve use of physician survey data and input from the HCPAC for both codes. We are finalizing work RVUs of 1.05 for CPT code 11730 and 0.38 for CPT code 11732, as well as the proposed PE refinements.

(4) Bone Biopsy Excisional (CPT Code 20245)

In CY 2014, CPT code 20245 was identified by the RUC's 10-Day Global Post-Operative Visits Screen.

For CY 2017, the RUC recommended a work RVU of 6.50 for CPT code 20245, including a change in global period from 10 to 0 days. We disagreed with this value given the significant reductions in the intraservice time, total time, and the change in the office visits assuming the change in global period. The intraservice and total times were decreased by approximately 33 and 53 percent respectively; while the elimination of three post-operative visits (one CPT code 99214 and two CPT code 99213 visits) alone would reduce the overall work RVU by at least 38 percent under the reverse building block methodology. We also note that the RUC-recommended work RVU of 6.50 only represents a 27 percent reduction relative to the previous work RVU of 8.95. To develop a work RVU for this service, we used a crosswalk from CPT code 19298 (Placement of radiotherapy after loading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance), since we believe the codes share similar intensity and total time and the same intraservice time of 60 minutes. Therefore, for CY 2017, we proposed a work RVU of 6.00 for CPT code 20245.

Comments: Several commenters, including the RUC, stated their objection to the proposed crosswalk, indicating that it underestimated the total time by 10 minutes and the physician work involved in furnishing the service. Commenters recommended CMS accept the RUC-recommended work RVU of 6.50.

The RUC also noted the current time of CPT code 20245 was based on a survey of 35 individuals more than 15 years ago and due to the previous flawed survey, the resulting IWPUT was almost zero. Given these discrepancies, the surveyed time of 60 minutes better reflects an appropriate level of intensity and complexity (IWPUT= 0.071) for this service relative to other 0-day global procedures.

Another commenter stated concern that the values proposed by CMS have been arrived at using methodologies that are not consistent with the RUC-recommended values, and therefore, are not appropriately relative to other similar services.

Response: Thank you for your comments. We present the information in Table 16 to illustrate the differences between the CMS crosswalked code and the additional RUC comparator codes.

TABLE 16—CROSSWALK FOR CPT CODE 20245

CPT code	Descriptor	Intra-service time	Total time	Work RVU
20245	Bone Biopsy Excisional	60	160	*6.50
19298	Place Breast Rad Tube/Cath	60	169	6.00
36247	Ins Cath ABDL/-Ext Art 3RD	60	131	6.29
43262	Endocholangiopancreatograp	60	138	6.60

*RUC recommended value.

Although the total times for CPT codes 19298 and 20245 are not identical, we continue to believe it is a more accurate comparison than the additional codes submitted by the RUC, which have 22–29 minutes less total time.

We note that according to the most recent survey, respondents lowered the work RVU of the 25th percentile, which we typically accept, from 6.06 RVUs to 4.94 RVUs when the code was revalued with a 0-day global period.

For CY 2017, we are finalizing the work RVU of 6.00 for CPT code 20245.

(5) Insertion of Spinal Stability Distractive Device (CPT Codes 22867, 22868, 22869, and 22870)

For CY 2016, the CPT Editorial Panel converted two Category III codes to Category I codes describing the insertion of an interlaminar/interspinous process stability device (CPT codes 22867 and 22869) and developed two corresponding add-on codes (CPT codes 22868 and 22870). The RUC recommended a work RVU of 15.00 for CPT code 22867, 4.00 for CPT code 22868, 7.39 for CPT code 22869, and 2.34 for CPT code 22870.

We believe that the RUC recommendations for CPT codes 22867 and 22869 overestimate the work involved in furnishing these services. We believe that a crosswalk to CPT code 36832 (Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)), which has a work RVU of 13.50 is a more accurate comparison. CPT code 36832 is similar in total time, work intensity, and number of visits to CPT code 22867. This crosswalk is supported by the ratio between total time and work in the key reference service, CPT code 63047 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar). Therefore, we proposed a work RVU of 13.50 for CPT code 22867. For CPT code 22869, we believed that CPT code 29881 (Arthroscopy, knee, surgical; with meniscectomy (medial OR lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed) is an appropriate crosswalk based on clinical similarity, as well as intensity and total time. CPT code 29881 has a work RVU of 7.03; therefore, we proposed a work RVU of 7.03 for CPT code 22869. We proposed the RUC-recommended work RVU for CPT codes 22868 and 22870 without refinement.

Comment: Several commenters disagreed with our proposed valuation of the work RVU for CPT codes 22867 and 22869. They stated that the RUC crosswalk for each of these codes, respectively, is either identical to or a better match than the proposed CMS crosswalk.

Response: We recognize that the RUC crosswalk of CPT code 29915 for CPT code 22867 has a total time that is more similar to the new code than the crosswalk we proposed (CPT code 36832). We consider multiple factors when identifying appropriate crosswalk codes. We note that RUC's crosswalk, CPT code 29915, had very low service utilization, 355 in 2015, and was last reviewed by CMS and the RUC in April 2010. CPT code 36832, in contrast, had service utilization of 21,529 in 2015, and was most recently reviewed in October 2013. We considered the combination of these factors in choosing a crosswalk and determining a proposed work RVU. Commenters did not present any additional clinical information or data about this code that would lead us to reconsider our proposed valuation; therefore, we are finalizing the work RVU of 13.50 for CPT code 22867.

With regard to CPT code 22869, we disagree that the RUC crosswalk to CPT code 29880 is a closer comparison than CPT code 29881. The intraservice time for the newly created CPT code 22869 (43 minutes) is between that of the RUC recommended crosswalk CPT code 29880 (45 minutes) and the CMS crosswalk CPTcode 29881 (40 minutes). Total time for CPT code 29881, however, is identical to total time for CPT code 22869 (194 minutes), whereas the RUC recommended crosswalk CPT code 29880 has a higher total time (199 minutes). We continue to believe, therefore, that our crosswalk is appropriate and we are finalizing the proposed work RVU of 7.03 for CPT code 22869.

(6) Biomechanical Device Insertion (CPT Codes 22853, 22854, and 22859)

For CY 2016, the CPT Editorial Panel established three new Category I add-on codes and deleted one code to provide a more detailed description of the placement and attachment of biomechanical spinal devices. For CPT code 22853, the RUC recommended a work RVU of 4.88. For CPT codes 22854 and 22859, the RUC-recommended work RVUs are 5.50 and 6.00, respectively.

In reviewing the code descriptors, descriptions of work and vignettes associated with CPT codes 22854 and 22859, we concluded that the two procedures, in addition to having identical work time, contain many clinical similarities and do not have quantifiable differences in overall intensity. Therefore, we proposed the RUC-recommended work RVU of 5.50 for both CPT code 22854 and CPT code 22859. We believe that the RUC-recommended work RVU of 4.88 for CPT code 22853 overestimates the work in the procedure relative to the other codes in the family. We proposed a work RVU of 4.25 for CPT code 22853 based a crosswalk from CPT code 37237 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery (List separately in addition to code for primary procedure)), which is similar in time and intensity to the work described by CPT code 22853.

Comment: Several commenters disagreed with our proposed valuation of the work RVU of 4.25 for CPT code 22853 rather than the RUC-recommended work RVU of 4.88. They requested clarification regarding our crosswalk for this new code to CPT code 37237 instead of the RUC-recommended crosswalk of CPT code 57267.

Response: We take many factors into consideration when valuing a work RVU for a new code. We note that CPT code 57267 and CPT code 37237 have identical intraservice times and very similar total work times. We note that CPT code 37237 was most recently valued in April 2013, whereas the RUC crosswalk CPT code 57267 was last reviewed in 2004. We continue to believe that CPT code 37237 is an appropriate crosswalk for valuing the new CPT code 22859. Therefore, we are finalizing our proposed work RVU of 4.25 for CPT code 22853.

Comment: We received several comments objecting to our proposed work RVU of 5.50 for CPT code 22859, which is identical to the work RVU proposed by the RUC and accepted by CMS for CPT code 22854. Commenters provided detailed descriptions of the two procedures in an effort to demonstrate the higher intensity required by CPT code 22859 compared with CPT code 22854, thereby justifying the RUC-recommended work RVU of 6.00 for CPT code 22859. Several commenters expressed confusion about the descriptors for all three of the new CPT codes (CPT codes 22853, 22854, and 22859), in general, and stated their concern that the code descriptors do not clearly differentiate the work involved in furnishing the services.

Response: While we are somewhat persuaded by commenters' detailed descriptions of the two procedures and the higher intensity of work involved in furnishing CPT code 22859 compared with CPT code 22854, we are concerned about a substantive disagreement between the RUC and survey respondents about the intensities of work involved in furnishing the services described by these new codes. The RUC and the survey respondents valued the

relative intensities of the two codes in the reverse order. The survey results indicated a work RVU of 8.16 (with 25th percentile of 7.0) for CPT code 22854 and a work RVU of 8.0 (with 25th percentile of 6.0) for CPT code 22859. The RUC reviewed the survey results and agreed that respondents overvalued the work involved in performing CPT code 22854. The RUC-recommended work RVU for CPT code 22854, which we are accepting as recommended, was established through a crosswalk to CPT code 37234. We agree that this is an appropriate crosswalk and valuation of this service. For CPT code 22859, the RUC also believed that the survey recommended work RVU of 8.0 was overvalued. The RUC recommended the 25th percentile of survey results, with a work RVU of 6.0. We find it difficult to reconcile the conflicting valuations by the survey and the RUC of the absolute and relative intensity of these new codes.

In addition to the survey results and RUC recommendations, we reviewed the descriptors of these codes and agree with commenters who found them vague and unclear. We share the concern of stakeholders who indicated that the lack of differentiation in the codes may lead to inconsistent use and reporting.

Given the disagreement between the RUC and survey respondents regarding the order and level of intensity of these services, along with confusion about the code descriptors, we find that valuing the services of 22854 and 22859 differently from each another is difficult to justify. Therefore, we are finalizing our proposed work RVU of 5.50 for CPT code 22859.

(7) Repair Flexor Tendon (CPT Codes 26356, 26357, and 26358)

In the CY 2016 PFS final rule with comment period, we established an interim final work RVU of 9.56 for CPT code 26356 after considering both its similarity in time to CPT code 25607 (Open treatment of distal radial extra-articular fracture) and the recommended reduction in time relative to the current times assumed for this procedure. We established an interim final work RVU of 10.53 for CPT code 26357 based on a direct crosswalk from CPT code 27654 (Repair, secondary, Achilles tendon, with or without graft), as we believed that this work RVU better reflected the changes in time for this procedure. For the last code in the family, we established an interim final work RVU of 12.13 for CPT code 26358, based on the RUC-recommended increment of 1.60 work RVUs relative to CPT code 26357.

Comment on the CY 2016 PFS final rule with comment period: We received several comments regarding the interim final work values for this family of codes. One commenter stated that it was inappropriate to use time ratios to evaluate CPT code 26356 as it was last valued in 1995, noting that there was an anomalous relationship between the current work RVU and the imputed time components in the RUC database. This commenter also pointed out that when the previous time was developed, fabrication of a splint was considered to be part of the intraservice work, while in the current survey instrument, the fabrication of the splint is considered to be part of the postservice work since it is a dressing. This commenter urged CMS to adopt the RUC recommendations. A different commenter agreed that the CMS crosswalk to CPT code 25607 was an appropriate crosswalk for CPT code 26356 and supported the CMS work RVU of 9.56.

Response in the CY 2017 PFS proposed rule: We appreciate the support from the commenter. We continue to believe that our crosswalk for this code is an appropriate choice, due to our estimate of overall work between CPT code 26356 and CPT code 25607. We appreciate the commenters' concerns regarding the time ratio methodologies and have responded to these concerns about our methodology in section II.L of this final rule. Although we note the commenter's statement about how the service period in which fabrication of a splint takes place may have evolved over time, we do not agree that this task would be responsible for a decrease in intraservice survey time, as the postservice survey time for CPT code 26356 remained unchanged at 30 minutes. If the decrease in intraservice time had been due to the shift of splinting from the intraservice period to the postservice period, then we would have expected to see an increase in the postservice period minutes. However, they remained exactly the same in the physician survey for CPT 26356. As we wrote earlier in this section, we believe in the validity of using pre-existing time values as a point of comparison, and we believe that we should account for efficiencies in time when the recommended work RVU does not account for those efficiencies. After consideration of comments received, we proposed to maintain CPT code 26356 at its current work RVU of 9.56 for CY 2017.

Comment on the CY 2016 PFS final rule with comment period: Several commenters disagreed with the work RVU for CPT code 26357. One commenter stated that the CMS crosswalk to CPT code 27654 had less total time and resulted in an inappropriately lower derived intensity. This commenter urged CMS to adopt the RUC-recommended work value. Another commenter stated that a better crosswalk for CPT code 26357 would be CPT code 25608 (Open treatment of distal radial intra-articular fracture or epiphyseal separation), the next code in the same upper extremity family that CMS used for the initial crosswalk. This commenter stated that the CMS crosswalk for CPT code 26357 created a rank order anomaly in terms of intensity within this family, and that the commenter's suggested crosswalk would create two pairs of matched codes, survey CPT codes 26356/26357 with crosswalk CPT codes 25607/25608.

Response in the CY 2017 PFS proposed rule: We appreciate the suggested crosswalk from the commenters, and we agree that the choice of the initial CMS crosswalk creates a rank order anomaly within the family in terms of intensity. As a result, after consideration of comments received, we proposed to instead value CPT code 26357 at the 25th percentile survey work RVU of 11.00 for CY 2017. This valuation corrects the anomalous intensity within the Repair Flexor Tendon family of codes, and preserves the RUC-recommended increment between CPT codes 26356 and 26357.

Comment on the CY 2016 PFS final rule with comment period: The commenters agreed that the RUC-recommended increment of 1.60 was appropriate for the work RVU of CPT code 26358 when added to the work RVU of CPT code 26357. However, commenters stated that this increment of 1.60 should be added to the RUC-recommended work value for CPT code 26357, and not the CMS refined value from the CY 2016 PFS final rule with comment period.

Response in the CY 2017 PFS proposed rule: We also continue to believe that the increment of 1.60 is appropriate for the work RVU of CPT code 26358. After consideration of comments received, we therefore proposed to set the work RVU for this code at 12.60 for CY 2017, based on the increment of 1.60 from CPT code 26357's proposed work RVU of 11.00.

In the CY 2017 proposed rule, we proposed to maintain the current direct PE inputs for all three codes.

The following is a summary of the comments we received regarding our proposed valuation of the Repair Flexor Tendon codes:

Comment: One commenter expressed support for the proposed work RVU for the flexor tendon codes.

Response: We appreciate the support from the commenters.

After consideration of comments received, we are finalizing our proposed valuation of the Repair Flexor Tendon codes.

(8) Closed Treatment of Pelvic Ring Fracture (CPT Codes 27197 and 27198)

For CY 2017, the CPT Editorial Panel deleted CPT codes 27193 and 27194 and replaced them with new CPT codes 27197 and 27198. The RUC recommended a work RVU of 5.50 for CPT code 27193, and a work RVU of 9.00 for CPT code 27198. We proposed to change the global period for these services from 90 days to 0 days because these codes typically represent emergent procedures with which injuries beyond pelvic ring fractures are likely to occur; we believe it is typical that multiple practitioners would be involved in providing post-operative care and it is likely that a practitioner furnishing a different procedure is more likely to be providing the majority of post-operative care. If other practitioners are typically furnishing care in the post-surgery period, we believe that the six post-service visits included in CPT code 27197, and the seven post-service visits included in CPT code 27198, would likely not occur. This is similar to our CY 2016 review and valuation of CPT codes 21811 (Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 1–3 ribs), 21812 (Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 4–6 ribs), and 21813 (Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 7 or more ribs). In our valuation of those codes, we determined that a 0-day, rather than a 90-day global period was preferable, in part because those codes describe rib fractures that would typically occur along with other injuries, and the patient would likely already be receiving post-operative care because of the other injuries. We believe that the same rationale applies here. To establish a work RVU for CPT code 27197, we proposed crosswalking this code to CPT code 65800 (Paracentesis of anterior chamber of eye (separate procedure); with removal of aqueous), due to its identical intraservice time and similar total time, after removing the work associated with postoperative visits, and its similar level of intensity. Therefore, we proposed a work RVU of 1.53 for CPT code 27197. For CPT code 27198, we proposed crosswalking this code to CPT code 93452 (Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed) which has an identical intraservice time and similar total time, after removing the work associated with post-operative visits from CPT code 27198. We proposed a work RVU of 4.75 for CPT code 27198.

Comment: Some commenters stated that the new coding for these services was designed, in part, to address the appropriateness of a 90-day global period by differentiating between higher energy and lower energy fractures. According to these commenters, the CPT Editorial Panel redefined these codes as treating injuries from higher energy and more unstable posterior pelvic ring injuries, and added a parenthetical directing physicians to use E/M billing for closed treatment of isolated lower energy fractures. These commenters say that the new coding clarifies when to use E/M coding for these services and when to bill these two codes. They state that these codes should thus remain valued with 90-day global periods while less complicated fractures will be billed with E/M coding.

Response: We took into consideration many factors when determining the appropriate global period of this service. While we understand that the new coding was partly designed to address the appropriateness of a 90-day global period, we continue to believe that a 0-day, rather than a 90-day, global period is more appropriate for this code, since we believe that the patient would likely already be receiving post-operative care because of other injuries. We also believe that the practitioner who performs the original procedure may not typically be performing the follow-up care, and shifting to a 0-day global period will allow the appropriate practitioner to report the follow up care, when appropriate.

Comment: A commenter stated that assigning a 0-day global period to this code will cause these codes to be different from all other closed fracture codes, which the commenter believes will lead to confusion for physicians and rank order anomalies.

Response: The commenter did not present sufficient information to explain why the variation in global periods for these kinds of services would uniquely cause rank order anomalies. We agree that it is preferable that codes for similar procedures have similar global periods; however, other factors specific to each code are taken into consideration when determining the appropriate global period. In the case of CPT codes 27197 and 27198, we continue to believe that the emergent nature inherent with the injuries considered typical would mean that other physicians would typically perform follow-up care. For detailed guidance on billing global surgical procedures, we direct readers to the Medicare Claims Processing Manual, Pub. 100–04; billing requirements and adjudication of claims requirements for global surgeries are under chapter 12, sections 40.2 and 40.4. We also note that if this procedure is billed concurrently with another procedure that is valued with a 10-day or 90-day global period, that the follow up visits associated with the latter procedure would occur as part of that package, while follow-up visits for these two codes would be reported using E/M coding.

Comment: A commenter states that, for procedures valued as part of a 90-day global period, the physician who is performing the primary portion of the treatment is obligated to follow the patient throughout the entire global period and furnish follow-up care.

Response: We understand the commenter's perspective that the treating physician is obligated to provide follow-up care within the global period; however, we do not believe that this necessitates the valuation of every surgical procedure with a 10-day or 90-day global period. While the treating physician would ideally provide follow-up care for these codes were they to be assigned 90-day global periods, we continue to believe that this would be an atypical situation for these types of treatments and for these types of injuries. We note that the assignment of a global period occurs in the process of evaluation of codes and we take into consideration factors specific to each procedure. There may be many instances when codes with similar procedures have different global periods. We are finalizing as proposed the work RVUs of 1.53 for CPT code 27197 and 4.75 for CPT code 27198, as well as an assignment of 0-day global periods.

(9) Bunionectomy (CPT Codes 28289, 28291, 28292, 28295, 28296, 28297, 28298, and 28299)

The RUC identified CPT code 28293 as a 90-day global service with more than 6 office visits and CPT codes 28290–28299 as part of the family of services. In October 2015, the CPT Editorial Panel created two new CPT codes (28291, 28295), deleted CPT codes 28290, 28293, and 28294 and revised CPT codes 28289, 28292, 28296,

28297, 28298 and 28299 based on the rationale that more accurate descriptions of the services needed to be developed.

For CPT codes 28289, 28292, 28296, 28297, 28298, and 28299, the RUC recommended and we proposed work RVUs of 6.90, 7.44, 8.25, 9.29, 7.75, and 9.29 respectively. For CPT code 28291, the RUC recommended a work RVU of 8.01 based on the 25th percentile of the survey. We believed the recommendation for this service overestimates the overall work involved in performing this procedure given the decrease in intraservice time, total time, and post-operative visits when compared to deleted predecessor CPT code 28293. Due to similarity in intraservice and total times, we believed a direct crosswalk of the work RVUs for CPT code 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers) to CPT code 28291 more accurately reflects the time and intensity of furnishing the service. Therefore, for CY 2017, we proposed a work RVU of 7.81 for CPT code 28291.

For CPT code 28295, the RUC recommended a work RVU of 8.57 based on the 25th percentile of the survey. We believed the recommendation for this service overestimates the work involved in performing this procedure given the similarity in the intensity of the services and identical intraservice and total times as CPT code 28296. Therefore, we proposed a direct RVU crosswalk from CPT code 28296 to CPT code 28295. For CY 2017, we proposed a work RVU of 8.25 for CPT code 28295.

Comments: A few commenters, including the RUC, objected to the proposed work RVUs for CPT codes 28291 and 28295. Commenters noted that deleted CPT code 28293 was marked by the RUC as ''not to use for validation of physician work''. The RUC noted the previous time was based on Harvard time and when reviewed in 1995, the RUC maintained the physician work and Harvard time because there was no compelling evidence to revise the value at that time.

The RUC acknowledged that the deleted CPT code 28293 had 30 minutes more intra-service time and a higher work RVU of 11.48 compared to the recommended work RVU of 8.01 for CPT code 28291. However, the RUC stated the differences in the physician work, time, intensity and the actual new service as described in CPT code 28291 were appropriately accounted for in its recommendation.

The RUC also stated disagreement with the proposed crosswalk of work RVUs from CPT code 28291 to CPT code 65780. The RUC stated it compared the family and relative ranking and believed CPT code 28291 was more complex and intense than CPT code 28298. The relative difference in work and complexity was reviewed and correctly ranked by the survey respondents at the 25th percentile, which corresponds with the RUC-recommended value.

One commenter stated that CPT code 28293 was deleted and a new CPT code was established because the two procedures were no longer synonymous. Also, the slight decrease in the intraoperative intensity with the new value is barely measurable, and therefore, the commenter does not agree with CMS that a work RVU of 7.81 is a more accurate valuation.

One commenter stated that CPT code 28295 is more intense than CPT code 28296 because CPT code 28295 requires separate areas of dissection. With CPT code 28296, the osteotomy and soft tissue procedure are performed at the same anatomic location. The commenter stated this nuance in complexity is the rationale for separate codes and is similar to the rationale for separate cervical versus lumbar spine codes or artery versus vein codes for vascular work.

Response: We appreciate additional information offered by the commenters. After consideration of comments received, we agreed with the additional information provided by commenters and are finalizing the RUC-recommend work RVUs of 6.90, 8.01, 7.44, 8.57, 8.25, 9.29, 7.75 and 9.29 for CPT codes 28289, 28291, 28292, 28295, 28296, 28297, 28298 and 28299; respectively.

(10) Endotracheal Intubation (CPT Code 31500)

In the CY 2016 PFS final rule with comment period (80 FR 70914), we identified CPT code 31500 as potentially misvalued. The specialty societies surveyed this code, and after reviewing the survey responses (which included increases in time) the RUC recommended a work RVU of 3.00 for CPT code 31500. After reviewing the RUC's recommendation, we proposed a work RVU of 2.66, based on a direct crosswalk to CPT code 65855 (Trabeculoplasty by laser surgery), which has similar intensity and service times.

Comment: Commenters requested that CMS finalize the RUC-recommended work RVU of 3.00 instead of CMS' proposed 2.66 work RVUs. The RUC stated that the surveyed median intraservice time is 10 minutes, representing a doubling of the current intraservice time of 5 minutes. Commenters also disagreed with CMS' proposed crosswalk from CPT code 65855. The RUC stated that given the emergent nature of the services reported with CPT code 31500, there are few relevant physician work and time-based comparisons within the resource-based relative value scale (RBRVS).

Response: We appreciate commenters' feedback on our proposal. As pointed out by the commenters, the survey data shows increased intraservice and total times for these services. We agree with commenters that due to the emergent nature of these services, there are few relevant physician work and time-based comparisons for this service. Therefore, due to the emergent nature of these services and service time increases, for CY 2017, we are finalizing a work RVU of 3.00 for CPT code 31500.

(11) Flexible Laryngoscopy (CPT Codes 31572, 31573, 31574, 31575, 31576, 31577, 31578, and 31579)

After we identified CPT codes 31575 and 31579 as potentially misvalued (80 FR 70912–70914), the RUC referred the entire flexible laryngoscopy family of codes back to the CPT Editorial Panel for revision and the addition of several codes representing new technology within this family of services. At the May 2015 CPT meeting, the CPT Editorial Panel added three new codes to describe laryngoscopy with ablation or destruction of lesion and therapeutic injection. Based on the survey results, the time resources involved in furnishing the procedures described by this code family experienced a significant reduction in the intraservice period, yet the recommended work RVUs were not similarly reduced. Therefore, in reviewing the recommended values for this family of codes we looked for a rationale for increased intensity and absent such rationale, proposed to adjust the recommend work RVUs to account for significant changes in time.

For CPT code 31575, we disagreed with the RUC-recommended work RVU of 1.00, and we instead proposed a work RVU of 0.94. We looked at the total time ratio for CPT code 31575, which is decreasing from 28 minutes to 24 minutes, and applied this ratio of 0.86 times the current work RVU of 1.10 to derive our proposed work RVU of 0.94. We supported this value for CPT code 31575 through a crosswalk to CPT code 64405 (Injection, anesthetic agent; greater occipital nerve), which shares 5 minutes of intraservice time and also has a work RVU of 0.94.

We agreed with the RUC that CPT code 31575 serves as the base code for the rest of the Flexible Laryngoscopy family. As a result, we proposed to

maintain the same RUC-recommended increments for the rest of the codes in this family, measuring the increments from CPT code 31575's refined work RVU of 0.94 instead of the RUC-recommended work RVU of 1.00. This meant that each of the work RVUs for the codes in the rest of the family decreased by 0.06 when compared to the RUC-recommended value. We therefore proposed a work RVU of 1.89 for CPT code 31576, a work RVU of 2.19 for CPT code 31577, a work RVU of 2.43 for CPT code 31578, a work RVU of 3.01 for CPT code 31572, a work RVU of 2.43 for CPT code 31573, a work RVU of 2.43 for CPT code 31574, and a work RVU of 1.88 for CPT code 31579.

Regarding the direct PE inputs, we proposed to use refined clinical labor time for ''Obtain vital signs'' for CPT codes 31577 and 31579 from 3 minutes to 2 minutes. We believe that this extra clinical labor time is duplicative, as these codes are typically performed with a same day E/M service. Each procedure is only allotted a maximum of 5 minutes for obtaining vital signs, and since 3 minutes are already included in the E/M code, we proposed to reduce the time to 2 minutes for these services. Similarly, we proposed to remove the 3 minutes of clinical labor time for ''Clean room/equipment by physician staff'' from CPT codes 31575, 31577, and 31579. These procedures are typically reported with a same day E/M service, making the clinical labor minutes for cleaning the room in these procedure codes duplicative of the time already included in the E/M codes.

For CPT code 31572, we proposed to remove the ''laser tip, diffuser fiber'' supply (SF030) and replace it with the ''laser tip, bare (single use)'' supply (SF029) already present in our direct PE database. We believe that the invoice for SF030 submitted with the RUC recommendation is not current enough to establish a new price for this supply; as a result, we substituted the SF029 supply for this input. We welcomed the submission of new invoices to accurately price the diffuser fiber with laser tip.

We also proposed to make significant changes to the prices of several of the supplies and equipment related to Flexible Laryngoscopy, as well as to the prices of scopes more broadly. We proposed to set the price of the disposable biopsy forceps supply (SD318) at $26.84, based on the submission of an invoice with a price of $536.81 for a unit size of 20. In our search for additional information regarding scope inputs, we obtained a quote from a vendor listing the current price for several equipment items related to the use of scopes. Since we believe that the prices in vendor quotes would typically be equal to or higher than prices actually paid by practitioners, we are updating the prices in our direct PE database to reflect this new information. As part of this process, we proposed to increase the price of the ''light source, xenon'' (EQ167) from $6,723.33 to $7,000 to reflect current pricing information. We also proposed to adjust the price of the ''fiberscope, flexible, rhinolaryngoscopy'' (ES020) from $6,301.93 to $4,250.00.

In accordance with the wider proposal that we made involving the use of scope equipment, we proposed to separate the scopes used in these procedures from the scope video systems. In the course of researching different kinds of scopes, we obtained vendor pricing for two different types of scopes used in these procedures. We proposed to price the ''rhinolaryngoscope, flexible, video, non-channeled'' (ES063) at $8,000 and the ''rhinolaryngoscope, flexible, video, channeled'' (ES064) at $9,000 in accordance with our vendor quotes. We proposed to use the non-channeled scope for CPT codes 31575, 31579, and 31574 and the channeled scope for CPT codes 31576, 31577, 31578, 31572, and 31573 in accordance with the RUC-recommended video systems that stipulated channeled versus non-channeled scope procedures.

We believe that the ''Video-flexible laryngoscope system'' listed in the recommendations is not a new form of equipment, but rather constitutes a version of the existing ''video system, endoscopy'' equipment (ES031). We did not add a new equipment item to our direct PE database; instead, we proposed to use the submitted invoices to update the price of the ES031 endoscopy video system. As the equipment code for ES031 indicates, we proposed to define the endoscopy video system as containing a processor, digital capture, monitor, printer, and cart. We proposed to price ES031 at $15,045.00; this reflected a price of $2,000.00 for the monitor, $9,000.00 for the processor, $1,750.00 for the cart, and $2,295.00 for the printer. These prices were obtained from our vendor invoice, with the exception of the printer, which is a crosswalk to the ''video printer, color (Sony medical grade)'' equipment (ED036).

We did not agree that there is a need for multiple different video systems for this collection of Flexible Laryngoscopy codes based on our understanding of the clinical differences among the codes. In keeping with this understanding, we proposed to use the same existing ''video system, endoscopy'' equipment (ES031) for the remaining codes in the family that included RUC recommendations for new equipment items named ''Video-flexible channeled laryngoscope system'' and ''Video-flexible laryngoscope stroboscopy system.'' For CPT codes 31576, 31577, 31578, 31572, and 31573, we proposed to replace the Video-flexible channeled laryngoscope system with the existing endoscopy video system (ES031) along with a channeled flexible video rhinolaryngoscope (ES064). For CPT code 31579, we proposed to rename the RUC-recommended ''Video-flexible laryngoscope stroboscopy system'' to the shortened ''stroboscopy system'' (ES065) and assign it a price of $19,100.00. This reflected the price of the StrobeLED Stroboscopy system included on the submitted invoice. We proposed to treat the stroboscopy system as a scope accessory, which was included along with the ''video system, endoscopy'' equipment (ES031) and the ''rhinolaryngoscope, flexible, video, non-channeled'' (ES063) for CPT code 31579. When the price of the scope, the scope video system, and the stroboscopy system were summed together, the total proposed equipment price was $42,145.00.

We proposed to refine the recommended equipment times for several equipment items to conform to changes in clinical labor time. These are: The fiberoptic headlight (EQ170), the suction and pressure cabinet (EQ234), the reclining exam chair with headrest (EF008), and the basic instrument pack (EQ137). We proposed to use the standard equipment time formula for scope accessories for the endoscopy video system (ES031) and the stroboscopy scope accessory system (ES065). We also proposed to refine the equipment time for the channeled and non-channeled flexible video rhinolaryngoscopes to use the standard equipment time formula for scopes. For this latter pair of two new equipment items, this proposal resulted in small increases to their respective equipment times.

The following is a summary of the comments we received regarding our proposed valuation of the Flexible Laryngoscopy codes:

Comment: Several commenters disagreed with the proposed work RVU for CPT code 31575. Commenters stated that the use of a work/time ratio was inconsistent with the methodology of magnitude estimation, and that reducing work RVUs by mathematical formula can arbitrarily manipulate intensities without allowing input from survey

recommendations provided by experts who perform the service. Commenters indicated their disapproval for a reverse building block methodology that assumes that if times for individual services change, work values must also change.

Response: We continue to believe that the use of these methodologies, including the use of time ratios, is an appropriate process for code valuation when recommended work RVUs do not appear to account for significant changes in time. As we stated earlier in our discussion on this topic in this final rule, we use time ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other methodologies for code valuation. We continue to believe that the decrease in total time for CPT code 31575 from 28 minutes to 24 minutes was not accounted for in the recommended work RVU, and as a result we proposed a work RVU of 0.94, supported by a crosswalk to CPT code 64405. We continue to believe that this valuation for CPT code 31575 more accurately captures the reduction in physician work caused by the decrease in the time required to perform the procedure, noting again that the statute specifically defines the work component as the resources in time and intensity required in furnishing the service. We believe that our crosswalk to CPT code 64405, which has very similar time and intensity values to CPT code 31575 at the same work RVU of 0.94, supports our valuation for this service.

Comment: Several commenters objected to the application of the work RVU increment to the rest of the codes in this family, measuring the increments from CPT code 31575's refined work RVU of 0.94 instead of the RUC-recommended work RVU of 1.00. Commenters stated that these codes were reviewed individually, not incrementally, and the use of an increment to reduce the work RVU of each code in the family by 0.06 was inappropriate. Commenters disagreed with the notion that when a base code's value is modified or reduced all other codes in the family should be reduced accordingly.

Response: We review codes individually for valuation. When we apply an increment from a base code to the rest of a code family, we do so only after reviewing each code individually and determining that the RUC-recommended relativity between the codes in the family is correct. For this particular family of codes, we stated our belief that the relativity between the codes in the family was accurate, and that the increment between the codes should be maintained after adjusting the work RVU for the base code (CPT code 31575) to account for its significant decrease in time. As we detailed in our discussion of code valuation methodologies earlier in this final rule, we use a variety of different methods, such as survey data, building blocks, crosswalks to key reference or similar codes, time ratios, and increments between codes within the same family. In our review of RUC-recommended values, we have observed that the RUC also uses a variety of methodologies to develop work RVUs for individual codes, and subsequently validates the results of these approaches through magnitude estimation or crosswalk to established values for other codes. We continue to believe that the use of an incremental methodology is the most accurate way to value this particular code family because it maintains the appropriate relativity among the Flexible Laryngoscopy codes.

Comment: One commenter disagreed with our refinement to remove the clinical labor time for ''Clean room/equipment by physician staff'' from the three codes in this family performed with a same day E/M service. The commenter stated that the clinical staff have to clean the equipment for procedure not used during the E/M service. According to the commenter, they clean that equipment separately and are assisting the physician during the entire procedure.

Response: In response to the commenter, we investigated this issue and determined that in the past we have sometimes provided 1 minute of clinical labor time for cleaning additional equipment beyond what would be cleaned during the E/M visit. As a result, we are restoring 1 minute of clinical labor time for ''Clean room/equipment by physician staff'' for CPT codes 31575, 31577, and 31579.

Comment: One commenter stated that there was a lack of clarity regarding the removal of the laser tip, diffuser fiber supply (SF030) from CPT code 31572. The commenter stated that the commenter supplied an invoice for the fibers, believed the invoice price was accurate, and believed the invoice should be utilized to set the price for this item.

Response: We continue to believe that the invoice for SF030 submitted with the RUC recommendation, which dates from 2009, is not current enough to establish a new price for this supply. We are continuing to maintain the laser tip, bare (single use) supply (SF029) in its place for CPT code 31572. As we discuss in the PE section of this final rule (II.A), we have concerns that the pricing for the laser tip, diffuser fiber supply has become outdated, and we are requesting the submission of additional current pricing information. We are maintaining the current pricing for this supply at $850 pending the submission of additional data.

We note as well that there were many comments addressing our proposal to reclassify scope equipment, as well as the proper pricing of the scope equipment utilized in this family of codes. These comments are summarized with responses in the PE section of this final rule (II.A).

After consideration of comments received, we are finalizing the work RVUs of the codes in the Flexible Laryngoscopy family at the proposed values. We are also finalizing the proposed direct PE inputs, with the exception of the refinement to the ''Clean room/equipment by physician staff'' clinical labor detailed above.

(12) Laryngoplasty (CPT Codes 31580, 31584, 31587, 31551–31554, 31591, and 31592)

CPT code 31588 (Laryngoplasty, not otherwise specified (*e.g.*, for burns, reconstruction after partial laryngectomy)) was identified as potentially misvalued based on the RUC's 90-Day Global Post-Operative Visits screen. When this code family was reviewed by the RUC, it was determined that some codes in the family required revision to reflect the typical patient before a survey could be conducted and the code family was referred to the CPT Editorial Panel for revision. At its October 2015 meeting, the CPT Editorial Panel approved the creation of six new codes, revision of three codes, and deletion of three codes. For CPT codes 31580, 31587, 31551, 31552, 31553, 31554, and 31592, CMS proposed the RUC-recommended work RVUs.

For CPT code 31584, the RUC recommended a work RVU of 20.00. We believed that the 25th percentile of the survey, which is a work RVU of 17.58, better represents the time and intensity involved with furnishing this service based on a comparison with and assessment of the overall intensity of other codes with similar instraservice and total time. This value is also supported by a crosswalk code of CPT code 42844 (Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with local flap (*e.g.*, tongue, buccal)), which has identical intraservice time and identical total time. Therefore, we proposed a work RVU of 17.58 for CPT code 31584.

Comment: Several commenters requested that we provide an explanation for our proposed work RVU of 17.58 for the revised CPT code 31584 instead of the RUC-recommended work RVU of 20.00. They stated that the modified code now represents the combination of two previously separate CPT codes (the existing CPT code 31584 combined with CPT code 31600) and that the work RVU should better reflect the sum of the total time for these combined procedures. Commenters further noted that the proposed work RVU of 17.58 is lower, even, than the existing work RVU for CPT code 31584. A commenter requested that CMS consider two additional codes for comparison: CPT code 37660 and CPT code 43280.

Response: We take multiple factors into account when valuing a service that replaces two previously separate codes. We consider the efficiencies of combining two services, as reflected in the adjustment upwards of the intra-service and total time for this code. We also review the code description and identify a value that is consistent with other, similar, 90-day global codes. Our valuation is above the median work RVU for a group of 28 codes with similar intraservice and total time. Commenters have not provided any additional information that would suggest this code should be valued differently from other 90-day global codes with similar time and intensity.

We reviewed the two additional codes that commenters recommended as comparisons. We note that CPT code 43280 (work RVU of 18.1) was most recently valued in 1997 and that for low-volume code CPT code 37660, physician intensity is considerably higher than that for CPT code 31584, suggesting a poor reference for comparing the work involved in furnishing the service. For these reasons, we do not believe this code is an appropriate comparison for CPT code 31584 and we are finalizing our work RVU of 17.58 for CPT code 31584.

For CPT code 31591, the RUC recommended a work RVU of 15.60. We believed that the 25th percentile of the survey, which is a work RVU of 13.56, better represents the time and intensity involved with furnishing this service based on a comparison of the overall intensity of other codes with similar instraservice and total time. The 25th percentile of the survey is additionally bracketed by two crosswalk codes that we estimate have slightly lower and slighter higher overall intensities, CPT code 36819 (Arteriovenous anastomosis, open; by upper arm basilic vein transposition), which has a work RVU of 13.29, and CPT code 49654 (Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible), which has a work RVU of 13.76; both of these codes have identical intraservice time and similar total time. Therefore, we proposed a work RVU of 13.56 for CPT code 31591.

Comment: Several commenters disagreed with our proposed work RVU of 13.56 for CPT code 31591, stating that the RUC-recommended work RVU of 15.60 better reflects the work required to perform the procedure.

Response: In developing our proposed valuation, we looked at other 90-day global codes with identical intraservice time and similar total time (between 275 and 335), and we note that the median work RVU of the resulting values (reflecting 33 codes) is 13.76. We chose the 25th percentile of the survey because of its closeness to the median work RVU of comparable services. We recognize that the RUC's crosswalk to CPT code 58544, with a work RVU of 15.60, has a lower total time than the codes we used as comparisons, but we note that this code has very low utilization, with 103 procedures billed in 2015. We continue to believe that two codes bracketing the 25th percentile of the work RVU for CPT code 31591 (CPT codes 36819 and 49654), as noted in the CY2017 PFS proposed rule, provide a better reference for valuing the new code, and that a work RVU of 13.56 adequately represents the time and intensity involved with furnishing the service. Therefore, we are finalizing our proposed work RVU of 13.56 for CPT code 31591.

Additionally, the RUC forwarded invoices provided by a medical specialty society for the video-flexible laryngoscope system used in these services. We discussed our proposed changes to the items included in equipment item ES031 (video system, endoscopy) in the CY 2017 proposed rule (81 FR 46247). Consistent with those proposed changes, we proposed to add a Nasolaryngoscope, non-channeled, to the list of equipment items used for CPT codes 31580, 31584, 31587, 31551–31554, 31591, and 31592, along with the modified equipment item ES031.

Comment: We received several comments, including from the RUC, about our proposal to implement a separate pricing approach for equipment inputs for this family of codes. Commenters requested a delay in implementing our approach until the RUC convened a PE subcommittee and provided CMS with specific recommendations for these codes.

Response: We appreciate the commenters' interests in making certain that there is appropriate opportunity for stakeholders to provide feedback and recommendations on the reclassification and pricing of scopes. Because these codes are currently under review, however, we believe that they should be valued according to a scheme that accurately describes the scope equipment typically used in the services. We continue to believe that our proposed classification system for scopes is the more proper methodology to use for valuation of these codes for the CY 2017. Please refer to II.A of the final rule for additional discussion on the new pricing process.

(13) Closure of Left Atrial Appendage With Endocardial Implant (CPT Code 33340)

The CPT Editorial Panel deleted category III CPT code 0281T (Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation) and created new CPT code 33340 to describe percutaneous transcatheter closure of the left atrial appendage with implant. The RUC recommended a work RVU of 14.00. We proposed a work RVU of 13.00 for CPT code 33340, which is the minimum survey result. Based on our clinical judgment and that the key reference codes discussed in the RUC recommendations have higher intraservice and total service times than the median survey results for CPT code 33340, we stated in the CY 2017 proposed rule that we believe a work RVU of 13.00 would more accurately represent the work value for this service.

Comment: We received several comments, including from the RUC. Commenters noted inaccuracies in CMS' description of the RUC recommendations including descriptions of the relationship between the RUC-recommended work RVU, survey results, and service times for the two key reference codes. Commenters requested that CMS finalize the RUC-recommended work RVU of 14.00.

Response: We appreciate the commenters' feedback and acknowledge that we inadvertently mischaracterized the RUC's recommendations related to this service. We agree that the survey results showed a 25th percentile survey result of 19.88 and that during the RUC meeting, this code was referred to the facilitation committee whereby the RUC identified two comparable codes with

14.00 work RVUs, which the RUC factored into its analysis and recommended valuation for this service. After consideration of the comments, we are finalizing the RUC-recommended work RVU of 14.00 for CPT code 33340.

(14) Valvuloplasty (CPT Codes 33390 and 33391)

The CPT Editorial Panel created new codes to describe valvuloplasty procedures and deleted existing CPT code 33400 (Valvuloplasty, aortic valve; open, with cardiopulmonary bypass). New CPT code 33390 represents a simple valvuloplasty procedure and new CPT code 33391 describes a more complex valvuloplasty procedure. We proposed to use the RUC-recommended values for CPT code 33390. For CPT code 33391, the RUC recommended a work RVU of 44.00, the 25th percentile survey result. The RUC estimated that approximately 70 percent of the services previously reported using CPT code 33400 would be reported using CPT code 33391, with 30 percent reported using new CPT code 33390. Therefore, the typical service previously reported with CPT code 33400 ought to now be reported with CPT code 33391. Compared to deleted CPT code 33400, the survey results for CPT code 33391 showed similar median intraservice times and decreased total times. Therefore, we proposed a work RVU of 41.50 for CPT code 33391, which is the current value of CPT code 33400. Given that the typical service should remain consistent between the two codes, we stated that we believe the work RVUs should remain consistent as well.

Comment: Commenters disagreed with CMS' proposed valuation of CPT code 33391, citing increased intensity and complexity of the procedures. Commenters noted that more complex patients are undergoing valvuloplasty (for instance, adult cardiac patients) when historically these patients would have received aortic valve replacements.

Response: As discussed in the CY 2017 proposed rule, the deleted CPT code 33400 is being replaced with two CPT codes that identify simple and complex procedures. The RUC's utilization crosswalk suggests that approximately 70 percent of the services that would previously have been reported using the combined code (CPT code 33400) would now be reported with CPT code 33391, the complex procedure. Based on the RUC's utilization crosswalk, the complex procedure would be the typical procedure reported under the combined code (CPT code 33400). The survey data for the complex procedure (CPT code 33391) showed similar median intraservice times and decreased total times compared to CPT code 33400. Therefore, for CY 2017, we are finalizing a work RVU of 35.00 for CPT code 33390 and a work RVU of 41.50 for CPT code 33391.

(15) Mechanochemical Vein Ablation (MOCA) (CPT Codes 36473 and 36474)

At the October 2015 CPT meeting, the CPT Editorial Panel established two Category I codes for reporting venous mechanochemical ablation, CPT codes 36473 and 36474. We proposed the RUC-recommended work RVU of 3.50 for CPT code 36473. For CPT code 36474, we proposed a work RVU of 1.75 and stated that we believed the RUC-recommended work RVU of 2.25 does not accurately reflect the typical work involved in furnishing this procedure. The specialty society survey showed that this add-on code has half the work of the base code (CPT code 36473). This value is supported by the ratio between work and time in the key reference service (CPT code 36476: Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)).

The RUC-recommended direct PE inputs for CPT codes 36473 and 36474 included inputs for an ultrasound room (EL015). Based on the clinical nature of these procedures, we stated in our proposal that we do not believe that an ultrasound room would typically be used to furnish these procedures. We proposed to remove inputs for the ultrasound room and subsequently include a portable ultrasound (EQ250), power table (EF031), and light (EF014). The RUC also recommended that the ultrasound machine be allocated clinical staff time based on the PACS workstation formula. We stated that we did not believe that an ultrasound machine would be used like a PACS workstation, as images are generated and reviewed in real time. Therefore, we proposed to remove all direct PE inputs associated with the PACS workstation.

Comment: We received several comments, including from the RUC. Commenters disagreed with CMS' proposed work RVU of 1.75 for CPT code 36474 and requested that CMS finalize the RUC's recommendation of 2.25 work RVUs. The RUC disagreed with CMS' rationale for the proposed work RVU for CPT code 36474. The RUC stated that the ratio between CMS' proposed physician time and physician work for the survey code is 0.058, whereas that same ratio for the key reference code used by the RUC is 0.0883, and that the divergent ratios between the two services are not comparable.

Response: The commenters recommended that we accept the RUC-recommended ratio of 36 percent between the RUC-recommended work RVUs for CPT codes 36473 and 36474. We disagree. The RUC survey reported 79 minutes of total time for CPT code 36473 and 30 minutes of total time for CPT code 36474, a decrease of greater than 50 percent between the base code and the add-on code. As discussed in the proposed rule, our proposed work RVU of 1.75 for CPT code 36474 is supported by the ratio between work and time in the key reference service. The RUC recommendations made reference to two identical sets of services that use differing mechanisms for ablating the vein (radiofrequency procedures reported with CPT codes 36475 and 36476 (work RVUs of 5.30 and 2.65); laser procedures reported with CPT codes 36478 and 36479 (work RVUs of 5.30 and 2.65)). Both key reference code sets have a work RVU ratio of 50 percent (5.30 versus 2.65) between the base codes and the add-on codes. Therefore, for CY 2017, we are finalizing a work RVU of 3.50 for CPT code 36473 and a work RVU of 1.75 for CPT code 36474.

Comment: Commenters requested that CMS restore the direct PE inputs for the ultrasound room, which includes the PACS workstation. Commenters stated that the PACS workstation is needed for these procedures to store and make images available for future use.

Response: Commenters suggested that the ultrasound room was necessary for this procedure since the ultrasound room includes a PACS workstation that would allow for storage of the images and subsequent future use. As we discussed in the proposed rule, during the typical procedure, the images would be used in real time rather than being stored for subsequent interpretation. Further, the ultrasound room would not be typically used during these procedures. Our proposal included a portable ultrasound that allows for use of the images during the course of the procedure.

Comment: One commenter requested that CMS include an additional direct PE input for a ClariVein catheter for both CPT codes 36473 and 36474, and included invoices related to this item. The commenter suggested that an additional catheter is necessary to prevent contamination during treatment of subsequent vessels if the catheter

used in an initial vessel were reused in a subsequent vessel.

Response: The invoice data submitted by the commenter appears to be applicable to the ClariVein catheters in some instances and in others to the ClariVein kits. Our review of the ClariVein kits indicated that the ClariVein catheters are part of the ClariVein kits. Because we lack clear product data regarding the cost of the ClariVein kits versus the ClariVein catheters and whether the catheters are included in the price of the kits, for CY 2017, we are finalizing our proposed direct PE inputs for the ClariVein kits for CPT codes 36473 and 36474 without modification. We welcome additional feedback from stakeholders regarding the product data and costs for the ClariVein catheters and ClariVein kits for consideration in future rulemaking.

(16) Dialysis Circuit (CPT Codes 36901, 36902, 36903, 36904, 36905, 36906, 36907, 36908, 36909)

In January 2015, a CPT/RUC workgroup identified the following CPT codes as being frequently reported together in various combinations: 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel), 35476 (Transluminal balloon angioplasty, percutaneous; venous), 36147 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); initial access with complete radiological evaluation of dialysis access, including fluoroscopy, image documentation and report), 36148 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); additional access for therapeutic intervention), 37236 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery), 37238 (Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein), 75791 (Angiography, arteriovenous shunt (*eg,* dialysis patient fistula/graft), complete evaluation of dialysis access, including fluoroscopy, image documentation and report (includes injections of contrast and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava), radiological supervision and interpretation), 75962 (Transluminal balloon angioplasty, peripheral artery other than renal, or other visceral artery, iliac or lower extremity, radiological supervision and interpretation), and 75968 (Transluminal balloon angioplasty, each additional visceral artery, radiological supervision and interpretation). These codes are frequently reported together for both dialysis circuit services and transluminal angioplasty services. At the October 2015 CPT Editorial Panel meeting, the panel approved the creation of nine new codes and deletion of four existing codes used to describe bundled dialysis circuit intervention services, and the creation of four new codes and deletion of 13 existing codes used to describe bundled percutaneous transluminal angioplasty services (see discussion of the latter code family in the next section). The Dialysis Circuit family of codes overlaps with the Open and Percutaneous Transluminal Angioplasty family of codes (CPT codes 37246–37249), as they are both being constructed from the same set of frequently reported together codes. We reviewed these two families of codes concurrently to maintain relativity between these clinically similar procedures based upon the same collection of deleted codes.

For CPT code 36901, we proposed a work RVU of 2.82 instead of the RUC-recommended work RVU of 3.36. When we compared CPT code 36901 against other codes in the RUC database, we found that the RUC-recommended work RVU of 3.36 would be the highest value in the database among the 32 0-day global codes with 25 minutes of intraservice time. Generally speaking, we are particularly skeptical of RUC-recommended values for newly ''bundled'' codes that appear not to recognize the full resource overlap between predecessor codes. Since the recommended values would establish a new highest value when compared to other services with similar time, we believed it likely that the recommended value for the new code does not reflect the efficiencies in time. Of course, were there compelling evidence for this valuation accompanying the recommendation, we would consider such information. We also noted that the reference code selected by the survey participants, CPT code 36200 (Introduction of catheter, aorta), has a higher intraservice time and total time, but a lower work RVU of 3.02 We believe that there are more accurate CPT codes that can serve as a reference for CPT code 36901. As a result, we proposed to crosswalk CPT code 36901 to CPT code 44388 (Colonoscopy through stoma; diagnostic). CPT code 44388 has a work RVU of 2.82, and we believe it is a more accurate crosswalk for valuation due to its similar overall intensity and shared intraservice time of 25 minutes with 36901 and similar total time of 65 minutes.

We proposed a work RVU of 4.24 for CPT code 36902 instead of the RUC-recommended work RVU of 4.83. The RUC-recommended work RVU is based upon a direct crosswalk to CPT code 43253 (Esophagogastroduodenoscopy, flexible, transoral), which shares the same 40 minutes of intraservice time with CPT code 36902. However, CPT code 43253 has significantly longer total time than CPT code 36902, 104 minutes against 86 minutes, which we believe reduces its utility for comparison. We instead proposed to crosswalk the work RVU for CPT code 36902 from CPT code 44408 (Colonoscopy through stoma), which has a work RVU of 4.24. In addition to our assessment that the two codes share similar intensities, CPT code 44408 also shares 40 minutes of intraservice time with CPT code 36902 but has only 95 minutes of total time and matches the duration of the procedure under review more closely than the RUC-recommended crosswalk to CPT code 43253. We also note that the RUC-recommended work increment between CPT codes 36901 and 36902 was 1.47, and by proposing a work RVU of 4.24 for CPT code 36902, we would maintain a very similar increment of 1.42. As a result, we proposed a work RVU of 4.24 for CPT code 36902, based on this direct crosswalk to CPT code 44408. For CPT code 36903, we proposed a work RVU of 5.85 instead of the RUC-recommended work RVU of 6.39. The RUC-recommended value is based on a direct crosswalk to CPT code 52282 (Cystourethroscopy, with insertion of permanent urethral stent). Like the previous pair of RUC-recommended crosswalk codes, CPT code 52282 shares the same intraservice time of 50 minutes with CPT code 36903, but has substantially longer total time (120 minutes against 96 minutes) which we believe limits its utility as a crosswalk. We proposed a work RVU of 5.85 based on maintaining the RUC-recommended work RVU increment of 3.03 as compared to CPT code 36901 (proposed at a work RVU of 2.82), the base code for this family of related procedures. We also point to CPT code 44403 (Colonoscopy through stoma; with endoscopic mucosal resection) as a reference point for this value. CPT code

44403 has a work RVU of 5.60, but also lower intraservice time (45 minutes as compared to 50 minutes) and total time (92 minutes as compared to 96 minutes) in relation to CPT code 36903, suggesting that a work RVU a bit higher than 5.60 would be an accurate valuation. Therefore, we proposed a work RVU of 5.85 for CPT code 36903, based on an increment of 3.03 from the work RVU of CPT code 36901.

We proposed a work RVU of 6.73 instead of the RUC-recommended work RVU of 7.50 for CPT code 36904. Our proposed value comes from a direct crosswalk from CPT code 43264 (Endoscopic retrograde cholangiopancreatography), which shares the same intraservice time of 60 minutes with CPT code 36904 and has a higher total time. We also looked to the intraservice time ratio between CPT codes 36901 and 36904; this works out to 60 minutes divided by 25 minutes, for a ratio of 2.4, and a suggested work RVU of 6.77 (derived from 2.4 times CPT code 36901's work RVU of 2.82). This indicates that our proposed work RVU of 6.73 maintains relativity within the Dialysis Circuit family. As a result, we proposed a work RVU of 6.73 for CPT code 36904, based on a direct crosswalk to CPT code 43264.

We proposed a work RVU of 8.46 instead of the RUC-recommended work RVU of 9.00 for CPT code 36905. We looked at the intraservice time ratio between CPT codes 36901 and 36905 as one potential method for valuation, which is a 1:3 ratio (25 minutes against 75 minutes) for this case. This means that one potential value for CPT code 36905 would be triple the work RVU of CPT code 36901, or 2.82 times 3, which results in a work RVU of 8.46. We also investigated preserving the RUC-recommended work RVU increment between CPT code 36901 and 36905, which was an increase of 5.64. When this increment is added to the work RVU of 2.82 for CPT code 36901, it also resulted in a work RVU of 8.46 for CPT code 36905. Therefore, we proposed a work RVU of 8.46 for CPT code 36905, based on both the intraservice time ratio with CPT code 36901 and the RUC-recommended work increment with the same code.

For CPT code 36906, we proposed a work RVU of 9.88 instead of the RUC-recommended work RVU of 10.42. We based the proposed value upon the RUC-recommended work RVU increment between CPT codes 36901 and 36906, which is 7.06. When added to the work RVU of 2.82 for CPT code 36901, the work RVU for CPT code 36906 would be 9.88. We are supporting this value through the use of two crosswalks that both share the same 90 minutes of intraservice time with 36906. These are CPT code 31546 (Laryngoscopy, direct, with submucosal removal of non-neoplastic lesion(s) of vocal cord) at a work RVU of 9.73 and CPT code 61623 (Endovascular temporary balloon arterial occlusion, head or neck) at a work RVU of 9.95.

The final three codes in the Dialysis Circuit family are all add-on codes, which make comparisons difficult to the global 0-day codes that make up the rest of the family. We proposed a work RVU of 2.48 instead of the RUC-recommended work RVU of 3.00 for CPT code 36907. Due to the difficulty of comparing CPT code 36907 with the non-add-on codes in the rest of the Dialysis Circuit family, we looked instead to compare the value to the add-on codes in the Open and Percutaneous Transluminal Angioplasty family of codes (CPT codes 37246–37249). As we stated previously, both of these groups of new codes are being constructed from the same set of frequently reported together codes. We reviewed these two families of codes together to maintain relativity across the two families, and so that we could compare codes that shared the same global period.

We proposed the RUC-recommended work RVUs for all four codes in the Open and Percutaneous Transluminal Angioplasty family of codes. As a result, we compared CPT code 36907 with the RUC-recommended work RVU of 2.97 for CPT code 37249, which is also an add-on code. These procedures should be clinically very similar, since both of them are performing percutaneous transluminal angioplasty on a central vein, and both of them are add-on procedures. We looked at the intraservice time ratio between these two codes, which was a comparison between 25 minutes for CPT code 36907 against 30 minutes for CPT code 37249. This produces a ratio of 0.83, and a proposed work RVU of 2.48 for CPT code 36907 when multiplied with the RUC-recommended work RVU of 2.97 for CPT code 37249. We noted as well that the intensity was markedly higher for CPT code 36907 as compared to CPT code 37249 when using the RUC-recommended work values, which did not make sense since CPT code 36907 would typically be a clinically less intense procedure. Using the intraservice time ratio results in the two codes having exactly the same intensity. As a result, we therefore proposed a work RVU of 2.48 for CPT code 36907, based on this intraservice time ratio with the RUC-recommended work RVU of CPT code 37249.

For CPT code 36908, we disagree with the RUC-recommended work RVU of 4.25, and we instead proposed a work RVU of 3.73. We did not consider the RUC work value of 4.25 to be accurate for CPT code 36908, as this was higher than our proposed work value for CPT code 36902 (4.24), and we did not believe that an add-on code should typically have a higher work value than a similar non-add-on code with the same intraservice time. We identified two appropriate crosswalks for valuing CPT code 36908: CPT code 93462 (Left heart catheterization by transseptal puncture through intact septum or by transapical puncture) and CPT code 37222 (Revascularization, endovascular, open or percutaneous, iliac artery). Both of these codes share the same intraservice time as CPT code 36908, and both of them also have the same work RVU of 3.73, which results in these codes also sharing the same intensity since they are all add-on codes. We therefore proposed a work value of 3.73 for CPT code 36908, based on a direct crosswalk to CPT codes 93462 and 37222.

Finally, we proposed a work RVU of 3.48 for CPT code 36909 instead of the RUC-recommended work RVU of 4.12. The RUC-recommended value comes from a direct crosswalk from CPT code 38746 (Thoracic lymphadenectomy by thoracotomy). We compared the RUC-recommended work RVU for this procedure to other add-on codes with 30 minutes of intraservice time and found that the recommended work RVU of 4.12 would overestimate the overall intensity of this service relative to those with similar times. In reviewing the range of these codes, we believed that a more appropriate crosswalk is to CPT code 61797 (Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator)) at a work RVU of 3.48. We believed that this value is more accurate when compared to other add-on procedures with 30 minutes of intraservice time across the PFS. As a result, we proposed a work RVU of 3.48 for CPT code 36909 based on a direct crosswalk from CPT code 61797.

We proposed to use the RUC-recommended direct PE inputs for these nine codes with several refinements. We did not propose to include the recommended additional preservice clinical labor for CPT codes 36904, 36905, and 36906. The preservice work description is identical for all six of the global 0-day codes in this family; there is no justification given in the RUC recommendations as to why the second three codes need additional clinical labor time beyond the minimal preservice clinical labor assigned to the

first three codes. We do not believe that the additional staff time would be typical. Patient care already would have been coordinated ahead of time in the typical case, and the need for unscheduled dialysis or other unusual circumstances would be discussed prior to the day of the procedure. We therefore proposed to refine the preservice clinical labor for CPT codes 36904, 36905, and 36906 to match the preservice clinical labor of CPT codes 36901, 36902, and 36903.

We proposed to refine the L037D clinical labor for ''Prepare and position patient/monitor patient/set up IV'' from 5 minutes to 3 minutes for CPT codes 36901–36906. The RUC recommendation included a written justification for additional clinical labor time beyond the standard 2 minutes for this activity, stating that the extra time is needed to prepare the patient's arm for the procedure. We agreed that extra time may be needed for this activity as compared to the default standard of 2 minutes; however, we proposed to assign 1 extra minute for preparing the patient's arm, resulting in a total of 3 minutes for this task. We did not believe that 3 extra minutes would be typically needed for arm positioning.

We proposed to remove the ''kit, for percutaneous thrombolytic device (Trerotola)'' supply (SA015) from CPT codes 36904, 36905, and 36906. We believed that this thrombolytic device kit and the ''catheter, thrombectomy-Fogarty'' (SD032) provide essentially the same supply, and the use of only one of them would be typical in these procedures. We believed that each of these supplies can be used individually for thrombectomy procedures. We proposed to remove the SA015 supply and retain the SD032 supply, and we solicited additional comment and information regarding the use of these two supplies.

We also proposed to remove the recommended supply item ''covered stent (VIABAHN, Gore)'' (SD254) and replace it with the ''stent, vascular, deployment system, Cordis SMART'' (SA103) for CPT codes 36903 and 36906. The Cordis SMART vascular stent was previously used in the past for CPT code 37238, which is the deleted code for transcatheter placement of an intravascular stent that CPT codes 36903 and 36906 are replacing. We did not have a stated rationale as to the need for this supply substitution, and therefore, we did not believe it would be appropriate to replace the current items with a significantly higher-priced item without additional information.

We also proposed to refine the quantity of the ''Hemostatic patch'' (SG095) from 2 to 1 for CPT codes 36904, 36905, and 36906. This supply was not included in any of the deleted base codes out of which the new codes are being constructed, and while we agreed that the use of a single hemostatic patch has become common clinical practice, we did not agree that CPT codes 36904–36906 would typically require a second patch. As a result, we proposed to refine the SG095 supply quantity from 2 to 1 for CPT codes 36904–36906, which also matches the supply quantity for CPT codes 36901–36903.

Included in the RUC recommendation for the Dialysis Circuit family of codes were a series of invoices for a ''ChloraPrep applicator (26 ml)'' supply. We solicited comments regarding whether the Betadine solution has been replaced by a Chloraprep solution in the typical case for these procedures. We also solicited comments regarding whether the ''ChloraPrep applicator (26 ml)'' detailed on the submitted invoices is the same supply as the SH098 ''chlorhexidine 4.0% (Hibiclens)'' applicator currently in the direct PE database.

Finally, we also solicited comments about the use of guidewires for these procedures. We requested feedback about which guidewires would be typically used for these procedures, and which guidewires are no longer clinically necessary.

The following is a summary of the comments we received regarding our proposed valuation of the Dialysis Circuit codes. Due to the large number of comments we received for this code family, we will first summarize the comments related to general code valuation, followed by the comments related to specific work RVUs, and finally the comments related to direct PE inputs.

Comment: Several commenters stated that the cumulative impact of reimbursement reductions for the Dialysis Circuit family of codes in physician work and practice expense would be quite dramatic. The commenters compared the total RVU of the old codes against the total RVU of the newly created codes and found a decrease of roughly 20–30 percent. Commenters expressed concern that if the proposed rates were to be implemented, many outpatient access centers that focus on providing care for ESRD patients might no longer be able to operate.

Response: We share the concern of the commenters in maintaining access to care for Medicare beneficiaries. We believe that improved payment accuracy under the PFS generally facilitates access to reasonable and necessary physicians' services.

We note that a change in overall RVUs for particular services, regardless of the magnitude of the change, may reflect improved accuracy. For example, comparing the summed total RVU of CPT codes 36147, 36148, 36870, and 37238 against the total RVU of CPT code 36906 is an accurate method to describe the services taking place under the coding schema effective for 2016 and 2017, respectively. Through the bundling of these frequently reported services, it is reasonable to expect that the new coding system will achieve savings via elimination of duplicative assumption of the resources involved in furnishing particular servicers. For example, a practitioner would not be carrying out the full preservice work four separate times for CPT codes 36147, 36148, 36870, and 37238, but preservice times were assigned to each of the codes under the old coding. We believe the new coding assigns a more accurate preservice time and thus reflects efficiencies in resource costs that existed regardless of how the services were previously reported.

Comment: Several commenters objected to the crosswalk codes used by CMS for proposed work valuation. Commenters stated that comparing the Dialysis Circuit codes to colonoscopy or endoscopic retrograde cholangiopancreatography (ERCP) codes was inappropriate, as it undervalued the technical skill and judgment necessary to furnish the services. In other words, the crosswalks chosen by CMS were invalid due to the differences in the procedures in question, with the Dialysis Circuit codes being more intensive procedures than the CMS crosswalks.

Response: We disagree with the commenters that the choice of crosswalk codes is inappropriate for work valuation. We believe that, generally speaking, codes with similar intensity and time values are broadly comparable across the PFS, as the fee schedule is based upon a relative value system. For the Dialysis Circuit codes in particular, we provided a specific rationale for each crosswalk detailing why we believed it to be an appropriate selection. Regarding the statement from the commenters that colonoscopy codes, such as CPT code 44388, are inappropriate for use as crosswalks in this family of codes, we note that the RUC-recommended work RVU for CPT code 36901 was based upon a direct crosswalk to the work RVU of a colonoscopy code (CPT code 45378). We continue to believe that the crosswalks for this family of codes are appropriate

choices, since they share highly similar intensity and time values with the reviewed codes.

Comment: Some commenters disagreed with the use of time ratios for work valuation. These commenters stated that the use of direct crosswalks based only on intraservice time comparison or ratios of intraservice time inappropriately discounted the variation in technical skill, judgment, and risk inherent to these procedures.

Response: We continue to believe that the use of these methodologies, including the use of time ratios, is an appropriate process for identifying potential values for particular codes, especially when the recommended work RVUs do not appear to account for significant changes in time. As we stated earlier in our discussion on this topic in this final rule, we use time ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other methodologies for code valuation. We continue to believe our valuation for the Dialysis Circuit codes accurately captures the reduction in physician work caused by the efficiencies gained in both time and intensity through the bundling together of frequently reported services.

Comment: One commenter disagreed with the use of CMS comparisons between the RUC-recommended work RVUs for the Dialysis Circuit codes and the work RVU for other codes with similar time values in the rest of the fee schedule, particularly for CPT code 36901. The commenter stated that whether or not CPT code 36901 had the highest work RVU among other 0-day global codes with 25 minutes of intra-service time was irrelevant. The commenter pointed out that some code must be the highest value because the RBRVS represents a range of services of varying intensity. The commenter stated that CMS' reasoning undervalued the importance of work intensity in favor of the more easily quantifiable time variable, which was clinically inaccurate and contradictory to the principles of the relative value system.

Response: We disagree with the commenter about the invalidity of comparing newly created codes to existing codes with similar time values on the PFS. While it is true that there must be a highest value for any particular subset of codes, we believe the best approach in establishing work RVUs for codes is to compare the service to other services with similar times and identify codes with similar overall intensities. As we wrote in the proposed rule with regards to CPT code 36901, we have reservations with RUC-recommended values for newly ''bundled'' codes that appear not to recognize the full resource overlap between predecessor codes. Since the recommended values would establish a new highest value when compared to other services with similar time, we believe it likely that the recommended value for the new code does not reflect the efficiencies gained through bundling. We believe that these comparisons to other codes with similar time values and intensities are an important tool in helping to maintain relativity across the fee schedule.

Comment: A commenter disagreed with the CMS valuation for these codes based on a clinical rationale pertaining to how the services are defined. The commenter stated that the dialysis access circuit is defined as originating in the artery adjacent to the arterial anastomosis and including all venous outflow (whether single or multiple veins) to the axillary-subclavian vein junction. While several different arteries and veins may be included in this definition, from a functional perspective it is a single ''vessel''. The commenter stated that because of this greater propensity for multiple lesions in these procedures, it is appropriate to define the access vessel as CPT has done and allow reporting of only a single angioplasty or stent in that entire conduit. However, the commenter reported that the survey built on the ''typical patient'' (51 percent of the cases) was unable to recognize the additional work of additional angioplasty or stent for the Dialysis Circuit family of codes, even though multiple or arterial lesions occur with significant frequency. Because the coding structure of the Dialysis Circuit family does not include a code for ''additional vessels'', the valuation of the codes needs to incorporate the resource cost of patient cases where multiple or arterial lesions occur. The commenter contended that this problem with the survey methodology affected the work intensity of these codes, and justifies a higher intensity for these procedures.

Response: We share the commenter's concerns with the survey data collected by the RUC. This is why we have long employed different approaches to identify potential values for work RVUs, such as time ratios, building blocks, and crosswalks to key reference or similar codes, in addition to the recommended survey data. We also note that our methodology generally values services based on assumptions regarding the typical case, not occasional complications that may require additional work when they occur. For the particular case of the Dialysis Circuit family of codes, we do not agree with the commenter that the single ''vessel'' classification of these procedures supports a higher intensity compared to other related codes. These codes have been defined by CPT in a similar fashion to the lower extremity revascularization codes, in which the code is only billed a single time regardless of the number of lesions or number of stents placed. Due to the similarity with these existing codes located elsewhere in the PFS, we do not believe that it would be appropriate to value the Dialysis Circuit codes differently.

Comment: Several commenters suggested that there was compelling evidence for the higher RUC-recommended work RVUs because the vignette developed by the CPT Editorial Panel does not accurately reflect the typical ESRD patient. Commenters stated that the vignette for the Dialysis Circuit codes significantly underestimated the age of the typical patient, and may have led survey respondents to report less time. According to commenters, the frail and elderly ESRD patients that constitute the typical patients for these procedures are much sicker than the typical patient in other codes on the PFS, and this serves to justify valuing these codes at a higher intensity.

Response: We appreciate the submission of additional information regarding the patient population for these codes. We recognize that some services may require additional work due to an unusually difficult patient population. However, we do not agree at this time that the Dialysis Circuit family of codes has a uniquely different patient population that justifies an increase in valuation over other comparable codes on the PFS. We note that for CPT code 36901, the RUC recommended a work RVU of 3.36 based on a direct crosswalk to CPT code 45378, a flexible colonoscopy code. Our proposed work RVU of 2.82 for the same code was based on a direct crosswalk to CPT code 44388, which is another colonoscopy code. The patient population for these two crosswalk codes is similar, and both codes share similar time and intensity. We believe that our crosswalk code is a more appropriate choice given the time values and the efficiencies gained from bundling. However, based on this recommended crosswalk code, we believe that the RUC considers the patient population for CPT code 45378 to be appropriate for comparison to CPT code 36901, and that the reviewed code does not possess an unusually resource-intensive patient population. This same

pattern holds true for the other codes in the Dialysis Circuit family, which were valued using similar comparisons to established codes with typical patient populations.

Comment: One commenter suggested that the difficulties posed by the patient population for the Dialysis Circuit codes were not sufficiently reflected in the RUC recommendations. The commenter stated that the patients receiving dialysis circuit services are extremely sick, and every step in the process of caring for those patients is more complex than those involved in caring for the average Medicare patient. The commenter stated that CMS underestimated the amount of time required to perform specific tasks and assumes that those tasks can be performed by individuals with lower levels of training and credentials than are used in typical practice. The commenter requested a series of direct PE refinements to this family of codes, many of which went above the original RUC recommendations, including clinical labor times significantly above the usual standards and using clinical labor staffing types outside the normal range. The commenter stated an intention to present data to support the recommendations at a later date.

Response: We appreciate the additional information provided by the commenter about this family of codes. We emphasize that we do not believe that the RUC need be the exclusive source of information used in valuation of PFS services, and we are supportive of the submission of additional data that can aid in the process of determining the resources that are typically used to furnish these services. Because we did not receive data from the commenter to support these increases above the RUC recommendations, we are not incorporating these changes into the Dialysis Circuit codes at this time. However, we urge interested stakeholders to consider submitting robust data regarding costs for these and other services.

We are also seeking information on how to reconcile situations where we have multiple sets of recommendations from the RUC and from other PFS stakeholders, both for this specific case and for the situation more broadly, given the need to maintain relativity among PFS services.

The following comments address the proposed work valuation of individual codes in the family.

Comment: A commenter contended that the proposed work RVU of 2.82 undervalues CPT code 36901. The commenter stated that compelling evidence regarding CPT's inaccurate description of the typical ESRD patient as 45 years old led to lower survey times and hence the ''new highest value'' problem mentioned by CMS. The commenter recommended that CMS should finalize the RUC work RVU of 3.36, or barring that, should finalize a work RVU of 3.02 based on a direct crosswalk to CPT code 36200. The commenter stated that this code is very similar clinically in work and intensity to CPT code 36901.

Response: We summarized and responded to the general issues surrounding patient populations above. We disagree with the commenter that CPT code 36200 is a more appropriate choice for a crosswalk code for CPT code 36901. CPT code 36200 has 5 additional minutes of intraservice time (30 minutes as compared to 25 minutes) and 25 additional minutes of total time (91 minutes as compared to 66 minutes). In addition to this substantial difference in time values, the intensity of CPT code 36200 is also significantly lower than CPT code 36901. If we were to adopt the recommended crosswalk to a work RVU of 3.02, the intensity of CPT code 36901 would be 50 percent higher than the intensity CPT code 36200. Since we are statutorily obligated to base our valuation on time and intensity, we believe that this makes CPT code 36200 an inferior choice for a crosswalk code when compared to our choice of CPT code 44388, which shares very similar time and intensity with CPT code 36901.

Comment: A commenter stated that CPT code 36902 should have a higher increment in work RVU from CPT code 36901 because it included work unable to be accounted for in a survey on the typical patient. The commenter indicated that according to published literature, more than one stenosis is present requiring angioplasty in 20–30 percent of dialysis access cases. A higher increment in work RVU from CPT code 36901 to 36902 would reflect the work of additional angioplasty on separate stenoses and arterial angioplasty that occurs in some cases, but cannot be reflected in a ''typical'' 51 percent case vignette. The commenter requested that CMS adopt the RUC-recommended work RVU for CPT code 36902.

Response: We generally establish RVUs for services based on the typical case. If a particular patient case requires treatment outside the defined dialysis circuit code descriptor, then additional catheter placement and imaging may be reported, assuming that all of the proper requirements for separate billing are met. We do not believe that it would be appropriate to increase the work RVU for CPT code 36902 based on these non-typical situations.

Comment: A commenter stated that the CMS proposed work RVU of 5.85 undervalues the work involved in the services described by CPT code 36903, based on the belief that the CPT patient vignette does not reflect the typical patient and that ''additional vessel'' angioplasty or stenting work is included in CPT code 36903 but was not able to be captured in a survey utilizing the ''typical'' patient.

Response: We addressed these issues in previous comment responses. We continue to believe that the proposed work RVU for CPT code 36903 is accurate.

Comment: A commenter disagreed with the proposed work RVUs for CPT codes 36904 and 36905. The commenter suggested that CMS should use time ratios from the base code in the family, CPT code 36901, starting from a work RVU of 3.02 instead of the proposed work RVU of 2.82. The commenter suggested that this would produce work RVUs for CPT codes 36904 and 36905 almost identical to the RUC-recommended values, which the commenter urged CMS to adopt.

Response: We agree with the commenter that the use of time ratios is one potential method to use in the process of determining code valuation. However, since we stated previously that we believe our proposed work RVU of 2.82 is more accurate for CPT code 36901 than the commenter's suggestion of 3.02, we do not believe that applying the same time ratios provides a rationale for adopting the RUC-recommended work RVUs for CPT codes 36904 and 36905.

Comment: A commenter disagreed with CMS' proposed work RVU of 9.88 for CPT code 36906 based upon the RUC-recommended increment of 7.06 from CPT code 36901. The commenter stated that the RUC value was well supported as the 25th percentile survey result and the survey times for the code were adversely impacted by CPT errors in the code descriptor and RUC survey limitations.

Response: We do not agree that the RUC's work valuation for CPT code 36906 maintains relativity within the fee schedule. We believe that the increment between CPT code 36901 and 36906 maintains relativity within the Dialysis Circuit family of codes, which is why we proposed to use it for valuation. However, we believe that the recommended work RVU for CPT code 36906 insufficiently accounted for the efficiencies in resource use achieved through bundling together its predecessor codes. We continue to

believe that the proposed work RVU of 9.88, bracketed between crosswalks to CPT codes 31546 and 61623, provides the most accurate valuation for this service.

Comment: A commenter disagreed with the proposed work RVU of 2.48 for CPT code 36907, and stated that the work RVU should be identical to CPT code 37249 at a value of 2.97. The commenter stated these two services are clinically identical, and the CMS contention that CPT code 36907 would typically be a clinically less intense procedure is not correct. According to the commenter, the intensity involved in both of these add-on codes is the work and risk of crossing the central venous stenosis and performing intervention within the thorax where complications could be severe. The commenter stated that there is no difference in this work intensity based upon the direction of approach—from the dialysis access or from a native (femoral) vein. Both require advancing a long wire from the access site through the stenosis, superior and inferior vena cava, and right atrium, which is needed no matter which direction one is approaching the lesion. As a result, the commenter suggested that CPT code 36907 should have the same work RVU as CPT code 37249.

Response: While we agree with the commenter that these two services are clinically similar procedures, we do not agree with the commenter that the work between the two is identical. In particular, we believe that the difference in the intraservice time (25 minutes for CPT code 36907 against 30 minutes for CPT code 37249) should be accounted for in the work valuation, as the former code takes 20 percent less time to perform. We note as well that under our proposed valuation, these two codes have exactly the same intensity, with the difference in the work value occurring solely as a result of the decreased time required to perform CPT code 36907. Since time is one of the resources we are obligated to use for code valuation, we believe that the proposed values for these two codes are more accurate than setting both of them to the same work RVU.

Comment: One commenter supported the proposed work RVUs of 3.73 for CPT code 36908 and 3.48 for CPT code 36909.

Response: We appreciate the support from the commenter.

The following comments address the proposed direct PE inputs for the Dialysis Circuit family of codes.

Comment: Several commenters urged CMS to accept the recommended additional preservice clinical labor for CPT codes 36904, 36905, and 36906. Commenters stated that the patient presentation and the requisite preservice clinical labor is inherently different for CPT codes 36904–36906 when compared with CPT codes 36901–36903. Commenters indicated that the latter group are elective procedures, which are scheduled and planned well in advance of the procedure and performed on days that do not conflict with the patient's dialysis schedule. In contrast, the former group are urgent procedures typically done when a patient presents to their dialysis treatment with a thrombosed access. According to the commenters, the urgent nature of these procedures, the need for additional preoperative testing because of missed dialysis, and the need for arranging unscheduled dialysis treatment requires additional preservice time for the procedural staff.

Response: We disagree with the commenters. We continue to note that the preservice work description is identical for all six of the 0-day global codes in this family. Generally speaking, we also typically provide less preservice clinical labor time for emergent procedures, not more preservice clinical labor time, as there is no time for these tasks to be performed. We continue to believe that all six of these codes are most accurately valued by sharing the same preservice clinical labor times.

Comment: Several commenters stated that the recommended 5 minutes of clinical labor for ''Prepare and position patient/monitor patient/set up IV'' were reasonable because these cases are done on the upper extremity using portable c-arm fluoroscopy. According to commenters, the additional time includes prepping and positioning the arm, applying appropriate shielding to the patient's torso, positioning the c-arm unit, and then positioning other radiation shielding devices. Commenters stated that each of these activities requires more time in the arm, which typically must be extended to the side to be accessible for access and imaging; this is different from procedures done in the long plane of the body including the torso and legs. The commenters stated that 5 minutes is a more accurate reflection of the required clinical labor time than the proposed 3 minutes.

Response: We continue to believe that additional time may be needed for this activity as compared to the default standard of 2 minutes. However, we maintain that the commenter's request for 3 additional minutes (for a total of 5 minutes) would not typically be required for arm positioning, as this additional clinical labor time is generally not included in similar procedures. We do not agree that the additional tasks described by the commenters would require the requested 5 minutes of clinical labor time, and we are maintaining our proposed value of 3 minutes.

Comment: Several commenters opposed the CMS proposal to remove the ''kit, for percutaneous thrombolytic device (Trerotola)'' supply (SA015) from the RUC recommended supplies for CPT code 36904, 36905, and 36906, under the belief that only one device would typically be used in these procedures. Commenters indicated that this understanding was incorrect. According to the commenters, a mechanical thrombectomy device and a Fogarty thrombectomy balloon serve different purposes and both are necessary to perform a dialysis access thrombectomy. Commenters provided lengthy clinical rationales to support their point of view, which can be summarized as follows: ''The Fogarty balloon is small and highly compliant allowing it to be pulled through the artery and into the access without damaging the vessels. The thrombectomy device cannot be used safely for this function. This device is larger so risks pushing the fibrin plug into the artery if passed across the arterial anastomosis from the access—risking distal arterial embolization. The device is also much more rigid being made from metal and with irregular shape that risks damaging the endothelium of the artery causing arterial injury.'' As a result, commenters requested that the listed devices ''catheter, thrombectomy-Fogarty'' (SD032) and ''kit, for percutaneous thrombolytic device (Trerotola)'' supply (SA015) both remain in the supply list for these codes.

Response: We appreciated the detailed presentation of additional clinical information regarding the use of the percutaneous thrombolytic device kit from the commenters. After review of the comments and the contents of the kit, we believe that its inclusion in these three procedures is appropriate. According to the device literature, the kit contains a rotor for macerating the clot, a catheter for removing the clot, and a sheath for introducing the device. We will therefore restore the SA015 supply to CPT codes 36904, 36905, and 36906. However, we are removing the Fogarty catheter (SD032) and 1 of the 2 vascular sheaths (SD136), as these are contained within the kit. The literature for the percutaneous thrombolytic device kit clearly stipulates that there is no need for additional catheters to remove the clot, which makes the

Fogarty catheter a duplicative supply which can be removed.

Comment: Several commenters disagreed with the CMS proposal to remove the recommended supply item ''covered stent (VIABAHN, Gore)'' (SD254) and replace it with the ''stent, vascular, deployment system, Cordis SMART'' (SA103) for CPT codes 36903 and 36906. Commenters stated that covered stents are the only stent devices that are FDA approved and supported by evidence from randomized controlled trials for use in dialysis access procedures. They are typically used in recurrent or elastic stenosis in dialysis access and have become the standard of care for these interventions. One commenter stated that Braid Forbes Health Research analyzed stent use in CPT code 37238 using CMS OPPS claims data, and found that the covered stent (VIABAHN, Gore), was used 67.5 percent of the time and the SA103, stent, vascular, deployment system, Cordis SMART, was used 32.5 percent of the time. Commenters stressed that bare metal stents, such as the Cordis SMART, are not indicated for use in the Dialysis Circuit procedures.

Response: We appreciate the submission of this additional clinical information regarding the use of stents for these procedures. After consideration of the comments, we are restoring the covered stent (VIABAHN, Gore) (SD254) to CPT codes 36903 and 36906 as originally recommended. Because we are including the SD254 covered stent, we are not adding the stent, vascular, deployment system, Cordis SMART (SA103) supply to these procedures.

Comment: Several commenters disagreed with the CMS proposal to reduce the quantity of the Hemostatic patch (SG095) from 2 to 1 for CPT codes 36904, 36905, and 36906. Commenters stated that two hemostatic patches are necessary in these procedures because they require two separate cannulations and sheaths. At the end of the case, both sheath sites are removed and covered with a hemostatic patch which aids in preventing bleeding and maintaining sterility. The commenters stressed that because there are two access sites, two hemostatic patches are required, one to cover each site.

Response: We appreciate the additional clinical information submitted by the commenters. In response to this information, we are finalizing inclusion of the second Hemostatic patch (SG095) to CPT codes 36904, 36905, and 36906, as recommended by the RUC.

Comment: In response to the CMS solicitation of feedback regarding the Chloraprep applicator (26 ml) supply, commenters indicated that Chloraprep solution has replaced Betadine solution when performing sterile preparation of the dialysis access circuit due to its greater efficacy as preoperative skin prep. Commenters indicated that this supply was most accurately represented by the submitted invoice. Another commenter stated that studies have shown that preparation of central venous sites with a 2% aqueous chlorhexidine gluconate (in 70% alcohol) is superior for skin site preparation to either 10% povidone-iodine or 70% alcohol alone, and that in 2002, the CDC recommended that 2% chlorhexidine be used for skin antisepsis prior to catheter insertion. One commenter recommended that CMS replace the Betadine povidone soln (SJ041) with two units of swab, patient prep, 3.0 ml (Chloraprep) supply (SJ088) in the inputs for CPT codes 36901–36906.

Response: We appreciate the submission of additional clinical information regarding the Chloraprep supply from the commenters. We agree with the recommended supply substitution, and we are therefore removing 60 ml of the Betadine solution (SJ041) and replacing it with two units of the swab, patient prep, 3.0 ml (Chloraprep) supply (SJ088) for CPT codes 36901–36906. We will add the Chloraprep applicator (26 ml) supply to the direct PE input database at a price of $8.48 based on an average of the three submitted invoices; it is not currently assigned to any codes. We also agree that it is a distinct supply from the ''chlorhexidine 4.0% (Hibiclens)'' (SH098) supply already located in the direct PE database.

Comment: Several commenters provided additional information regarding the use of guidewires in these procedures. Commenters stated that the three wires used in the Dialysis Circuit codes are the minimum required for these interventions and frequently additional wires would be needed in more complicated cases or in cases in which more than one access must be used. Commenters stated that the guidewires submitted are the bare minimum needed for the typical case.

Response: We appreciate the additional information from the commenters regarding the use of guidewires. We proposed to use the RUC-recommended quantities for these supplies, and we are not finalizing any changes.

Comment: One commenter stated that vascular procedures involving fluoroscopy or radiography require the use of a radio-opaque ruler (SD249) to accurately size or locate tributaries and lesions beneath the skin. The commenter indicated that some of the base procedure codes (CPT codes 36903 and 36906) include this supply, while it is missing from CPT codes 36902 and 36905 and should be included.

Response: Based upon recommendations from the RUC and specialties, we believe that the use of this supply is typical in stent procedures such as CPT codes 36903 and 36906. It was included in CPT code 37238, which is a predecessor code for these two procedures. However, the radio-opaque ruler does not appear to be typical in the other dialysis codes and we do not believe that it would be typically required in the non-stent procedures, as it was not included in any of the other predecessor codes.

Comment: One commenter requested that CMS include additional miscellaneous supplies that were missing or underrepresented in the cost inputs. These supplies were not included in the RUC recommendations for these codes. The commenter also requested increasing the quantity of each category of gloves to 3 and the quantity of gowns to 3 for each of the base codes (CPT codes 36901–36906) to more accurately reflect the typical use of these items in the dialysis circuit procedures.

Response: We believe the supplies as recommended are typical for these procedures. We also believe the proposed number of gloves and gowns would be sufficient for the typical case; we currently do not have any data to suggest that there is a need for additional gloves or gowns in these procedures. The remainder of the additional miscellaneous items appear to be new supplies with no included invoices. Many of these new items may have analogous supplies already present in our direct PE database. For the others, we will consider pricing them if invoices are submitted as part of our normal process for updating supply and equipment costs.

After consideration of comments received, we are finalizing the work RVUs for the Dialysis Circuit codes as proposed. We are also finalizing the proposed direct PE inputs, with the refinements detailed above.

(17) Open and Percutaneous Transluminal Angioplasty (CPT Codes 37246, 37247, 37248, and 37249)

In January 2015, a CPT/RUC workgroup identified the following CPT codes as being frequently reported together in various combinations: 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or

branches, each vessel), 35476 (Transluminal balloon angioplasty, percutaneous; venous), 36147 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); initial access with complete radiological evaluation of dialysis access, including fluoroscopy, image documentation and report), 36148 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); additional access for therapeutic intervention), 37236 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery), 37238 (Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein), 75791 (Angiography, arteriovenous shunt (eg, dialysis patient fistula/graft), complete evaluation of dialysis access, including fluoroscopy, image documentation and report (includes injections of contrast and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava), radiological supervision and interpretation), 75962 (Transluminal balloon angioplasty, peripheral artery other than renal, or other visceral artery, iliac or lower extremity, radiological supervision and interpretation), and 75968 (Transluminal balloon angioplasty, each additional visceral artery, radiological supervision and interpretation).

At the October 2015 CPT Editorial Panel meeting, the panel approved the creation of four new codes and deletion of 13 existing codes used to describe bundled percutaneous transluminal angioplasty services. The Open and Percutaneous Transluminal Angioplasty family of codes overlaps with the Dialysis Circuit family of codes (CPT codes 36901–36909), as they are both being constructed from the same set of frequently reported together codes. We reviewed these two families of codes concurrently to maintain relativity between these clinically similar procedures based upon the same collection of deleted codes. After consideration of these materials, we proposed to accept the RUC-recommended work RVU for CPT codes 37246, 37247, 37248, and 37249.

For the clinical labor direct PE inputs, we proposed to use the RUC-recommend inputs with several refinements. Our proposed inputs refined the recommended clinical labor time for ''Prepare and position patient/monitor patient/set up IV'' from 5 minutes to 3 minutes for CPT codes 37246 and 37248. The RUC recommendation included a written justification for additional clinical labor time beyond the standard 2 minutes for this activity, stating that the extra time was needed to move leads out of X-ray field, check that X-ray is not obstructed and that there is no risk of collision of X-ray equipment with patient. As we wrote for the same clinical labor activity in the Dialysis Circuit family, we agreed that extra time might be needed for this activity as compared to the default standard of 2 minutes; however, we assigned 1 extra minute for the additional positioning tasks, resulting in a total of 3 minutes for this task. We did not believe that 3 extra minutes would be typically needed for preparation of the X-ray. The equipment times for the angiography room (EL011) and the PACS workstation (ED050) were also refined to reflect this change in clinical labor.

We proposed to remove the ''drape, sterile, femoral'' supply (SB009) and replace it with a ''drape, sterile, fenestrated 16in x 29in'' supply (SB011) for CPT codes 37246 and 37248. The two base codes out of which these new codes are being constructed, CPT codes 35471 and 35476, both made use of the SB011 fenestrated sterile drape supply, and there was no rationale provided for the switch to the SB009 femoral sterile drape in the two new codes. We solicited comment on the use of sterile drapes for these procedures, and what rationale there was to support the use of the SB009 femoral sterile drape as typical for these new procedures.

The following is a summary of the comments we received regarding our proposed valuation of the Open and Percutaneous Transluminal Angioplasty codes.

Comment: One commenter disagreed with the CMS proposed value of 3 minutes for the ''Prepare and position patient/monitor patient/set up IV'' clinical labor task. The commenter stated that the recommended 5 minutes of time was needed to move leads out of X-ray field, check that X-ray is not obstructed and that there is no risk of collision of X-ray equipment with patient. The commenter also indicated that the patient's arm needs to be positioned on an arm board, and requested time for this activity.

Recommended: We continue to believe that additional time may be needed for this activity as compared to the default standard of 2 minutes. However, we maintain that the commenter's request for 3 additional minutes (for a total of 5 minutes) would not typically be required for preparing the X-ray and conducting arm positioning. We do not agree that the additional tasks described by the commenters would require the requested 5 minutes of clinical labor time, and we are maintaining our proposed value of 3 minutes.

Comment: Several commenters objected to the proposed replacement of the ''drape, sterile, femoral'' supply (SB009) with the ''drape, sterile, fenestrated 16in x 29in'' supply (SB011) for CPT codes 37246 and 37248. Commenters stated that the vast majority of these new procedures will be performed from a femoral or jugular approach and will utilize a standard femoral drape. According to the commenters, the fenestrated drape provides a limited sterile field (16x29in) which does not allow room for sterile manipulation of wires and catheters as they extend away from the entry into the vascular system. With the creation of the new dialysis access circuit CPT code family, commenters indicated that the use of extremity access and fenestrated drapes would become much less typical for the new angioplasty code set.

Response: We appreciate the presentation of additional clinical information from the commenters regarding the sterile drape most appropriate for these procedures. As a result, we are finalizing inclusion of the sterile femoral drape supply (SB009) to CPT codes 37246 and 37248. We will therefore not be adding the fenestrated drape supply (SB011) to these procedures.

After consideration of comments received, we are finalizing the proposed work RVUs for the four codes in the family. We are also finalizing the proposed direct PE inputs, with the refinement to the sterile femoral drape detailed above.

(18) Esophagogastric Fundoplasty Trans-Oral Approach (CPT Code 43210)

For CY 2016, the CPT Editorial Panel established CPT code 43210 to describe trans-oral esophagogastric fundoplasty. The RUC recommended a work RVU of 9.00 and for CY 2016, we established an interim final work RVU of 7.75 for CPT code 43210. We noted that a work RVU of 7.75, which corresponds to the 25th

percentile of the survey, more accurately reflected the resources used in furnishing this service.

Comment on the CY 2016 PFS final rule with comment period: Commenters urged CMS to accept the RUC-recommended work RVU of 9.00 for CPT code 43210. The commenters believed that the RUC-recommended value compared well with the key reference service, CPT code 43276 (Endoscopic retrograde cholangiopancreatography (ERCP); with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged), which has a work RVU of 8.94 and an intraservice time of 60 minutes. Commenters believed that due to similar intraservice times and intensities, that CPT code 43210 should be valued nearly identically to CPT code 43276. Some commenters also stated that to maintain relativity within the upper GI code families, CPT code 43210 should not have a lower work RVU than CPT code 43276 since the majority of survey participants indicated that CPT code 43210 is more complex than CPT code 43276. Additionally, one commenter noted that an esophagogastroduodenoscopy (EGD) is used twice during this service, before and after fundoplication. The commenter stated that because this is a multi-stage procedure, other EGD codes are not comparable. The commenter also pointed out that this technology has a small number of users and urged CMS to accept the RUC-recommended work RVU of 9.00 until there is additional utilization, and to consider reviewing this code again in subsequent years.

Response in the CY 2017 PFS proposed rule: We referred this code to the CY 2016 multi-specialty refinement panel for further review, which recommended we accept the RUC-recommended value of 9.00 work RVUs. There are four ERCP codes with 60 minutes of intraservice time, three of which have work RVUs of less than 7.00 and only one of the four codes has a work RVU higher than 7.75 RVUs (8.94). Based on our estimate of overall work for this service, we continue to believe that the 25th percentile of the survey more accurately reflects the relative resource costs associated with this service. Therefore, for CY 2017, we proposed a work RVU of 7.75 for CPT code 43210.

The following is a summary of the comments we received regarding our proposed valuation of CPT code 43210:

Comment: Commenters indicated that the survey results were limited since this is a new technology. Commenters requested that CMS finalize the RUC-recommended work RVU of 9.00, with the understanding that the service will be reviewed again in the near future with more robust survey data as the technology continues to be adopted. Commenters disagreed with CMS' comparison to other EGD codes for purposes of establishing the work RVU, due to differences in the inherent clinical procedural steps involved with this code, including that EGD is used more than once (pre- and post-fundoplication) to ensure successful completion of the procedure.

Response: While it may be true that multiple EGDs may be performed during this procedure, the surveyees are familiar with the service and we assume included this information in their proposed time and work recommendations. However, the values recommended by the survey and the RUC are not consistent with other codes with similar times and intensities. We noted in the CY 2016 interim final rule that CPT code 43240 (Drainage of cyst of the esophagus, stomach, and/or upper small bowel using an endoscope) has 10 minutes more intraservice time and a work RVU of 7.25. Therefore, we are finalizing for CY 2017 a work RVU of 7.75 for CPT code 43210.

(19) Esophageal Sphincter Augmentation (CPT Codes 43284 and 43285)

In October 2015, the CPT Editorial Panel created two new codes to describe laparoscopic implantation and removal of a magnetic bead sphincter augmentation device used for treatment of gastroesophageal reflux disease (GERD). The RUC noted that the specialty societies conducted a targeted survey of the 145 physicians who have been trained to furnish these services and who are the only physicians who have performed these procedures. They noted that only 18 non-conflicted survey responses were received despite efforts to follow up and that nine physicians had no experience in the past 12 months with the procedure. The RUC agreed with the specialty society that the expertise of those responding was sufficient to consider the survey; however, neither the RUC nor the specialty society used the survey results as the primary basis for their recommended value.

For CPT code 43284, the RUC recommended a work RVU of 10.13. We compared this code to CPT code 43180 (Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (*e.g.,* Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed), which has a work RVU of 9.03 and has identical intraservice time and similar total time. We stated in the proposed rule that we believe the overall intensity of these procedures is similar; therefore, we proposed a work RVU of 9.03 for CPT code 43284.

For CPT code 43285, the RUC recommended a work RVU of 10.47. We used the increment between the RUC-recommended work RVU for this code and CPT code 43284 (0.34 RVUs) to develop our proposed work RVU of 9.37 for CPT code 43285.

Comment: We received many comments on our proposal from various stakeholders including practitioners, manufacturers, the RUC, and medical specialty societies representing various surgical specialties. For CPT code 43284, commenters indicated that CMS' proposed crosswalk from CPT code 43180 was inadequate with regard to time and complexity of the services. Commenters stated that CPT code 43180 has 10 minutes less immediate post-service time and one less post-operative visit. Some commenters stated that it appears that the difference between the specialty society median survey total time for 43284 and the total time for CMS' proposed crosswalk from CPT code 43180 was too great to discount. Commenters also disagreed that CPT code 43284 and CMS' proposed crosswalk from CPT code 43180 had similar complexity considering that one of the procedures was performed on a natural orifice with endoscopy versus a procedure with a surgical incision. Commenters indicated that management of surgical patients with incisions necessitates a more thorough evaluation of the body than an endoscopic procedure.

For CPT code 43285, commenters noted that although CPT code 47562 (the RUC-recommended crosswalk) requires more intraservice time than the aggregate survey median time for CPT code 43285, the median intraservice time may be understated because of the number of people without experience, and suggested that the total time for CPT codes 43285 and 47562 is nearly identical and both require similar work and intensity. Commenters stated that only 18 non-conflicted survey responses were received despite the efforts of the specialty societies, and that nine physicians had no experience with the procedure in the past 12 months. Commenters also noted that the RUC recommendations used the specialty society survey times, but provided a crosswalk for work RVU valuation.

Many commenters expressed additional concerns about the specialty society survey data, indicating that the survey median and 25th percentile work RVUs were inconsistent with the total physician work for services reported with CPT codes 43284 and 43285. Commenters stated that to accept the results of the survey is to essentially state that the opinions of inexperienced surgeons is adequate to determine the value of a surgical procedure and lacked input from surgeons experienced in performing the procedure. Commenters suggested that CMS maintain carrier pricing for services reported with CPT codes 43284 and 43285 while the specialty societies conduct new surveys that include data from surgeons experienced with the procedures. Some commenters suggested that the work of CPT codes 43284 and/or 43285 is more similar to fundoplication procedures reported with CPT code 43280 (a work RVU of 18.10). Other commenters suggested valuations for these procedures ranging from 14 to 17 work RVUs, stating that the services reported with CPT codes 43284 and 43285 were slightly less complicated than fundoplication procedures, but more complex than the valuations reflected in the survey results, RUC recommendations, and CMS proposed values.

Response: We appreciate the feedback received from stakeholders regarding valuation of these services. After considering the comments received, for CY 2017, we are finalizing the RUC-recommended values for CPT codes 43284 (a work RVU of 10.13) and 43285 (a work RVU of 10.47). We recognize commenters' concerns regarding the specialty society survey data and believe these codes may be potentially misvalued. We look forward to receiving feedback from interested parties and specialty societies regarding accurate valuation of these services for consideration during future rulemaking.

(20) Percutaneous Biliary Procedures Bundling (CPT Codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47541, 47542, 47543, and 47544)

This group of fourteen codes was reviewed by the RUC at the April 2015 meeting. We established interim final values for this group of codes during the CY 2016 PFS rulemaking cycle, and subsequently received updated RUC recommendations from the October 2015 meeting for the CY 2017 PFS rulemaking cycle. Our proposals for these codes incorporated both the updated RUC recommendations, as well as public comments received as part of the interim final status of these procedures.

We received several comments regarding the CMS refinements to the work values for this family of codes in the CY 2016 final rule with comment period. The relevance of many of these comments has been diminished by the new series of RUC recommendations for work values that we received as a result of the October 2015 meeting. Given that we proposed the updated RUC-recommended work RVUs for CPT codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47542, 47543, and 47544, we solicited additional comments relative to these proposed values. We agreed that the second round of physician surveys conducted for the October 2015 RUC meeting more accurately captured the work and time required to perform these procedures. The one exception was CPT code 47541; the survey times for this procedure were identical as conducted for the April and October 2015 RUC meetings, yet the RUC recommendation increased from a work RVU of 5.61 in April to a work RVU of 7.00 in October. Given that the time values for the procedure remained unchanged between the two surveys, we do not understand why the work RVU would have increased by nearly 1.50 in the intervening months. Since this code also has an identical intraservice time (60 minutes) and total time (121 minutes) as CPT code 47533, we do not agree that it should be valued at a substantially higher rate compared to a medically similar procedure within the same code family. We therefore proposed to crosswalk the work value of CPT code 47541 to the work value of CPT code 47533, and we proposed a work RVU of 5.63 for both procedures.

We also note that many of the codes in the Percutaneous Biliary Procedures family were previously included in Appendix G, and were valued under the assumption that moderate sedation was typically performed on the patient. As part of the changes for services previously valued with moderate sedation as inherent, we are removing a portion of the work RVU and preservice work time from CPT codes 47532, 47533, 47534, 47535, 47536, 47538, 47539, 47540, and 47541. For example, we proposed a work value for CPT code 47541 with a 0.25 reduction from 5.63 to 5.38, and a 10 minute reduction in its preservice work time from 33 minutes to 23 minutes, to reflect the work that will now be reported separately using the new moderate sedation codes. CPT codes 47542, 47533, and 47544 also were valued with moderate sedation; however, as add-on codes, they are not subject to alterations in their work RVUs or work times since the moderate sedation code with work RVUs and work time (99152) will only be billed once for each base-code and not additionally with the add-on codes. These changes are reflected in Appendix B and the work time file posted to the web; see section II.D for more details.

For the direct PE inputs, we did not propose to include the recommended L051A clinical labor for ''Sedate/apply anesthesia'' and the L037D for ''Assist Physician in Performing Procedure'' for CPT codes 47531 and 47537. As we wrote in the CY 2016 final rule with comment period (80 FR 71053), we believe that this clinical labor describes activities associated with moderate sedation, and moderate sedation is not typical for these procedures. We also proposed to refine the L037D clinical labor for ''Clean room/equipment by physician staff'' from 6 minutes to 3 minutes for all of the codes in this family. Three minutes is the standard for this clinical labor activity, and we continued to maintain that the need for additional clinical labor time for this cleaning activity would not be typical for these procedures.

Comment on the CY 2016 PFS final rule with comment period: One commenter disagreed with our refinement to replace supply item ''catheter, balloon, PTA'' (SD152) with supply item ''catheter, balloon ureteral (Dowd)'' (SD150). The commenter stated that a Dowd catheter is designed and FDA approved for use in the prostatic urethra by retrograde placement through the penile urethra, and it is not designed for use in an antegrade ureteral dilation procedure. The commenter stated that this replacement is inappropriate. The updated RUC recommendations for this family of codes also restored the balloon PTA catheter.

Response in the CY 2017 PFS proposed rule: We proposed again to replace the recommended supply item ''catheter, balloon, PTA'' (SD152) with supply item ''catheter, balloon ureteral (Dowd)'' (SD150). We believed that the use of this ureteral balloon catheter, which is specifically designed for catheter and image guidance procedures, would be more typical than the use of a PTA balloon catheter. While we recognize that the Dowd catheter is not FDA approved, it is our understanding that the PTA balloon catheter has also not been FDA approved for use in these procedures. We were uncertain if the commenter was requesting that we should no longer include catheters that lack FDA approval in the direct PE database; this

would preclude the use of most of the catheters in our direct PE database. We solicited additional comment on the use of FDA approved catheters; in the meantime, we continued our long-standing practice of using the catheters in the direct PE database without explicit regard to FDA approval in particular procedures.

We also proposed to remove the recommended supply item ''stone basket'' (SD315) from CPT code 47543 and add it to CPT code 47544. Based on the code descriptors, we believed that the stone basket was intended to be included in CPT code 47544 and was erroneously listed under CPT code 47543. We solicited comments from the public to help clarify this issue.

We noted again that many of the codes in the Percutaneous Biliary Procedures family were previously included in Appendix G, and as part of the change in moderate sedation reporting, we removed some of the recommended direct PE inputs related to moderate sedation from CPT codes 47532, 47533, 47534, 47535, 47536, 47538, 47539, 47540, and 47541. We removed the L051A clinical labor time for ''Sedate/apply anesthesia'', ''Assist Physician in Performing Procedure (CS)'', and ''Monitor pt. following moderate sedation''. We also removed the conscious sedation pack (SA044) supply, and some or all of the equipment time for the stretcher (EF018), the mobile instrument table (EF027), the 3-channel ECG (EQ011), and the IV infusion pump (EQ032). These changes are reflected in the public use files posted to the web; see section II.D for more details.

The following is a summary of the comments we received regarding our proposed valuation of the Percutaneous Biliary Procedures codes.

Comment: Several commenters disagreed with the proposed work RVU of 5.45 for CPT code 47541. Commenters stated that although CPT codes 47541 and 47533 share similar time values, the patient population for CPT code 47541 is more complex with post-surgical anatomy and atypical problems. Therefore, the commenters stated that the direct crosswalk creates a sharp rank order anomaly within the family, and requested that CMS adopt the RUC-recommended work RVU.

Response: We agree with the commenters that the proposed work RVU for CPT code 47541 has the potential to create an anomalous relationship between the services in this family of codes. After considering the comments, we are finalizing a work RVU of 6.75 for CPT code 47541, which is the RUC-recommended work RVU of 7.00 after removing 0.25 RVUs to account for the fact that moderate sedation will now be billed separately for this service.

Comment: One commenter requested 2 minutes for the clinical labor task ''Sedate/apply anesthesia'' and 15 minutes for the clinical labor task ''Assist Physician in Performing Procedure'' for CPT codes 47531 and 47537. The commenter agreed with CMS that moderate sedation was not typical for either procedure, but stated that the 2 minutes was for the RN to administer the pre-procedure prophylactic antibiotics and the 15 minutes for assisting the physician was unrelated to moderate sedation.

Response: We disagree with the commenter that the clinical labor time for these tasks would be typical for CPT codes 47531 and 47537. For the 2 minutes of apply anesthesia time, we do not agree that this clinical labor time should be assigned when the clinical staff is performing an entirely different activity. We have not assigned clinical labor time in this way in the past, and the request for 2 minutes related to administering pre-procedure prophylactic antibiotics was never discussed in the recommendations for these procedures.

For the 15 minutes of assist physician time, the commenter did not provide a justification for why an additional staff member would be needed or what the staff member would be doing. CPT codes 47531 and 47537 already contain two clinical staff members, one technician to assist the physician and another technician to acquire images, plus a circulator. The other codes in the Percutaneous Biliary Procedures family previously had a third RN clinical staff member to administer the sedation to the patient, before moderate sedation was split off into its own separate procedure codes. However, CPT codes 47531 and 47537 do not typically require sedation, and we do not agree that this additional clinical staff member would be required to perform the procedures.

Comment: Several commenters again objected to the proposed replacement of the recommended supply item ''catheter, balloon, PTA'' (SD152) with supply item ''catheter, balloon ureteral (Dowd)'' (SD150). Commenters stated that this would not reflect the practice patterns of the Interventional Radiology community, as it is atypical and even quite rare to use ureteral balloon dilatation catheters in the biliary tree. The commenters provided information regarding the size of uretal balloon catheters, indicating that the maximum diameter is 8mm (Bard) or 7mm (Cook Medical). According to commenters, these sizes are frequently inadequate to treat the wide variety of pathologies in the biliary tree where often balloon sizes up to 12 mm are required. As a result, the commenters stated that the change of the balloon catheter supply item does not accurately represents the actual supplies utilized in real practice, nor does the Dowd ureteral balloon catheter satisfy the clinical need performed during the procedure.

Response: We appreciate the additional clinical information supplied by the commenters regarding the current use of balloon catheters. However, although commenters stated that Bard catheters and Cook Medical catheters are frequently too small to treat some of the wide variety of pathologies that occur in the biliary tree, commenters did not indicate what size balloon catheter would be typically used for these particular procedures in the Percutaneous Biliary Procedures, or provide a specific rationale for why the catheter we proposed (the Dowd ureteral balloon catheter) would not be appropriate for these procedures. We note again that we are required to assess resources based on the typical case, and the commenters did not provide data to indicate that the proposed Dowd catheter would be inadequate in the typical case for these procedures in question, only that it may be insufficient for certain pathologies in the biliary tree. We continue to believe that the Dowd ureteral balloon catheter, which is specifically designed for catheter and image guidance procedures, would be more typical than the use of a PTA balloon catheter.

Comment: One commenter indicated that the stone basket supply (SD315) had indeed been incorrectly assigned to CPT code 47543, and thanked CMS for moving it to CPT code 47544 where it was intended.

Response: We appreciate the response from the commenter.

After consideration of comments received, we are finalizing our proposed work RVUs for the Percutaneous Biliary Procedures family of codes, with the one change to a work RVU of 6.75 for CPT code 47541. We are finalizing our proposed direct PE inputs without refinement.

(21) Percutaneous Image Guided Sclerotherapy (CPT Code 49185)

For CY 2016, we established an interim final work RVU of 2.35 for CPT code 49185 based on a crosswalk from CPT code 62305 (Myelography via lumbar injection, including radiological supervision and interpretation; 2 or more regions (*e.g.*, lumbar/thoracic,

cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical)); which we believed accurately reflected the time and intensity involved in furnishing services reported with CPT code 49185. We also requested stakeholder input on the price of sclerosing solution (supply item SH062) as the volume of the solution in this procedure (300 mL) is much higher than other CPT codes utilizing sclerosing solution (between 1 and 10 mL).

Comment on the CY 2016 PFS final rule with comment period: In response to the CY 2016 PFS final rule with comment period (80 FR 71054), commenters disagreed with CMS' crosswalk from CPT code 62305. Commenters suggested that the RUC's recommended crosswalk from CPT code 31622 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)) was a more appropriate comparison due to the similarity of the services. Commenters requested that CPT code 49185 be referred to the refinement panel. The requests did not meet the requirements related to new clinical information for referral to the refinement panel. We continue to believe that for CPT code 49185 a crosswalk from the value of CPT code 62305 is accurate due to similarities in overall work.

Commenters also stated that the procedure reported with CPT code 49185 required a separate clinical labor staff type. The commenter noted that, due to the inclusion of this additional individual, the L037D clinical labor and additional gloves were appropriate to include in the procedure. The commenter did not provide any evidence for this claim.

Response in the CY 2017 PFS proposed rule: We continue to believe that this additional use of clinical staff would not be typical for CPT code 49185. This procedure does not involve moderate sedation, and therefore, we do not believe that there would be a typical need for a third staff member. Additionally, we did not receive any information regarding the sclerosing solution (supply item SH062) that supports maintaining an input of 300 mL, which far exceeds the volume associated with other CPT codes.

Therefore, for CY 2017, we proposed a work RVU of 2.35 for CPT code 49185. We sought stakeholder feedback regarding why a different work RVU or crosswalk would more accurately reflect the resources involved in furnishing this service. We also proposed to maintain our direct PE refinements from the CY 2016 PFS final rule with comment period, but proposed to refine the direct practice expense inputs for the sclerosing solution (supply item SH062) from 300 mL to 10 mL, which is the highest level associated with other CPT codes utilizing sclerosing solution.

The following is a summary of the comments we received regarding our proposed valuation of CPT code 49185.

Comment: Commenters requested that CMS use the RUC-recommended crosswalk from CPT code 31622 instead of the CMS-proposed crosswalk from CPT code 62305. Commenters stated that CMS' crosswalk undervalues the services, the RUC-recommended crosswalk has analougous clinical activities during the procedure, as well as a similar risk, and the intensity of work involved for services reported with CMS' comparison code is less than during sclerotherapy. Commenters suggested that the sclerotherapy procedure includes inherent risks and challenges that are not adequately accounted for in CMS' proposed crosswalk.

Response: We disagree with commenters that the RUC's recommended crosswalk from CPT code 31622 has analogous clinical activities compared to CMS' proposed crosswalk from CPT code 62305. CMS' crosswalk code refers to a procedure with injection, drainage, and aspiration, which has more clinical similarity to CPT code 49185 than the RUC's recommended crosswalk from 31622, which is used to report a broncoscopy procedure. We continue to believe that a work RVU of 2.35 is an appropriate valuation for services reported using CPT code 49185 and we maintain that CPT code 62305 is an accurate crosswalk, since CPT codes 49185 and 62305 have similar service times. Therefore, for CY 2017, we are finalizing a work RVU of 2.35 for CPT code 49185.

Comment: Commenters disagreed with CMS' proposal to include a direct PE input of 10 mL of sclerosing solution (supply item SH062) and requested that CMS accept the RUC's recommendation to include 300 ml of sclerosing solution as part of the direct PE inputs for this procedure. One commenter indicated that other services that utilize sclerosing solution are used to describe injection of sclerosant into vascular structures which tend to be relatively small in size, and therefore, use a much smaller volume. Another commenter stated that for this procedure, the sclerosing solution is injected and drained three separate times, equating to 100 mL per injection, and that use of lesser volumes of sclerosant or less than three administrations of the sclerosant during the procedure would allow for more frequent recurrence necessitating additional procedures.

Response: We appreciate the commenters' feedback regarding the direct PE inputs for CPT code 49185. We inadvertently included the RUC-recommended quantity of 300 mL for the sclerosing solution (supply item SH062) in developing the proposed rates for this code. For CY 2017, we are finalizing the RUC-recommended direct PE inputs, including 300 mL of sclerosing solution. We welcome stakeholder feedback regarding the appropriate PE inputs for this procedure for consideration for CY 2018, including volume and pricing of the sclerosing agent.

(22) Genitourinary Procedures (CPT Codes 50606, 50705, and 50706)

In the CY 2016 PFS final rule with comment period, we established as interim final the RUC-recommended work RVUs for all three codes. We did not receive any comments on the work values for these codes, and we proposed to maintain all three at their current work RVUs.

The RUC recommended the inclusion of ''room, angiography'' (EL011) for this family of codes. As we discussed in the CY 2016 PFS final rule with comment period, we did not believe that an angiography room would be used in the typical case for these procedures, and we therefore replaced the recommended equipment item ''room, angiography'' with equipment item ''room, radiographic-fluoroscopic'' (EL014) for all three codes on an interim final basis. We also stated our belief that since the predecessor procedure codes generally did not include an angiography room and we did not have a reason to believe that the procedure would have shifted to an angiography room in the course of this coding change, we did not believe that the use of an angiography room would be typical for these procedures.

Comment on the CY 2016 PFS final rule with comment period: Several commenters disagreed with the CMS substitution of the fluoroscopic room in place of the angiography room. The commenters stated that all three of these procedures were previously reported using CPT code 53899 (Unlisted procedure, urinary system) which does not have any PE inputs, and the RUC recommendations included as a reference CPT code 50387 (Removal and replacement of externally accessible transnephric ureteral stent), which includes an angiography room. The commenters suggested that CPT code 50387 was an example of a predecessor code that included the use of an angiography room, along with other

codes that are being bundled together to create the new Genitourinary codes.

Response in the CY 2017 PFS proposed rule: We did not agree with the commenters' implication that because CPT code 50387 was an appropriate reference code for use in valuation, that it necessarily would have previously been used to describe services that are now reported under CPT codes 50606, 50705, or 50706. Our perspective was consistent with the RUC-recommended utilization crosswalk for the three new codes, which did not suggest that the services were previously reported using 50706. We did not believe that use of one particular code for reference in developing values for another necessarily meant that the all of the same equipment would be used for both services.

We did not believe that these codes described the same clinical work either. CPT code 50387 is for the ''Removal and replacement of externally accessible transnephric ureteral stent'' while CPT code 50606 describes an ''Endoluminal biopsy of ureter and/or renal pelvis'', CPT code 50705 refers to ''Ureteral embolization or occlusion'', and CPT code 50706 details ''Balloon dilation, ureteral stricture.'' Additionally, the codes do not have the same global periods, which makes comparisons between CPT code 50387 and CPT codes 506060, 50705, and 50706 even more difficult. We noted that while the commenter stated that CPT code 50387 was provided as a reference for these procedures, 50387 is not listed as a reference for any of these three codes, or mentioned at all in the codes' respective summary of recommendations. However, we acknowledged that among the procedures that are provided as references, many of them included the use of an angiography room, such as CPT code 36227 (Selective catheter placement, external carotid artery) and CPT code 37233 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel). Therefore, we agreed that the use of the angiography room in these procedures, or at least some of its component parts, might be warranted.

Comment on the CY 2016 PFS final rule with comment period: A commenter stated that the substitution of the fluoroscopic room for the angiography room was clinically unjustified. The commenter stated that the angiography room was needed for these procedures to carry out 3-axis rotational imaging (so as to avoid rolling the patient), ensure sterility, and avoid unacceptable radiation exposure to physicians, their staff, and their patients. The commenter indicated that the only piece of equipment listed in the angiography room that would not be typically utilized for these procedures is the Provis Injector. All of the other items were used for these Genitourinary procedures. The commenter urged CMS to restore the angiography room to these procedures.

Response in the CY 2017 PFS proposed rule: We agreed that it is important to provide equipment that is medically reasonable and necessary. Our concern with the use of the angiography room for these codes was that we did not believe all of the equipment would be typically necessary to furnish the procedure. For example, the commenter agreed that the Provis Injector would not be required for these Genitourinary codes. Therefore, we proposed to remove the angiography room from these three procedures and add in its place the component parts that make up the room. Table 17 detailed these components:

TABLE 17—ANGIOGRAPHY ROOM (EL011) COMPONENTS

Component
100 KW at 100 kV (DIN6822) generator
C-arm single plane system, ceiling mounted, integrated multispace
T motorized rotation, multiple operating modes
Real-time digital imaging
40 cm image intensifier at 40/28/20/14cm
30 x 38 image intensifier dynamic flat panel detector
Floor-mounted patient table with floating tabletop designed for angiographic exams and interventions (with peistepping for image intensifiers 13in+)
18 in TFT monitor
Network interface (DICOM)
Careposition: radiation free positioning of collimators
Carewatch: acquisition and monitoring of configurable dose area product
Carefilter: Cu-prefiltration
DICOM HIS/RIS
Control room interface
Injector, Provis
Shields, lower body and mavig
Leonardo software
Fujitsu-Siemens high performance computers
Color monitors
Singo modules for dynamic replay and full format images
Prepared for internal networking and Siemens remote servicing, both hardware and software

We included all of the above components except the Provis Injector, as commenters indicated that its use would not be typical for these procedures. We welcomed additional comments regarding if these or other components were typically used in these Genitourinary procedures. We lacked pricing information for these components; we therefore proposed to include each of these components in the direct PE input database at a price of $0.00 and we solicited invoices from the public for their costs to be able to price these items for use in developing final PE RVUs for CY 2017.

We also noted that we believed that this issue illustrated a potentially broad problem with our use of equipment ''rooms'' in the direct PE input database. For most services, we only include equipment items that are used and unavailable for other uses due to their use during the services described by a particular code. However, for items included in equipment ''rooms,'' we allocate costs regardless of whether the individual items that comprise the room are actually used in the particular service.

To maintain relativity among different kinds of procedures, we were interested in obtaining more information specifying the exact resources used in furnishing services described by different codes. We hoped to address this subject in greater detail in future rulemaking.

The following is a summary of the comments we received regarding our proposed valuation of the Genitourinary codes:

Comment: Many commenters objected to the removal of the angiography room from these codes and its replacement with the component parts of the room. Commenters stated that it was misguided to unbundle the components of the angiography room when one equipment item within the room is not utilized. They indicated that there are numerous cases where an equipment room is used despite the fact that not every item in the room is needed for a service, because in practice the rooms are configured for the most typical type of procedure performed within the room and it would not be efficient or realistic to remove items from a room when a less typical service is needed. For the specific case of the Provis Injector equipment, commenters stated it could not be used elsewhere and there was no way to create a separate angiography room for nonvascular procedures that did not require the injector.

Commenters did not generally agree with the CMS proposal to price all of the components of the angiography room at $0.00 pending invoices from the public regarding their individual cost. Commenters stated that the resource cost of the angiography room components was clearly not $0.00, since the equipment in total costs over $1.3 million. Commenters stated that it was

not realistic to submit 21 separate invoices during the 60 day comment period, and furthermore that the components of the angiography room are typically not sold separately.

Response: We appreciate the feedback from commenters regarding the difficulties involved in pricing the components for the angiography room. We have longstanding issues with the equipment rooms as they are currently constituted, due to our belief that all of the components of the room may not typically be used in performing the procedure in question. We continue to believe that these three codes do not make use of all of the components of the angiography room, and we believe that this code family serves as a clear example of the problems in relativity associated with the use of ''rooms'' as equipment items for a limited set of services under the PFS. However, we agree with the commenters that it is not likely that the components of the angiography room do not have a price. Therefore, while we continue to seek invoices for more detailed pricing information, we are restoring the angiography room (EL011) equipment to these three codes, with an equipment time of 47 minutes for CPT code 50606, 62 minutes for CPT code 50705, and 62 minutes for CPT code 50706, in each case consistent with the equipment time in CY 2016. We intend to continue to consider the use of equipment ''rooms'' more broadly for future rulemaking.

After consideration of comments received, we are finalizing our work values for the three Genitourinary codes as proposed. We are finalizing the proposed direct PE inputs as well, with the changes to the angiography room as detailed above.

(23) Electromyography Studies (CPT Code 51784)

We identified CPT code 51784 as potentially misvalued through a screen of high expenditure services by specialty. This family also includes CPT code 51785 (Needle electromyography studies (EMG) of anal or urethral sphincter, any technique) but was not included in this survey. Both services have 0-day global periods. The RUC recommended a work RVU of 0.75 for CPT code 51784. We believe that this service is more accurately valued without a global period, since that is more consistent with other diagnostic services, and specifically, with all the other diagnostic electromyography services. We proposed to eliminate the global period and proposed the RUC-recommended work RVU of 0.75 for CY 2017. We also proposed to change the global period for CPT code 51785 from 0-day to no global period, to be consistent with the global period for CPT code 51784. Additionally, we proposed to add CPT code 51785 to the list of potentially misvalued codes to update the value of the service considering the change in global period, and to maintain consistency with CPT code 51784.

Comment: A commenter supported CMS' proposal to accept the RUC-recommended work value. The commenter requested that CMS indicate any global period changes and requests for codes as part of the family when CMS initially nominates a code or reviews the RUC level of interest (LOI) prior to distribution.

Another commenter, while supporting our acceptance of the RUC-recommended work RVU for CPT code 51784, did not support adding CPT code 51785 to the potentially misvalued code list as that code was addressed recently when the new CPT codes were created for urodynamic testing procedures.

Response: We appreciate commenters' perspectives. We note that CPT code 51785 has not been valued since January 2003, at the same RUC meeting wherein CPT code 51784 was valued. We encourage stakeholders to submit the entire code family when submitting codes for inclusion on the list of potentially misvalued codes.

Comment: One commenter stated that there is no difference in the work value of CPT code 51784 whether it has a 0-day global period versus an XXX global period, and should not be considered as potentially misvalued.

Response: We note that CPT code 51784 was identified as potentially misvalued through a screen of high expenditure services by specialty. In the standard process of code valuation, CMS decided to change the global period to XXX, indicating no global period, so that the code is more closely aligned with other similar services.

Comment: One commenter did not agree that CMS should accept the RUC-recommended work values, stating that the RUC-recommended work RVU underestimates the work involved in furnishing this service.

Response: We remind commenters and stakeholders that disagree with CMS values, including those based on RUC recommendations, that in addition to submitting comments on our proposed rules, they may also nominate codes as potentially misvalued through the public nomination process. After consideration of comments, we are finalizing the work and global period changes as proposed.

(24) Cystourethroscopy (CPT Code 52000)

In the CY 2016 PFS final rule with comment period, CMS identified CPT code 52000 through the screen for high expenditure services. We stated in the CY 2017 proposed rule that the RUC-recommended work RVU of 1.75 for CPT code 52000 is higher than the work RVUs for all 0-day global codes with 10 minutes of intraservice time and we did not believe that the overall intensity of this service was greater than all of the other codes. Instead, we proposed that this code compares favorably to CPT code 58100 (Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure)), which has a work RVU of 1.53, and has identical intraservice time and similar total time. Therefore, we proposed a work RVU of 1.53 for CPT code 52000, using a direct crosswalk to CPT code 58100.

Comment: Commenters requested that CMS finalize the RUC-recommended work RVU of 1.75 for this procedure. Commenters stated that the RUC-recommended crosswalk codes were a more accurate comparison of physician work, time, and intensity for procedures reported with CPT code 52000.

Response: The RUC-recommended work RVU of 1.75 is higher than the work RVUs associated with all other codes with 0-day global periods and 10 minutes of intraservice time, and we continue to believe that the work and intensity of this service is similar to other CPT codes with 10 minutes of intraservice time. Therefore, we are finalizing a work RVU of 1.53 for CPT code 52000.

(25) Biopsy of Prostate (CPT Code 55700)

In the CY 2016 PFS final rule with comment period, CMS identified CPT code 55700 as potentially misvalued based on the high expenditure by specialty screen.

The RUC subsequently reviewed this code for physician work and practice expense and recommended a work RVU of 2.50 based on the 25th percentile of the survey. We believed the RUC-recommended work RVU overestimates the work involved in furnishing this service given the reduction in total service time; specifically, the reduction in preservice and postservice times. The RUC recommendation also appears overvalued when compared to similar 0-day global services with 15 minutes of intraservice time and comparable total times. To develop a proposed work RVU, we crosswalked the work RVUs

for this code from CPT code 69801 (Labyrinthotomy, with perfusion of vestibuloactive drug(s), transcanal), noting similar levels of intensity, similar total times, and identical intraservice times. Therefore, we proposed a work RVU of 2.06 for CPT code 55700.

Comments: A few commenters, including the RUC, noted the RUC compared CPT code 55700 to other 0-day global services with 15 minutes of intraservice time and stated that the RUC-recommended value was appropriate. The RUC noted that the overall work of the surveyed code was similar to services: CPT code 93503 (Insertion and placement of flow directed catheter (eg, Swan-Ganz) for monitoring purposes) (work RVU = 2.91, intraservice time of 15 minutes) and CPT code 36556 (Insertion of non-tunneled centrally inserted central venous catheter; age 5 years or older) (work RVU = 2.50, intraservice time of 15 minutes). The RUC determined that these services required the same intra-service time, comparable physician work and intensity and recommended CMS accept the RUC-recommended work RVU of 2.50. Additionally, the RUC continued to urge specialty societies to submit invoices for new equipment.

Response: We appreciate additional information offered by the commenters. After consideration of comments received, we agree with the additional information provided by commenters and are finalizing the RUC-recommended work RVU of 2.50.

(26) Laparoscopic Radical Prostatectomy (CPT Code 55866)

In the CY 2016 PFS final rule with comment period, we established an interim final work RVU of 21.36 for CPT code 55866 based on a direct crosswalk to CPT code 55840 (Prostatectomy, retropubic radical, with or without nerve sparing). We stated that we believed these codes were medically similar procedures with nearly identical time values, and we did not believe that the difference in intensity between CPT code 55840 and CPT code 55866 was significant enough to warrant the RUC-recommended difference of 5.50 work RVUs. We also compared CPT code 55866 to the work RVU of 25.18 for CPT code 55845, and stated our belief that, in general, a laparoscopic procedure would not require greater resources than an open procedure.

Comment on the CY 2016 PFS final rule with comment period: Several commenters disagreed with the statement that a laparoscopic procedure, such as CPT code 55866, would generally require fewer resources than an open procedure, such as CPT code 55840. Commenters stated that developing the skill necessary to perform a minimally invasive laparoscopic surgery requires a greater degree of experience and specialized training than that required to perform an open prostatectomy. Commenters indicated that this level of practitioner skill should be reflected in the work RVU for the procedure, as intensity is based in part upon skill, mental effort, and psychological stress.

Response in the CY 2017 PFS proposed rule: We agreed with the commenters that skill and technique, as well as mental effort and psychological stress on the part of the practitioner contribute to the overall intensity of the furnishing a given service, and therefore, are one of the two components in determining code-level work RVUs. However, we did not believe that relative increases in requisite skill or technique can be considered alone. Although the development of new technology (such as robotic assistance) may create a greater burden of knowledge on the part of the practitioner, it can also make procedures faster, safer, and easier to perform. This means that there may be reductions in time for such a procedure (which is the other component of the work RVU), but also that the mental effort and psychological stress for a given procedure may be mitigated by the improvements in safety. Therefore, we did not agree that a newer procedure that includes additional technology and requires greater training would inherently be valued at a higher rate than an older and potentially more invasive procedure.

Comment on the CY 2016 PFS final rule with comment period: A commenter stated that CPT code 55866 describes two very different procedures in one code. The descriptor for the code states ''includes robotic assistance when performed'', and the procedure is performed differently depending on whether or not the robotic assistance is included. The commenter indicated that the vast majority of radical prostatectomies are performed with the robot, and although the outcomes are the same in both cases, the procedures are completely different.

Response in the CY 2017 PFS proposed rule: We agreed with the commenter that the descriptor includes the possibility for confusion, especially on the part of the survey respondents. Valuing this code based on the typical case is difficult when the procedure differs depending on the inclusion or exclusion of robotic assistance. We suggested that valuation might be improved if the CPT Editorial Panel were to consider further revisions to this code to describe the two cases of laparoscopic radical prostatectomy: With and without robotic assistance.

Comment on the CY 2016 PFS final rule with comment period: One commenter stated that the application of the phase-in transition for facility-only codes like CPT code 55866 would have a particularly egregious impact in the second year of the transition. The commenter urged CMS to ensure that its implementation of the phase-in transition does not undermine the protections created by the statute.

Response in the CY 2017 PFS proposed rule: Please see sections II.G and II.H for a discussion of the phase-in transition and its implementation in its second year.

Comment on the CY 2016 PFS final rule with comment period: Several commenters requested that CMS refer CPT code 55866 to the refinement panel for review. At the refinement panel, the presenters brought up new evidence in the form of a study published in 2016 describing discharge data for radical laparoscopic prostatectomies. The presenters stated that there were many more people included in this study as opposed to the 30 respondents in the survey data, and that on average the robotic procedure took 90 minutes longer than the open procedure. The additional time needed to perform the procedure, as indicated by this new study's results, was presented as a new rationale as to why CMS should accept the RUC-recommended work RVU.

Response in the CY 2017 PFS proposed rule: CPT code 55866 was referred to the CY 2016 Multi-Specialty Refinement Panel per the request of commenters. The outcome of the refinement panel was a median work RVU of 26.80, the same value as the RUC recommended in the previous rulemaking cycle. After consideration of the comments and the results of the refinement panel, we proposed for CY 2017 to maintain the interim final work RVU of 21.36 for CPT code 55866. We were interested in the results of the study mentioned at the refinement panel, and we stated that we would consider incorporating this data into the valuation of this code, including, if appropriate, adjustments to the work times used in PFS ratesetting. We also solicited that the study be submitted through the public comment process so that we could allow it proper consideration along with other information submitted by the public, rather than using the results of a single study to propose valuations. We were also curious about the time values

regarding the duration of CPT code 55866. One of the members of the refinement panel stated that on average the robotic procedure took 90 minutes longer than the open procedure. This was not what was indicated by the survey data from the RUC recommendations, which had the two procedures valued at virtually identical times (same intraservice time, 6 minutes difference total time). We therefore solicited comment on whether the times included in this study were more accurate than the time reflected in the RUC surveys.

The following is a summary of the comments we received regarding our proposed valuation of CPT code 55866:

Comment: One commenter agreed that the code descriptor for CPT code 55866 might have caused confusion by the RUC survey respondents. The commenter stated that they were encouraged by the CMS comments that the valuation might be improved if the CPT Editorial Panel were to consider further revisions to this code to describe a laparoscopic radical prostatectomy with and without robotic assistance. The commenter requested a strong statement from CMS urging the CPT Editorial Panel to create two unique codes: One for laparoscopic radical prostatectomy and one for robotic radical prostatectomy.

Response: We believe that there are potential problems with CPT code 55866 as it is currently described and with the corresponding RUC recommendation. Commenters presented data suggesting that there are significant differences between the robotic and non-robotic versions of the procedure in the length of time required to perform the operation. However, the same data also suggests that the non-robotic version of the laparoscopic radical prostatectomy has become comparatively rare. Given the information presented by commenters, we believe that valuation might be improved with further revisions to this code. However, we note that we do not direct the work of the CPT Editorial Panel, and we also note the comparative rarity of the non-robotic version of the procedure.

Comment: Several commenters referenced a study entitled ''Robot-assisted versus Open Radical Prostatectomy: A Contemporary Analysis of an All-payer Discharge Database'' by J.L. Leow, S.L. Chang, and colleagues. This study was published in February 2016, and it detailed how university investigators analyzed more than 600,000 men undergoing radical prostatectomy in the United States from 2003–2013, which showed that the robotic approach took on average 90 minutes longer than an open radical prostatectomy. Commenters noted how this contrasted to the RUC survey data that had only 32 respondents and recommended an intraservice time equal to an open radical prostatectomy (180 minutes). The commenters presented the study data in favor of demonstrating how the robotic approach to radical prostatectomy detailed in CPT code 55866 takes significantly more time to perform than the open approach detailed in the CMS crosswalk code 55840. Commenters recommended that CMS adopt the RUC-recommended work RVU of 26.80 based on this new clinical evidence contained in the study.

Response: We appreciate the submission of this additional clinical information from the commenters. We have had longstanding interest in using robust data sources regarding the resource costs of PFS services, and we believe that the use of such additional outside data sources can improve the accuracy of the valuation of services. However, we do note that the cited study was not specifically designed to measure intraoperative times and did not use the same ''skin to skin'' definition of intraservice time typically used in the development of times included in PFS ratesetting.

In this case of the particular comment, we note the potential logical dissonance of the commenter urging us to adopt the RUC-recommended work value derived from the RUC survey by citing alternative data that calls into question the accuracy of the time data from the same RUC survey. In other words, we are troubled with the idea that we should consider survey data as valid for work while rejecting its validity for time, given that time is one of the two elements of overall work.

Despite these concerns, we agree that the study presents additional data indicating that there is a significant difference between the open and robotic-assisted forms of laparoscopic radical prostatectomy, and that the robotic form described by CPT code 55866 likely takes a longer time to perform. Based on this presentation of additional clinical evidence, we agree with the commenters that the recommended work RVU of 26.80 is a more appropriate value for this procedure.

After consideration of comments received, we are finalizing a work RVU of 26.80 for CPT code 55866.

(27) Hysteroscopy (CPT Codes 58555, 58558, 58559, 58560, 58561, 58562, and 58563)

During CY 2016 PFS rulemaking, we identified CPT code 58558 as a potentially misvalued code via the high expenditure specialty screen. CPT codes 58559–58563 were also included in the RUC's January 2016 review of this family of codes.

For CPT code 58555, the RUC recommended a work RVU of 3.07. We proposed that the 25th percentile survey result, a work RVU of 2.65, accurately reflects the resources involved in furnishing this service. We stated that this value is bracketed by two crosswalk codes, CPT code 43191 (Esophagoscopy, rigid, transoral; diagnostic, including collection of specimen(s) by brushing or washing when performed (separate procedure)), which has a work RVU of 2.49, and CPT code 31295 (Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (for example, balloon dilation), transnasal or via canine fossa), which has a work RVU of 2.70. CPT codes 43191 and 31295 have identical intraservice times and similar total times when compared with CPT code 58555.

For CPT code 58558, the RUC recommended a work RVU of 4.37. However, we believed that a direct crosswalk from CPT code 36221 (Non-selective catheter placement, thoracic aorta, with angiography of the extracranial carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed), which has a work RVU of 4.17, and identical intraservice time, and similar total time, more accurately reflects the time and intensity of furnishing this service. Our proposed work RVU was additionally supported by using an increment between this code and the base code for this family, CPT code 58555. The increment between the RUC-recommended values for these two codes is 1.3. That increment added to the proposed work RVU of 2.65 for the base code, CPT code 58555, results in a work RVU of 3.95. Therefore, we proposed a work RVU of 4.17 RVUs for CPT code 58558.

For CPT code 58559, the RUC recommended a work RVU of 5.54. However, we believed that a direct crosswalk from CPT code 52315 (Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); complicated), which has a work RVU of 5.20, a similar intraservice

time, and similar total time as compared with CPT code 58559 more accurately reflects the time and intensity of furnishing this service. This proposed value was additionally supported by using an increment between CPT code 58559 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 2.47. That increment added to the proposed value for the base code, CPT code 58555, would result in a work RVU of 5.12. Therefore, we proposed a work RVU of 5.20 for CPT code 58559.

For CPT code 58560, the RUC recommended a work RVU of 6.15. We stated in the proposed rule that we believe that a direct crosswalk from CPT code 52351 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; diagnostic), which has a work RVU of 5.75 and which has more intraservice time and very similar total time, more accurately reflects the time and intensity of furnishing this service. Our proposal further supported this value by using an increment between CPT code 58560 and the base code for this family, CPT code 58555. We stated that the increment between the RUC recommended values for the two codes is 3.08. That increment added to the proposed value for the base code, CPT code 58555, would result in a work RVU of 5.73. Therefore, we proposed a work RVU of 5.75 for CPT code 58560.

For CPT code 58561, the RUC recommended a work RVU of 7.00. We stated in the proposed rule that we believe that a direct crosswalk from CPT code 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel), which has a work RVU of 6.60 and which has similar intraservice and total times, more accurately reflected the time and intensity of furnishing this service. We also noted that our proposal was further supported by using an increment between CPT code 58561 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 3.93. That increment added to the proposed value for the base code, CPT code 58555, would result in a work RVU of 6.58. Therefore, we proposed a work RVU of 6.60 for CPT code 58561.

For CPT code 58562, the RUC recommended a work RVU of 4.17. However, we believed that a direct crosswalk of the work RVUs for CPT code 15277 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children), which has a work RVU of 4.00 and which has identical intraservice time and similar total time, more accurately reflects the time and intensity of furnishing this service. The RUC also used this code as one of its supporting codes for its recommendation. This value is additionally supported by using an increment between CPT code 58562 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 1.10. That increment added to the proposed value for the base code, CPT code 58555, results in a work RVU of 3.75. Therefore, we proposed a work RVU of 4.00 for CPT code 58562.

For CPT code 58563, the RUC recommended a work RVU of 4.62. However, we believed that a direct crosswalk of the work RVUs for CPT code 33962 (Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, 6 years and older (includes fluoroscopic guidance, when performed)), which has a work RVU of 4.47 and that has identical intraservice time and similar total time, more accurately reflects the resources involved in furnishing this service. This value is additionally supported by using an increment between CPT code 58563 and the base code for this family, CPT code 58555. The increment between the RUC recommended values for the two codes is 1.55. That increment added to the proposed value for the base code, CPT code 58555), results in a work RVU of 4.20. We note that CPT code 58563 has the same instraservice time and the same total time as CPT code 58558; however, we agreed that the intensity would be slightly higher for this service. Therefore, we proposed a work RVU of 4.47 for CPT code 58562.

The RUC submitted invoices for two new equipment items used in furnishing CPT code 58558, the hysteroscopic fluid management system and the hysteroscopic resection system. We proposed to use these invoice prices for the hysteroscopic fluid management system, which totaled $14,698.38. The hysteroscopic resection system included the price of the hysteroscope, as well as other items necessary for tissue removal. However, we generally price endoscopes separately and not as a part of a system. To maintain consistency, we proposed not to include the hysteroscope from the Resection System. Instead, we proposed to update the equipment item ''endoscope, rigid, hysteroscopy'' (ES009) with the invoice price, $6,207.50. We did not propose to include the sterilization tray from the hysteroscopic resection system because we believe this tray has generally been characterized as an indirect practice expense. For the hysteroscopic resection system, we proposed to include the hysteroscopic tissue remover ($18,375), the sheath ($1,097.25), and the calibration device ($300), and created a new equipment item code, priced at $19,857.50 in the proposed direct PE input database. We did not propose to include the calibration device since the submitted price was not documented with a paid invoice.

Comment: Commenters, including the RUC, disagreed with CMS' proposed refinements to the work RVUs for these procedures, and requested that CMS finalize the RUC-recommended work values for these codes. Commenters suggested that these procedures are more complex in cases where it is more difficult to find and feed the scopes through the cervix. Commenters suggested that it appeared as though CMS used a time to work ratio to value these services, stating further that, for example, CPT code 58555 requires a forced dilation of a natural orifice, very small in size and can be difficult to identify in a post-menopausal patient or a patient with prior cervical surgery. Commenters suggested that the CMS crosswalk codes are for a natural orifice that might not require any dilation or only a 10% dilation, and the orifice is consistently the same with little variation among patients.

Response: While we appreciate the commenters' feedback, we do not consider forced or difficult dilation as described by the commenter to be typical based on the RUC's clinical vignette and that the difficulty of forced dilation at the time of surgery can often be offset by preoperative cervical ripening. Therefore, we are finalizing the following work RVUs for each code in this family.

- CPT code 58555, 2.65 work RVUs;
- CPT code 58558, 4.17 work RVUs;
- CPT code 58559, 5.20 work RVUs;
- CPT code 58560, 5.75 work RVUs;
- CPT code 58561, 6.60 work RVUs;
- CPT code 58562, 4.00 work RVUs; and
- CPT code 58563, 4.47 work RVUs.

Comment: Regarding the direct PE inputs for CPT code 58558, one commenter requested that CMS add a procedure kit and update the prices for these supplies to reflect the cost of providing this procedure in the physician office setting. The commenter also submitted invoices related to other direct PE inputs for this code, including invoices for the incisor blade and the procedure kit, which the commenter

indicated includes inflow tubing, outflow tubing, and the non-sterile components of jumper cables and a tissue trap.

Response: We appreciate the feedback we received regarding the direct PE inputs for CPT code 58558. We agree with the addition of the hysteroscopic procedure kit and are creating a new supply item ''hysteroscopic fluid management tubing set'' using a single invoice price of $320. Additionally, we note that we inadvertently did not remove the existing direct PE inputs related to suction, which we proposed to replace with the hysteroscopic fluid management system. Therefore, we are removing direct PE inputs for the following items:

- Supply item SD009: Canister, suction;
- Supply item SD031: Catheter, suction; and
- Equipment item EQ235: Suction machine (Gomco).

The commenter also included an additional invoice for the incision instrument. Based on this new information, we are renaming this new supply item, ''hysteroscopic tissue removal device,'' with a final price of $629.00, which is the simple average of the two invoice prices we have received for this supply item ($599 and $659 respectively). Additionally, we note that our proposed summary price for the hysteroscopic resection system was added incorrectly. The correct price is $19,772.25. We are also modifying the equipment title to ensure clarity of items included in the hysteroscopic resection system (control unit, footpiece, handpiece, sheath and calibration device).

(28) Intracranial Endovascular Intervention (CPT Codes 61645, 61650, and 61651)

For CY 2016, we established an interim final work RVU of 15.00 for CPT code 61645, 10.00 for CPT code 61650 and 4.25 for CPT code 61651. The RUC-recommended values for CPT codes 61645, 61650 and 61651 were 17.00, 12.00 and 5.50, respectively. We valued CPT code 61645 by applying the ratio between the RUC-recommended reference code, CPT code 37231 (revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed), to the work and time for CPT code 61645. We valued CPT code 61650 based on a crosswalk to CPT code 37221 (revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed), due to similar intensity and intraservice time. We valued CPT code 61651 based on a crosswalk to CPT code 37223 (revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (list separately in addition to the code for primary procedure)), due to similar intraservice time and intensity.

Both CPT codes 61645 and 61650 included postservice work time associated with a level 3 inpatient hospital visit. In the CY 2016 PFS final rule with comment period, we stated that we believe that for the typical patient, these services would be considered hospital outpatient services, not inpatient services. As a result, the intraservice time of the hospital observation care service was valued in the immediate postservice time. We refined the work time for CPT code 61645 by removing 55 minutes of work time associated with CPT code 99233, and added 30 minutes of time to the immediate postservice time. Therefore, the total time for CPT code 61645 was reduced to 241 minutes and the immediate postservice time increased to 83 minutes. We also removed the inpatient visit from CPT code 61650, which reduced the total time to 206 minutes and increased the postservice time to 75 minutes.

Comment on the CY 2016 PFS final rule with comment period: Commenters disagreed with our categorization of these codes as typically outpatient. Commenters stated that according to Medicare claims data, the predecessor codes were performed primarily on an inpatient basis. Additionally, commenters pointed out that the new codes would typically be performed on acute stroke patients. Commenters also said as the new codes are inpatient-only, the CMS reductions in work and time based on the assumption of outpatient status are flawed and suggested we accept the RUC-recommended values. Commenters also requested that these codes be referred to the refinement panel.

Response in the CY 2017 PFS proposed rule: For CY 2016, we valued CPT codes 61645, 61650, and 61651 based on comparisons to CPT codes 37231, 37221, and 37223, respectively. We continue to believe that these crosswalks are appropriate comparisons based on intensity and intraservice time, and because no persuasive information was presented at the refinement panel that indicated that these comparisons are not accurate. Therefore, for CY 2017, we proposed work RVUs of 15.00 for CPT code 61645, 10.00 for CPT code 61650, and 4.25 for CPT code 61651. We also proposed time inputs based on our refinements of the RUC recommendations, including removing the time associated with a hospital inpatient visit (CPT code 99233) from the intraservice work time, and adding 30 minutes to the immediate postservice time for both CPT codes 61645 and 61650.

We do not believe that 0-day global codes should include post-operative visits; rather, if global codes require post-operative visits, they are more appropriately assigned 10- or 90-day global periods based on our current criteria. Our policy has been to remove the visit from the post-operative period and the associated minutes from the total time while adding 30 minutes to the immediate postservice period without necessarily making an adjustment to the work RVU (see the CY 2010 PFS proposed rule, 74 FR 33557; also see the CY 2011 PFS proposed rule, 75 FR 40072). We solicited comment on the inclusion of post-operative visits in valuation of codes with 0-day global periods. Both CPT codes 61645 and 61650 are assigned 0-day global periods, and the refinements we proposed reflected changes to more appropriately value these codes with 0-day global periods.

The following is a summary of the comments we received regarding our proposed valuations for the intracranial endovascular intervention family:

Comment: Commenters, including the RUC, requested that CMS finalize the RUC-recommended work RVUs for CPT codes 61645, 61650 and 61651. The RUC suggested that evaluating the actual physician work performed in the inpatient setting is more accurate than applying a crosswalk to a CPT code that is performed predominantly in the outpatient setting. As examples, the RUC noted that CPT code 61645 would not be performed in the outpatient setting, and CPT codes 61650 and 61651 would be performed in the intensive care unit. For CPT codes 61645 and 61650, commenters also expressed concern about CMS' proposed refinements to remove the time associated with a postservice visit from each code and subsequently adding 30 minutes to the immediate postservice period for each of these codes. The RUC suggested that these CMS refinements artificially reduced the total work time for CPT codes 61645 and 61650.

Response: We continue to believe that our crosswalks for each of these codes accurately reflect the physician work involved in these procedures due to similarities in intensity and intraservice time. For example, our proposed work RVU of 15.00 for CPT code 61645 would be the highest work value among comparable codes with similar intraservice times. We note that we identified three CPT codes with similar intraservice times (CPT codes 33955, 33956, and 33988) that had higher work RVUs than our proposed work RVU of 15.00, but these three CPT codes are used to report extracorporeal membrane oxygenation or extracorporeal life support services (ECMO/ECLS) procedures, which we do not believe are comparable to the CPT codes in this family.

Regarding physician time for CPT codes 61645 and 61650, as we discussed in the proposed rule, we do not believe that 0-day global codes should include post-operative visits; rather, if global codes require post-operative visits, they are more appropriately assigned 10- or 90-day global periods based on our current criteria. Our policy has been to remove the visit from the post-operative period and the associated minutes from the total time while adding 30 minutes to the immediate postservice period without necessarily making an adjustment to the work RVU (see the CY 2010 PFS proposed rule, 74 FR 33557; also see the CY 2011 PFS proposed rule, 75 FR 40072).

Therefore, for CY 2017, we are finalizing a work RVU of 15.00 for CPT code 61645, a work RVU of 10.00 for CPT code 61650, and a work RVU of 4.25 for CPT code 61651.

(29) Epidural Injections (CPT Codes 62320, 62321, 62322, 62323, 62324, 62325, 62326, and 62327)

We proposed the RUC-recommended work RVU for all eight of the codes in this family.

We proposed to remove the 10–12mL syringes (SC051) and the RK epidural needle (SC038) from all eight of the codes in this family. We stated that these supplies were duplicative, as they are included in the epidural tray (SA064). As an alternative, we raised the possibility of removing the epidural tray and replacing it with the individual supply components used in each procedure; we solicited public comment on either the inclusion of the epidural tray or its individual components for this family of codes.

The following is a summary of the comments we received regarding our proposed valuation of the Epidural Injection codes:

Comment: A few commenters expressed their support for the proposed work values.

Response: We appreciate the support from the commenters.

Comment: Several commenters disagreed with the proposed removal of the 10–12mL syringes (SC051) and the RK epidural needle (SC038) due to the CMS belief that they are duplicative of the supplies in the epidural tray (SA064). Commenters stated that although there are three syringes listed in the epidural tray, none of the syringes in the tray are the 10–12mL syringe. In addition, none of the needles currently listed in the epidural tray (SA064) are an epidural needle. As a result, commenters indicated that there was no reason to replace the epidural tray with its individual components.

Response: We appreciate this clarification from the commenters regarding the components that make up the epidural tray. Taking this information into account, we are restoring the 10–12mL syringes (SC051) and the RK epidural needle (SC038) to all eight of the codes in this family.

After consideration of comments received, we are finalizing the proposed work RVUs for the Epidural Injection codes. We are also finalizing the proposed direct PE inputs, with the addition of the 10–12mL syringes and the RK epidural needle detailed above.

(30) Endoscopic Decompression of Spinal Cord (CPT Code 62380)

For CY 2016, the CPT Editorial Panel created CPT code 62380 to describe the endoscopic decompression of neural elements. The RUC recommended a work RVU of 10.47 based on a crosswalk to CPT code 47562 (Laparoscopy, surgical; cholecystectomy) with a higher intraservice time than reflected in the survey data. Since we believe CPT codes 62380 and 47562 are similar in intensity, we believe using the same work RVU as the crosswalk code overestimates the work involved in furnishing CPT code 62380. Reference CPT code 49507 (Repair initial inguinal hernia, age 5 years or older; incarcerated or strangulated) has a work RVU of 9.09 and has similar intensity and an identical intraservice time compared to CPT code 62380. Therefore, we proposed a work RVU of 9.09 for CPT code 62380.

Comment: Some commenters reiterated that the RUC-recommended direct crosswalk to CPT code 47562 is appropriate since this code has a similar physician time, and the IWPUT of the RUC-recommended work RVU is 0.085, a comparable valuation when compared with other spinal decompression procedures. The RUC agreed that the intensity of CPT code 62380 was greater, which offsets the 10 minute difference in intraservice time between the two codes. The RUC indicated that the difference in intensity between these procedures is based on CPT code 62380 involving decompression about neural elements and the spinal cord, where the opportunity for complications and for loss of function is high. One commenter indicated that CMS' proposed work RVU would fall below the minimum survey results.

A few commenters expressed concerns about the structure of the CPT code descriptors and RUC-recommended valuations. Commenters suggested that the CPT Editorial Panel and the RUC did not take certain indications into account such as differences between the physician work required for endoscopic tubular microdiscectomy compared to lumbar spinal stenosis decompression and posterior cervical posterior laminoforaminotomy. Commenters indicated that the specialty society survey data was inadequate due to the inexperience of the survey respondents, with others suggesting that the survey times were not reflective of some practitioners' experience or patient complexity.

The commenters indicated that the current RUC recommendations for full endoscopic tubular endoscopic surgery are based on limited experience among survey respondents with lumbar microdiscectomy, and insufficient experience with lumbar spinal stenosis decompression and posterior cervical foraminotomy without fusion and are invalid for these indications. Commenters requested that the current CPT codes and valuations for full endoscopic lumbar spinal stenosis decompression and posterior cervical foraminotomy without fusion remain unchanged until further RUC survey data are examined. Some commenters suggested alternative crosswalks including CPT code 61548 (Hypophysectomy or excision of pituitary tumor, transnasal or transseptal approach, nonstereotactic) with a work RVU of 23.37, CPT code 63030 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar) with a work RVU of 13.18, and CPT code 63056 (Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (*e.g.,* herniated intervertebral disc), single segment;

lumbar (including transfacet, or lateral extraforaminal approach) (*e.g.,* far lateral herniated intervertebral disc)) with a work RVU of 21.86.

Response: As discussed above, commenters raised multiple concerns about the accuracy of the survey results, the RUC's recommended valuation of this service, and our subsequent proposed refinements. Therefore, at this time, we are finalizing contractor pricing for CPT code 62380. We note that the summary of recommendations (SOR) included with the RUC recommendations indicated that the expert panel reviewing the survey data for this procedure believed the survey median and 25th percentile work RVU were inconsistent with the physician work as it related to other major open spine procedures. Subsequently, the RUC recommended a work RVU of 10.47 based on a crosswalk from CPT code 47562 (Laparoscopy, surgical; cholecystectomy). The RUC noted that procedures reported with CPT code 62380 have ten minutes less intraoperative time compared to the RUC's recommended crosswalk from CPT code 62380, but suggested that the physician work of endoscopic decompression in the small disc interspace near the spinal nerve roots of the cauda equina is more complex and will require more post-discharge office work for required imaging to confirm stabilization and for physical therapy orders and monitoring.

We note that based on the RUC's utilization crosswalk, services that will be reported in CY 2017 with CPT code 62380 are currently reported using either CPT code 22899 (Unlisted procedure, spine) or CPT code 0275T (Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect guidance (*e.g.,* fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar)), which are both contractor priced for CY 2016. We welcome feedback from interested parties and specialty societies regarding valuation of this service for consideration in future rulemaking.

(31) Paravertebral Block Injection (CPT Codes 64461, 64462, and 64463)

In CY 2015, the CPT Editorial Panel created three new codes to describe paravertebral block injections at single or multiple levels, as well as for continuous infusion for the administration of local anesthetic for post-operative pain control and thoracic and abdominal wall analgesia. For the CY 2016 PFS final rule with comment period, we established the RUC-recommended work RVUs of 1.75 and 1.10 as interim final for CPT codes 64461 and 64462, respectively. For CPT code 64463, we utilized a direct crosswalk from three other injection codes (CPT codes 64416 (Injection, anesthetic agent; brachial plexus, continuous infusion by catheter (including catheter placement), 64446 (Injection, anesthetic agent; sciatic nerve, continuous infusion by catheter (including catheter placement), and 64449 (Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)), which all had a work RVU of 1.81, as we believed this crosswalk more accurately reflected the work involved in furnishing this service.

Comment on the CY 2016 PFS final rule with comment period: We received comments from the RUC stating CPT code 64463 was more comparable to CPT code 64483 (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single), which has a work RVU of 1.90 and requires the same physician work and time to perform. The RUC recommended we accept a work RVU of 1.90, which is the 25th percentile of the survey. Another commenter stated that our interim final work RVU for CPT code 64463 was inappropriate since imaging guidance is not part of our comparison codes. The commenter advocated for us to accept the survey respondent's selection of CPT code 64483 as the most appropriate comparison code and assign a work RVU of 1.90.

Response in the CY 2017 PFS proposed rule: After reviewing and considering the comments, we stated we continued to believe that CPT codes 64416, 64446, and 64449, all of which have 20 minutes of intraservice time, are better crosswalks to CPT code 64463, which also has 20 minutes of intraservice time and a similar total time. In contrast, the crosswalk code recommended by commenters, CPT 64483, only has 15 minutes of intraservice time. Therefore, for CY 2017 we proposed a work RVU of 1.81 for CPT code 64463.

The following is a summary of the comments we received regarding our proposed valuations for the Paravertebral Block Injection family:

Comment: One commenter stated that CMS based its decision on an inappropriate comparison of CPT code 64463 with codes that describe continuous peripheral nerve blocks that do not include imaging guidance. The commenter stated that the imaging component included in CPT code 64463 was justification for at least the 0.09 difference between the RUC recommendation and the CMS proposed value. The commenter offered CPT code 47000 (Biopsy of liver, needle; percutaneous), which has identical intraservice time and a work RVU of 1.90 as a comparator code.

Response: We appreciate the additional information offered by the commenters and we agree with the commenter's statement that the image guidance component of this service was justification for the 0.09 difference between the RUC recommendation and the CMS proposed value. After review and consideration of the comments, we are finalizing the RUC-recommended work RVUs of 1.75, 1.10 and 1.90 for CPTs code 64461, 64462 and 64463, respectively for CY 2017.

(32) Implantation of Neuroelectrodes (CPT Codes 64553 and 64555)

The RUC identified CPT codes 64553 and 64555 as a site of service anomaly during the CY 2016 PFS rulemaking cycle. In the Medicare claims data, these services were typically reported in the nonfacility setting, yet the survey data were predicated on a facility-based procedure. We agreed with the RUC that these two codes should be referred to the CPT Editorial Panel to better define the services, in particular to investigate the possibility of establishing one code to describe temporary or testing implantation and another code to describe permanent implantation. We maintained the CY 2015 work RVUs and direct PE inputs for these two codes on an interim basis until receiving updated recommendations from the CPT Editorial Panel and the RUC.

Comment on the CY 2016 PFS final rule with comment period: A commenter requested that CMS allow practitioners to bill the MACs separately for a percutaneous electrode kit (SA022) for CPT code 64555. The commenter stated that without allowing for a separate payment for the percutaneous electrode kit, the payment for the procedure would be insufficient to cover the physician's costs.

Response in the CY 2017 PFS proposed rule: We agreed that CPT codes 64553 and 64555 as currently constructed were potentially misvalued codes, which is why we maintained the CY 2015 work RVUs and direct PE inputs on an interim basis. We believe that the disposable supplies furnished incident to the procedure are paid through the nonfacility PE RVUs. The

percutaneous electrode kit (SA022) was not previously included in the direct PE inputs for either of these two services, and since we proposed to maintain current direct PE inputs pending additional recommendations, we do not agree that disposable supplies should be separately payable. We proposed to maintain the interim final work RVUs and direct PE inputs for these two codes, and we looked forward to reviewing recommendations regarding these procedures again for future rulemaking.

Additionally, we were alerted to a discrepancy regarding the times for these codes in the CY 2016 work time file. Our proposed CY 2017 work time file addressed this discrepancy by reflecting the RUC recommended times of 155 minutes for CPT code 64553 and 140 minutes for CPT code 64555.

The following is a summary of the comments we received regarding our proposed valuation of the Implantation of Neuroelectrodes codes:

Comment: One commenter responded to the CMS request for information about whether there was a need for separate codes for temporary/testing and permanent placement for neuroelectrodes. The commenter stated that it did not support the creation of new separate codes at this time. The commenter stressed that the current codes account for the work of both temporary/testing and permanent placement, making the creation of new codes unwarranted.

Response: We appreciate the submission of this information from the commenter. We did not receive any comments addressing the proposed valuation of these codes.

After consideration of comments, we are finalizing the proposed work RVUs and proposed direct PE inputs for CPT codes 64553 and 64555.

(33) Ocular Reconstruction Transplant (CPT Code 65780)

In CY 2015, the RUC identified CPT code 65780 as potentially misvalued through a misvalued code screen for 90-day global services that included more than 6 office visits. The RUC recommended a direct work RVU crosswalk from CPT code 27829 (Open treatment of distal tibiofibular joint (syndesmosis) disruption, includes internal fixation, when performed). After examining comparable codes, we determined the RUC-recommended work RVU of 8.80 for CPT code 65780 would likely overstate the work involved in the procedure given the change in intraservice and total times compared to the previous values. We believed that the ratio of the total times (230/316) applied to the work RVU (10.73) more accurately reflected the work involved in this procedure. Therefore, we established an interim final work RVU of 7.81 for CPT code 65780.

Comment on the CY 2016 PFS final rule with comment period: The RUC and other commenters disagreed with our interim final values based on objections to our use of time ratios in developing work RVUs for PFS services.

Response in the CY 2017 PFS proposed rule: We stated that we appreciate the commenters' concerns and responded to these concerns about our methodology in section II.L of the CY 2017 proposed rule. After review of the comments, we continued to consider the work RVU of 7.81 to accurately represent the work involved in CPT code 65780. We believed this service was similar in overall intensity to CPT code 27766 (Open treatment of medial malleolus fracture, includes internal fixation, when performed) that has a work RVU of 7.89 and a total time that more closely approximates that of CPT code 65780.

In the CY 2017 proposed rule, we proposed a work RVU of 7.81 for CPT code 65780.

We did not receive any comments in response to our proposed valuation on CPT code 65780; therefore, we are finalizing a work RVU of 7.81 as proposed.

(34) Trabeculoplasty by Laser Surgery (CPT Code 65855)

In CY 2015, the RUC identified CPT code 65855 as potentially misvalued through the review of 10-day global services with more than 1.5 postoperative visits. The RUC noted that the code was changed from a 90-day to a 10-day global period when it was last valued in 2000. However, the descriptor was not updated to reflect that change. CPT code 65855 describes multiple laser applications to the trabecular meshwork through a contact lens to reduce intraocular pressure. The current practice is to perform only one treatment session during a 10-day period and then wait for the effect on the intraocular pressure. The descriptor for CPT code 65855 has been revised and removes the language ''1 or more sessions'' to clarify this change in practice.

The RUC recommended a work RVU of 3.00 for CPT code 65855. While the RUC-recommended value represents a reduction from the CY 2015 work RVU of 3.99, we stated that significant reductions in the intraservice time, the total time, and the change in the office visits represent a more significant change in the work resources involved in furnishing the typical service. The intraservice and total times were decreased by approximately 33 percent while the elimination of two postoperative visits (CPT code 99212) alone would reduce the overall work RVU by at least 24 percent under the reverse building block method. However, the RUC-recommended work RVU only represents a 25 percent reduction relative to the previous value. To identify potential work RVUs for this service, we calculated an intraservice time ratio between the CY 2015 intraservice time, 15 minutes, and the RUC-recommended intraservice time, 10 minutes, and applied this ratio to the current work RVU of 3.99 to arrive at a work RVU of 2.66 for CPT code 65855, which we established as interim final for CY 2016.

Comment on the CY 2016 PFS final rule with comment period: A few commenters, including the RUC, provided explanations as to how the RUC recommendation had already accounted for the reduction in physician intraservice time and post-operative visits. Some commenters disagreed with CMS' interim final values based on objections to CMS' use of time ratios in developing work RVUs for PFS services.

Response in the CY 2017 PFS proposed rule: We stated that we appreciated the commenters' concerns regarding the time ratio methodologies and responded to those concerns about our methodology in section II.H.2 of the CY 2017 proposed rule. After considering the explanations provided by commenters through public comments describing the RUC's methodologies in more detail, we agreed that the proposed value did not accurately reflect the physician work involved in furnishing the service.

In the CY 2017 proposed rule, we proposed the RUC-recommended work RVU value of 3.00 for CPT code 65855.

We did not receive any comments in response to our proposed valuation on CPT code 65855; therefore, we are finalizing a work RVU of 3.00 as proposed.

Comment: A few commenters stated their support of CMS' decision to propose the RUC-recommended value for CY 2017 and strongly urged us to finalize the proposal.

Response: Thank you for your comments. For CY 2017 we are finalizing the RUC-recommended work RVU of 3.00 for CPT code 65855.

(35) Glaucoma Surgery (CPT Codes 66170 and 66172)

The RUC identified CPT codes 66170 and 66172 as potentially misvalued through a screen for 90-day global codes that included more than six office visits. We believed the RUC-recommended work RVU of 13.94 for CPT code 66170 did not accurately account for the reductions in time. Specifically, the survey results indicated reductions of 25 percent in intraservice time and 28 percent in total time. These reductions suggested that the RUC-recommended work RVU for CPT code 66170 overstated the work involved in furnishing the service, since the recommended value only represented a reduction of approximately seven percent. We believed that applying the intraservice time ratio, the ratio between the CY 2015 intraservice time, 60 minutes, and the RUC-recommended intraservice time, 45 minutes, applied to the current work RVU, 15.02, resulted in a more appropriate work RVU of 11.27. Therefore, for CY 2016, we established an interim final work RVU of 11.27 for CPT code 66170.

For CPT code 66172, the RUC recommended a work RVU of 14.81. After comparing the RUC-recommended work RVU for this code to the work RVU for similar codes (for example, CPT code 44900 (Incision and drainage of appendiceal abscess, open) and CPT code 52647 (Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed))), we believed the RUC-recommended work RVU of 14.81 overstated the work involved in this procedure. For the same reasons and following the same valuation methodology utilized above, we applied the intraservice time ratio between the CY 2015 intraservice time and the survey intraservice time, 60/90, to the CY 2015 work RVU of 18.86. This resulted in a work RVU of 12.57 for CPT code 66172. Therefore, for CY 2016, we established an interim final work RVU of 12.57 for CPT code 66172.

Comment on the CY 2016 PFS final rule with comment period: Several commenters, including the RUC, objected with our interim final values based on objections to our use of time ratios in developing work RVUs for PFS services. Commenters also requested CMS refer CPT codes 66170 and 66172 to the refinement panel.

Response in the CY 2017 PFS proposed rule: We acknowledged commenters' concerns regarding the time ratio methodologies and responded to those concerns in section II.H.2 of the CY 2017 proposed rule (81 FR 46162). CPT codes 66170 and 66172 were referred to the CY 2016 multi-specialty refinement panel per commenters' request. The outcome of the refinement panel was a median of 13.94 RVUs for CPT code 66170 and 14.84 RVUs for CPT code 66172. Due to the new information presented to the refinement panel regarding the level of intensity required to perform millimeter incisions in the eye, we agreed with the assessment of the refinement panel and proposed a work RVU of 13.94 for CPT code 66170 and 14.84 for CPT code 66172 for CY 2017.

The following is a summary of the comments we received regarding our proposed valuations for the Glaucoma Surgery family:

Comments: Several commenters stated their support of CMS' decision to propose the values recommended by the refinement panel for CPT codes 66170 and 66172. Some commenters, including the RUC, also brought to our attention discrepancies between our proposal for these codes in the CY 2017 proposed rule and the work RVUs posted in Addendum B on the CMS Web site.

Response: For CY 2017, we are finalizing a work RVU of 13.94 for CPT code 66170 and a work RVU of 14.84 for CPT code 66172. We appreciate commenters bringing this issue regarding conflicting information in the CY 2017 PFS proposed rule preamble text and the public use files published on the CMS Web site. We have corrected this discrepancy in this final rule and the associated public use files.

(36) Retinal Detachment Repair (CPT Codes 67101, 67105, 67107, 67108, 67110, and 67113)

For CY 2015, the CPT Editorial Panel made several changes to CPT codes 67101 and 67105. These changes include revising the code descriptors to exclude ''diathermy'' and ''with or without drainage of subretinal fluid'' and removing the reference to ''1 or more sessions.'' The recommended global period also changed from 90 days to 10 days. For CPT code 67101, we proposed the RUC recommended work RVU of 3.50, which was based on the 25th percentile of the survey. For CPT code 67105, the RUC recommended a work RVU of 3.84 based on the 25th percentile of the survey. The RUC also stated that CPT code 67105 was a more intense procedure, and therefore, it should have a higher work RVU than CPT code 67101. Currently, CPT code 67101 has a higher work RVU than CPT code 67105 and according to the surveys, the intraservice and total times remain higher for CPT code 67101. We do not understand why the RUC believes that CPT code 67105 is more work than CPT code 67101. Therefore, we did not propose the RUC-recommended work RVU of 3.50 for CPT code 67105. We did not find evidence that CPT code 67105 is more intense than CPT code 67101 and accordingly, proposed a lower work RVU for CPT code 67105. To value CPT code 67105, we used the RVU ratio between CPT codes 67101 and 67105. We divided the current work RVU of 8.53 for CPT code 67105, by the current work RVU of 8.80 for CPT code 67101 and multiplied the quotient by the RUC-recommended work RVU of 3.50 for CPT code 67101 to arrive at a work RVU of 3.39. Therefore, for CY 2017, we proposed a work RVU of 3.39 for CPT code 67105.

CPT codes 67107, 67108, 67110, and 67113 were identified through the Relative Assessment Workgroup process under the 90-day global post-operative visit screen in CY 2015. The RUC recommended a work RVU of 16.00 for CPT code 67107, which corresponded to the 25th percentile of the survey. While the RUC recommendation represented a five percent reduction from the current work RVU of 16.71, we believed the RUC recommendation still overvalued the service given the 15 percent reduction in intraservice time and 25 percent reduction in total time.

We used the intraservice time ratio between the existing and new time values to identify an interim final work RVU of 14.06. We believed this value accurately reflected the work involved in this service and was comparable to other codes that have the same global period and similar intraservice time and total time. For CY 2016, we established an interim final work RVU of 14.06 for CPT code 67107. For CPT code 67108, the RUC recommended a work RVU of 17.13 based on the 25th percentile of the survey, which reflected a 25 percent reduction from the current work RVU. The survey results reflected a 53 percent reduction in intraservice time and a 42 percent reduction in total time. We believed the RUC-recommended work RVU overestimated the work, given the significant reductions in intraservice time and total time and does not maintain relativity among the codes in this family. To determine the appropriate value for this code and maintain relativity within the family, we preserved the 1.13 work RVU increment recommended by the RUC between this code and CPT code 67107

and applied that increment to the interim final work RVU of 14.06 for CPT code 67107. Therefore, we established an interim final work RVU of 15.19 for CPT code 67108. For CPT code 67110, the RUC recommended maintaining the current work RVU of 10.25. To maintain appropriate relativity with the work RVUs established for the other services within this family, we used the RUC-recommended 5.75 work RVU differential between CPT code 67107 and CPT code 67110 to establish the CY 2016 interim final work RVU of 8.31 for CPT code 67110. For CPT code 67113, the RUC recommended and we established an interim final work RVU of 19.00 based on the 25th percentile of the survey.

Comment on the CY 2016 PFS final rule with comment period: We received several comments disagreeing with our interim final values based on objections to our use of time ratios in developing work RVUs for PFS services. Some commenters also stated that by using some RUC-recommended increments and rejecting others, we have not only established inconsistencies within the family of codes, but potentially opened up anomalies across a wide range of services. The RUC also expressed disagreement with using the recommended work RVU increments without using the recommended work RVU. Some commenters also stated the new IWPUT values for these three services are inappropriately low and pointed to the derived per minute intensity of 0.064 for CPT code 67110 as particularly problematic.

Response in the CY 2017 PFS proposed rule: We disagreed with the statement about inconsistencies as the codes in this family are valued relative to one another based on the times and level of physician work required for each code.

We also stated that generally we do not agree that a low IWPUT itself indicates overall misvaluation as the validity of the IWPUT as a measure of intensity depends on the accuracy of the assumptions regarding the number, level, and work RVUs attributable to visits for services in the post-operative global period for individual services.

We provided an example where a service with an unrealistic number or level of postoperative visits may have a very low derived intensity for the intra-service time. CPT codes 67107, 67108, and 67110 were referred to the CY 2016 multispecialty refinement panel per commenters' request. The outcome of the refinement panel was a median work RVU of 16.00, 17.13, and 10.25, respectively. After consideration of the comments and the results of the refinement panel, we proposed a work RVU of 16.00, 17.13, and 10.25 for CPT codes 67107, 67108, and 66110, respectively, for CY 2017.

The following is a summary of the comments we received regarding our proposed valuations for the Retinal Detachment Repair family:

Comments: A few commenters, including the RUC, noted that CPT codes 67101 and 67105 were last valued by the Harvard study. The RUC stated that during the Harvard studies, CPT code 67101 was valued higher due to greater total time. However, now photocoagulation is reported at vastly higher levels than the cryotherapy procedure, as it is considered to be a more effective treatment. A few commenters stated that given the changing nature of the service since the last valuation, the intensity of CPT code 67105 is now greater and urged CMS to accept the RUC-recommended values.

For CPT codes 67107, 67108, 67110, and 67113, several commenters supported CMS' decision to propose the values recommended by the refinement panel and urged CMS to finalize these proposed values. A few commenters, including the RUC, brought to our attention discrepancies between our proposal for these codes and the work RVUs posted in Addendum B on the CMS Web site.

Response: We note that, according to the surveys, the intraservice and total times were significantly higher for CPT code 67101 and note the specialty societies recommended a higher work RVU for CPT code 67101 prior to the RUC meeting. Although commenters state that photocoagulation (CPT code 67105) is typically billed more frequently than diathermy (CPT code 67101), we do not believe the utilization rate of a service in and of itself is reason enough to warrant an increase in RVUs. Therefore, for CY 2017, we are finalizing a work RVU of 3.50 and 3.39 for CPT codes 67101 and 67105, respectively.

We appreciate commenters bringing to our attention the issue regarding conflicting information in the CY 2017 PFS proposed rule preamble text and the public use files published on the CMS Web site. We have corrected this discrepancy in this final rule and the public use files.

For CY 2017, we are finalizing a work RVU of 16.00, 17.13, 10.25 and 19.00 for CPT codes 67107, 67108, 66110 and 67113, respectively, in agreement with the refinement panel recommendations.

(37) Fetal MRI (74712 and 74713)

For CY 2016, we established the RUC-recommended work RVU of 3.00 as interim final for CPT code 74712. We established an interim final work RVU of 1.78 for CPT code 74713 based on a refinement of the RUC-recommended work RVU of 1.85 using the ratio of work to time for both codes. This proposed value also corresponds to the 25th percentile survey result.

Comment on the CY 2016 PFS final rule with comment period: Commenters stated that the work RVU of 1.78 for CPT code 74713 did not reflect the higher intensity inherent in the procedure's typical patient. The commenter explained that the typical patient is pregnant with twins and has a higher likelihood of complications related to congenital anomalies, as well as of ischemic brain injury with twin gestations. The commenter further stated that twin gestations are more difficult to image. Commenters requested that CPT code 74713 be referred to the multispecialty refinement panel.

Response in the CY 2017 PFS proposed rule: CPT code 74713 was referred to the CY 2016 multispecialty refinement panel. After considering the comments and the results of the refinement panel, we agreed with commenters that an RVU of 1.78 underestimated the work for CPT code 74713.

In the CY 2017 proposed rule, we proposed a work RVU of 1.85 for the service for CY 2017.

We did not receive any comments in response to our proposed valuation on CPT code 74713; therefore, we are finalizing the proposed work RVU.

(38) Abdominal Aortic Ultrasound Screening (CPT Code 76706)

For CY 2017, the CPT Editorial Panel created a new code, CPT code 76706, to describe abdominal aortic ultrasound screening, currently described by HCPCS code G0389. The specialties that surveyed CPT code 76706 for the RUC were vascular surgery and radiology, and the direct PE inputs recommended by the RUC included an ultrasound room. Based on an analysis of Medicare claims data, the dominant specialties furnishing the service are family practice and internal medicine. We believe that these specialties may more typically use a portable ultrasound device rather than an ultrasound room. Therefore, we proposed to accept the RUC-recommended work RVU of 0.55, and the RUC-recommended PE inputs for this service, but we solicited comment regarding whether or not it would be more accurate to substitute a portable ultrasound device or possibly a hand-held device for an ultrasound room for CPT code 76706. We note that while the phase-in of significant

reductions in RVUs ordinarily would not apply to new codes, we believe that it would be appropriate to consider this change from a G-code to a CPT code to be fundamentally similar to an editorial coding change since the service is not described differently, and therefore, we proposed to apply the phase-in to this service by comparing the previous value of the G-code to the value for the new CPT code.

Comment: One commenter stated that this service should be furnished by a physician or surgeon that specializes in vascular disease. The commenter noted that CMS should assign inputs based on which specialties would more appropriately furnish a given service. Another commenter disagreed with our statement in the CY 2017 proposed rule that the dominant specialties furnishing this service are family practice and internal medicine. The commenter stated that these specialties are more likely to make use of a portable ultrasound device rather than an ultrasound room. One commenter says that this service is underutilized, and CMS should implement policies which support screening.

Response: We appreciate the commenters' perspectives. We note that, in evaluating codes in the Medicare Physician Fee Schedule (MPFS), we price codes based on the typical service. Our review of the Medicare claims data indicates that the combined utilization for the technical component of this service and the service billed globally is typically billed under the PFS by family practice and internal medicine, which is why we solicited comment on whether the PE inputs for this service should be revised.

Comment: A commenter supported our decision to apply the phase-in to this code.

Response: We thank the commenter for the support.

Comment: A commenter agreed with CMS that family practice physicians typically use a portable ultrasound device rather than an ultrasound room. The commenter stated that CMS should continue to include an ultrasound room as a direct PE input, unless other specialties furnishing the service indicate that they do not typically make use of an ultrasound room.

One commenter states that abdominal aortic aneurysm screenings are performed on nonportable machines in either ambulatory or hospital settings, and therefore, an ultrasound room is appropriate.

Response: We thank the commenters, and we will take this information regarding the appropriate PE inputs for this service into consideration for future rulemaking. While the specialty mix of the practitioners furnishing services can be helpful in identifying typical PE inputs, we continue to seek definitive information regarding the most appropriate PE inputs for this code. For CY 2017, we are finalizing the RUC-recommended work and PE inputs, as proposed.

(39) Fluoroscopic Guidance (CPT Codes 77001, 77002, and 77003)

In the CY 2015 PFS final rule with comment period, CMS indicated that while CPT codes 77002 and 77003 had been previously classified as stand-alone codes without global periods, we believe their vignettes and CPT Manual parentheticals are consistent with an add-on code as has been established for CPT code 77001. Therefore, the global periods for CPT codes 77002 and 77003 now reflect an add-on code global period with modifications to the vignettes and parentheticals.

For CPT code 77001, we proposed the RUC-recommended work RVU of 0.38. We stated that the RUC-recommended work RVUs for CPT codes 77002 and 77003 did not appear to account for the significant decrease in total times for these codes relative to the current total times. We noted that these three codes describe remarkably similar services and have identical intraservice and total times. Based on the identical times and notable similarity for all three of these codes, we proposed a work RVU of 0.38 for all three codes.

The following is a summary of the comments we received regarding our proposed valuation of the Fluoroscopic Guidance codes:

Comment: A few commenters disagreed with the change in the global period for CPT codes 77002 and 77003 to reflect their status as add-on codes. The commenters stated that this would imply that the imaging-related preservice and postservice activities inherent to these image guidance codes are captured by the base codes with which they are reported, which simply is not the case. The commenters provided an example of how reporting of radiation specific information, such as fluoroscopy time, is not included in the postservice activities of the base codes.

Response: CPT codes 77002 and 77003 were surveyed under the assumption that they would be classified as add-on codes, and the RUC recommendations for both work RVUs and direct PE inputs reflect this status. We do not believe that it would be appropriate to assign these codes a different global period after they were surveyed and valued with the understanding that they would be classified as add-on codes.

Comment: Many commenters disagreed with the proposed work RVU of 0.38 for CPT codes 77002 and 77003. Commenters stated that these two codes should not share the same work RVU as CPT code 77001, on the basis that the physician work, intensity and complexity of codes 77002 and 77003 are greater than the first code in the family. Commenters stated that the intensity and complexity increases in parts of the body where there are additional anatomy considerations, such as superficial and deep structures to consider with CPT code 77002, as well as additional neuro and spinal structures to consider when performing CPT code 77003. One commenter suggested that there was clinical data indicating that CPT codes 77002 and 77003 take longer to perform than CPT code 77001, in contradiction of the RUC survey data that assigned all three codes identical time values. The commenter stated that this was likely due to the greater complexity and procedural variability of the latter two codes. Another commenter recognized that these codes describe similar services but stressed that they do not describe identical services, which was especially important for CPT code 77003 as it pertains to spinal procedure and carries more risk than the other two codes.

Response: We recognize the concerns raised by the commenters in assigning the same work RVU of 0.38 to the three codes in the Fluoroscopic Guidance family. We note that even in cases where we assign the same work RVU, we do not believe that the services are identical, only that they share the same overall resources in work as measured in RVUs. We also appreciate the reference to additional clinical data from one commenter suggesting that CPT codes 77002 and 77003 take longer to perform than CPT code 77001. We have longstanding concerns about using survey data alone for code valuation, and we are always interested in investigating additional sources of information to assist in this process. We encourage future commenters to submit this data as part of their public comment so that it can be used by CMS as part of the code valuation process. Based on the submission of this additional data, we believe that the CPT codes 77002 and 77003 are more accurately valued at a higher RVU than CPT code 77001.

After consideration of comments received, we are finalizing the RUC-recommended work RVUs for all three codes in the family, which is an increase from the proposed work RVU of 0.38 to a work RVU 0.54 for CPT code

77002 and to 0.60 for CPT code 77003. We are finalizing the proposed work RVU of 0.38 for CPT code 77001 without change.

(40) Mammography—Computer Aided Detection Bundling (CPT Codes 77065, 77066 and 77067)

Section 104 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) required us to create separate codes with higher payment amounts for digital mammography compared to film mammography, which was the technology considered to be typical at the time. In addition, the statute required additional payment to be made when computer-aided detection (CAD) was used.

In CY 2002, we began valuing digital mammography services using three G-codes, G0202, G0204, and G0206 to describe screening mammography, unilateral diagnostic mammography, and bilateral diagnostic mammography, respectively. CMS implemented the requirements of BIPA section 104(d)(1), which applied to tests furnished in 2001, by using the work RVUs of the parallel CPT codes, but establishing a fixed PE RVU rather than using PE RVUs developed under the standard PE methodology. The fixed amount of PE RVUs for these codes has generally remained unchanged since implementation of the G-codes that specifically described digital imaging.

Most mammography services under Medicare have since been billed with these G-codes when digital mammography was used, and with CPT codes 77055, 77056, and 77057 when film mammography was used. The use of CAD has been reported with CPT codes 77051 and 77052. For CY 2017, the CPT Editorial Panel deleted CPT codes 77051, 77052, 77055, 77056, 77057 and created three new CPT codes, 77065, 77066, and 77067, to describe mammography services bundled with CAD. For CY 2017, the RUC recommended work RVUs of 0.81 for CPT code 77065, 1.00 for CPT code 77066, and 0.76 for CPT code 77067, as well as new PE inputs for use in developing resource-based PE RVUs based on our standard methodologies. The RUC recommended these inputs and only one medical specialty society provided us with a set of single invoices to price the equipment used in furnishing these services.

We reviewed these coding changes and proposed changes to valuation for these codes for CY 2017. The revised CPT coding mitigates the need for both separate G-codes and the CAD add-on codes. Based upon these coding changes and the RUC-recommended input values, overall Medicare payment for mammography services would be drastically reduced. This is particularly true for the technical component of these services, which could possibly be reduced up to 50 percent relative to the PE RVUs currently used for payment for these services.

Based on our initial review of the recommended inputs for the new codes, we believed that these changes would likely result in values more closely related to the relative resources involved in furnishing these services. However, we recognized that these services, particularly the preventive screenings, are of particular importance to the Medicare program and the health of Medicare beneficiaries. We were concerned that making drastic changes in coding and payment for these services could be disruptive in ways that could adversely impact beneficiary access to necessary services. We also recognized that unlike almost any other high-volume PFS service, the RVUs used for payment for many years have not been developed through the generally applicable PFS methodologies, and instead reflect the statutory directive under section 104 of the BIPA. Similarly, we recognized that the changes in both coding and valuation are significant changes for those who provide these services. Therefore, instead of proposing to simultaneously adopt the revised CPT coding and drastic reductions in overall payment rates, we believed it was advisable to propose to adopt the new coding, including the elimination of separate billing for CAD, for CY 2017 without proposing immediate implementation of the recommended resource inputs. We anticipated that we would consider the recommended inputs, including the pricing of the required equipment, as carefully as possible prior to proposing revised PE values through subsequent rulemaking.

Therefore, for CPT codes 77065, 77066, and 77067, we proposed to accept the RUC-recommended work RVUs, but to crosswalk the PE RVUs for the technical component of the current corresponding G-codes, as we sought further pricing information for these equipment items.

Since the publication of the proposed rule, we have determined that for several reasons related to claims processing systems, Medicare claims systems will be unable to process claims using CPT codes 77065, 77066, and 77067 for CY 2017. However, given the parallel structure of these new CPT codes, 77065, 77066, and 77067 to existing G-codes G0206, G0204, and G0202, we anticipate that the claims systems will be fully capable of processing the appropriate payment policies and prices discussed below for CPT codes 77065, 77066, and 77067 by using the existing G-codes. Therefore, for CY 2017, we will operationalize the new coding rules, including adoption of the new code descriptors for CPT codes 77065, 77066, and 77067 through use of the three current G-codes. For the purposes of discussion below, we discuss policies and payment rates for these three codes using the CPT numbers. Therefore, in the preamble discussion below, references to the G-codes refer to the descriptors, policies, and rates for CY 2016 and references to the new CPT codes refer to the 2017 descriptors, policies and rates that will be implemented through revisions to the current G-codes. We anticipate being able to adopt the CPT coding for CY 2018.

In addition to soliciting comment on this proposal, we also solicited input on rates for these services in the commercial market to help us understand the potential impacts of any future proposed revisions to PFS payment rates.

Finally, we noted that by proposing to adopt the new coding for CY 2017, any subsequent significant reduction in RVUs (greater than 20 percent) for the codes would be subject to the statutory phase-in under section 1848(c)(7).

To help us examine the resource inputs for these services, we solicited public comment on the list of items recommended as equipment inputs for mammography services. We also invited commenters to provide any invoices that would help with future pricing of these items.

TABLE 18—RECOMMENDED EQUIPMENT ITEMS FOR MAMMOGRAPHY SERVICES

#	Item description	Quantity	Purpose
1	2D Selenia Dimensions Mammography System.	1	Mammography unit and in-room console itself.

TABLE 18—RECOMMENDED EQUIPMENT ITEMS FOR MAMMOGRAPHY SERVICES—Continued

#	Item description	Quantity	Purpose
2	Mammo Accreditation Phantom	1	Required for MQSA. The phantom is currently valued into the existing mammography room.
3	Phantom Case	1	Protects expensive required phantom from damage.
4	Paddle Storage Rack	3	It requires 3 racks to hold and prevent damage to all of the paddles that are part of the typical standard mammography system.
5	Needle Localization Kit	1	Needed for a full functioning mammography room. Allows for the performance of needle localizations. Input is not separately in the PE for the mammography guided procedure codes, 19281–19282, as a fully functioning mammography room is needed for those procedures.
6	Advanced Workflow Manager System	1	Workflow system connecting mammography room and workstations.
7	Cenova 2D Tower System	1	CAD server, and also used for post-processing.
8	Image Checker CAD (9.4) License for One FFDM.	1	License required for using CAD. This is a one-time fee.
9	Film Digitizing System (.....	1	Digitizes analog films to digital for comparison purposes.
10	Mammography Chair	1	A special chair needed for patients who cannot stand to safely have their mammogram performed.
11	Laser Imager Printer	1	Prints high resolution copies of the mammograms to send to surgeons and oncologists, and to use in the OR.
12	Barcode Scanner	1	Allows selection of individual patient file for interpretation.
13	MRS V7 SQL Reporting System	1	MQSA requires that the facility develop and maintain a database that tracks recall rates from screening, true and false positive and true and false negative rates, sensitivity, specificity, and cancer detection rate. A reporting system is required to build the required database and produce the federally required quality audit. Components below needed for the reporting system. The reporting system is currently valued into the existing mammography room.
14	Worksheet Printing Module	1	Database reports are required for federal tracking purposes. This is used to generate reports for MQSA.
15	Site License	1	License for site to use the reporting system. This is a one-time fee.
16	Additional Concurrent User License	3	Licenses for radiologists to use the reporting system. A minimum of three additional licenses is typical.
17	Densitometer	1	Required for MQSA.

We also received specialty society recommendations for a new Equipment Item, a physician PACS mammography workstation. We note that we discuss physician PACS workstation in section II.A of this rule. The items that comprise the physician PACS mammography workstation are listed in Table 19. We requested public comment as to the appropriateness of this list and if some items are indirect expenses or belong in other codes. We also invited commenters to provide any invoices that would help with future pricing of these items.

TABLE 19—PHYSICIAN PACS MAMMOGRAPHY WORKSTATION

PC Tower.
Monitors 5 MP (mammo) (x2).
3rd & 4th monitor (for speech recognition, etc.).
Admin Monitor (the extra working monitor).
Keyboard & Mouse.
Powerscribe Microphone.
Software—SV APP SYNC 1.3.0.
Software—R2 Cenova.

We also note that for CY 2015, the CPT Editorial Panel created CPT codes 77061, 77062, and 77063 to describe unilateral, bilateral, and screening digital breast tomosynthesis, respectively. CPT code 77063 is an add-on code to CPT code 77057, the CPT code for screening mammography. To be consistent with our use of G-codes for digital mammography, we did not implement two of these three CPT codes for Medicare purposes. We only adopted CPT code 77063 as an add-on code to HCPCS code G0202. Instead of adopting stand-alone CPT codes 77061 and 77062, we created a new code, G0279 Diagnostic digital breast tomosynthesis, as an add-on code to the diagnostic digital mammography HCPCS codes G0204 and G0206 and assigned it values based on CPT code 77063. Pending revaluation of the mammography codes using direct PE inputs, we proposed in CY 2017 to maintain the current coding structure for digital breast tomosynthesis with the technical change that HCPCS code G0279 be reported with CPT codes 77065 or 77066 as the replacement codes for HCPCS codes G0204 and G0206.

Comment: Many commenters expressed support for our decision to prevent a drastic reduction in payment for the technical component of these services by maintaining the PE RVUs from CMS' digital mammography coding. A few commenters expressed concern that shifting to our standard resource-based PE valuation methodology in future rulemaking would drastically reduce payments. Some commenters agreed that CMS does not have sufficient pricing data to value digital mammography. One commenter stated that the RUC-recommended direct PE inputs do not need to be reconsidered, as they include pricing data provided by the specialty that most frequently furnishes the service.

Response: We will continue to carefully consider the potential negative impact that our valuation of these services will have on beneficiary access as we evaluate all relevant sources of data in future rulemaking, including data provided by the RUC.

Comment: A commenter did not support our intention to seek more pricing information in the commercial market, stating that commercial payers are generally more responsive to market incentives to reduce rather than increase prices.

Response: We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) that describes CMS' methodology in evaluating practice expense. We would consider a variety of different data sources, pending their availability and applicability. We believe that having

more information regarding pricing in the commercial market may help us to contextualize recommended pricing, as well as potential impact of significant changes in payment.

Comment: One commenter expressed concern that, despite our maintenance of PE RVUs and our acceptance of RUC-recommended work RVUs, these services will still see significant payment reductions.

Response: We are accepting the RUC-recommended work RVUs, which equal the sum of the base code work RVUs for mammography and for CAD. The work RVUs for the new mammography coding are therefore not changing from their current values. Furthermore, as we are retaining the PE RVUs from the digital mammography G-codes in the new coding, the practice expense valuation is not changing. Therefore, payment amounts for mammography services will not see significant reductions for CY 2017. We expect to revalue these services through our standard code valuation process in future rulemaking.

Comment: One commenter said that CMS should accept the RUC-recommended direct PE inputs.

Response: As noted earlier, we did not propose the RUC-recommended inputs for these three codes for several reasons, including our concerns that drastic changes in coding and payment for these services could be disruptive in ways that could adversely affect beneficiary access to necessary services, and that unlike almost any other high-volume PFS service, the RVUs used for payment for many years have not been developed through the generally applicable PFS methodologies. Therefore, instead of proposing to simultaneously adopt the revised CPT coding and drastic reductions in overall payment rates, we believed it was advisable to propose to adopt the new coding, including the elimination of separate billing for CAD, for CY 2017 without proposing immediate implementation of the recommended resource inputs.

Comment: One commenter requested clarification regarding if the PE RVUs were valued using the RUC-recommended direct PE inputs, as these inputs were posted in Public Use Files (PUFs) for the CY 2017 Proposed Rule.

Response: We thank the commenter for pointing out that direct PE inputs were posted for these codes. These inputs were inadvertently included in the Public Use Files. We reiterate that we are not implementing PE inputs for these services, and we are instead crosswalking the PE RVUs from the digital mammography HCPCS codes G0202, G0204, and G0206, as doing so prevents a drastic reduction in payments. We included potential direct PE inputs in the text of the CY 2017 proposed rule to facilitate public comment and information in anticipation of developing updated PE RVUs for these services in future rulemaking.

Comment: A commenter stated that this coding violates statutory requirements set forth by BIPA that required the agency to: (1) create separate codes with higher payment amounts for digital mammography compared to film mammography and (2) pay separately when computer-aided detection (CAD) was used.

Response: The BIPA requirements specifically refer to screening and diagnostic mammography furnished during the period beginning on April 1, 2001, and ending on December 31, 2001. CMS chose to retain the payment rates for the technical component following this period.

Comment: A number of commenters volunteered to help CMS in pricing direct PE inputs for these services.

Response: We thank the commenters and seek as much information as possible regarding appropriate establishment of direct PE inputs for these services.

Comment: A commenter stated that the potential reductions to the technical component that we are avoiding would have been based on flawed methodology, particularly stating that the PE per hour values used in PE ratesetting methodology is inaccurate as it is based on the Physician Practice Expense Information Survey (PPIS) from 2007–2008, which the commenter considers to be flawed. The commenter also stated that the interest rate applied to high cost capital equipment such as imaging is inappropriately low, and that the equipment utilization rate assumption is inappropriately high.

Response: We note that the 90 percent equipment utilization rate only applies to diagnostic imaging services with equipment priced at $1 million dollars or more. The most recent recommended inputs for these services do not include imaging equipment priced at $1 million dollars or more, so the 90 percent equipment utilization would not apply. However, we would address any application of a different utilization rate through notice and comment rulemaking when valuing the codes under our standard PE methodology. As always, we welcome information about the validity of the assumptions we make in calculation of direct and indirect costs in terms of PE. We previously noted our interest in improving PE calculations through incorporation of alternative data sources and we continue to seek information from interested stakeholders as to the kinds of data sources that might be available.

For CY 2017, we are finalizing the proposed work RVUs and PE RVUs associated with CPT codes 77067, 77066 and 77065 for use with HCPCS codes G0202, G0204, and G0206, respectively.

(41) Radiation Treatment Devices (CPT Codes 77332, 77333, and 77334)

We identified CPT codes 77332, 77333, and 77334 through the high expenditures by specialty screen. These services represent an incremental increase of complexity from the simple to the intermediate to the complex in design of radiation treatment devices. The RUC recommended no change from the current work RVUs of 0.54 for CPT code 77332, 0.84 for CPT code 77333 and 1.24 for CPT code 77334. We believed the recommended work RVUs overstate the work involved in furnishing these services, as they do not sufficiently reflect the degree to which the RUC concurrently recommended a decrease in intraservice or total time. For CPT code 77332, we believed the RUC recommendation to maintain its current value despite a 34 percent decrease in total time appeared to ignore the change in time. Therefore, we proposed a value for this code based on a crosswalk from the value from CPT code 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), due to its identical intraservice time, similar total time, and similar level of intensity. We therefore proposed a work RVU of 0.45 for CPT code 77332. We further supported this valuation with 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), which has similar physician time and intensity measurements and a work RVU of 0.45. As these codes are designed to reflect an incremental increase in work value from simple, to intermediate, and complex device designs, we used an incremental difference methodology to value CPT codes 77333 and 77334. We proposed a work RVU of 0.75 for CPT code 77333, maintaining its recommended increment from CPT code 77332. For CPT code 77334, we proposed a work RVU of 1.15, which would maintain its increment from CPT code 77332.

Comment: Several commenters did not support CMS' use of CPT code 93287 as a crosswalk code to value CPT code 77332, as it is not a radiology service.

Response: We appreciate the commenters' concern about using a non-radiology service to assist in our valuation of this code family. We note that it is fundamental to the validity of the relative value system that codes furnished by different kinds of physicians remain valid relative to each other. We commonly value codes by use of crosswalks to other codes that are similar in terms of time and intensity, and this may extend across different mixes of specialties furnishing each service on the MPFS.

Comment: One commenter did not support CMS' pointing to the RUC's recommendation of a reduction of total time without a commensurate reduction in work RVU, as the current time is a CMS/Other source time, which is not derived from a survey and was assigned over 20 years ago.

Response: We utilize a variety of methodologies and approaches in developing work RVUs, and we believe that the total time value for this service is one of several appropriate criteria that can be used to estimate the overall time and intensity. We believe that the intraservice and total times listed for this service are valid elements in allowing us to determine an appropriate work RVU. Furthermore, we note that the current times assigned to this code have been used to allocate indirect PE to services furnished by the same specialties, and use of this value is consistent with code valuation methodology.

Comment: One commenter asked for clarification regarding if CMS is comparing the total time for CPT code 93287 to the current physician time of 77332 or to the survey time on which the RUC recommendation was based. One commenter stated that CMS' characterization of the intraservice time of crosswalk CPT code 93287 as identical to CPT code 77332 is incorrect; the intraservice time for 77332 is 15 minutes, and the intraservice time of CPT code 93287 is 13.5 minutes.

Response: We thank the commenter for bringing this to our attention; our previous statement that the intraservice time of CPT code 93287 is identical to the RUC-recommended intraservice time is incorrect. The RUC-recommended intraservice time of 15 minutes is similar, but not identical to the intraservice time of CPT code 93287 which is 13.5 minutes. We continue to believe that a work RVU of 0.45 is appropriate because we continue to believe the overall work for these services is approximately the same as 97760. As further support for our proposed value, we refer to 93016 (Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; supervision only, without interpretation and report) which has an intraservice time that is identical to the RUC-recommended intraservice time for 77332, as well as a similar total time.

Comment: One commenter stated that these codes have XXX global periods, and therefore, do not have standard pre or post service packages. These standard pre and post services packages did not exist at the time that this service was valued, thus the convention of eliminating pre-service time and applying minimal post-service time to services with XXX global periods was not applied at that time.

Response: We appreciate the commenter's concerns about standard time packages not being applied to these codes. We continue to believe, however, that use of the RUC-recommended time to value the work RVU in this case is appropriate because we believe that time values are a critical element of establishing work RVUs.

Comment: A few commenters stated that CMS' proposed reduction in the work RVUs for CPT codes 77333 and 77334 based on an incremental relationship with CPT code 77332 is arbitrary, and that a reduction to the work RVU for CPT code 77332 does not automatically justify a reduction to the other two family codes.

A commenter supported the use of incremental valuation methodology in theory but did not believe it is appropriately applied to these codes, because the commenter believes that the valuation of CPT code 77332, upon which the increments are based, is incorrect.

Response: We refer readers to a discussion of the methodology for establishing work RVUs in section II.L.2 of this final rule. As outlined there, we frequently use an incremental methodology to identify potential work RVUs for particular codes. We note that we are maintaining the RUC-recommended incremental relationship between these three codes. This code family is structured to represent simple, intermediate, and complex procedures, and we seek to maintain that structure for this code family. Therefore, we are finalizing the work RVUs as proposed. We provide the information in Table 20 to illustrate our valuation of CPT code 77332 and its value relative to our crosswalk codes:

TABLE 20—VALUATION OF CPT CODE 77332 RELATIVE TO CROSSWALK CODES

HCPCS	Description	Intra time	Total time	Work RVU	IWPUT
77332—Current	Treatment devices, design and construction; simple (simple block, simple bolus).		28	.54	
77332—CMS	Treatment devices, design and construction; simple (simple block, simple bolus).	15	18	.45	0.0126
93287	Peri-procedural device evaluation & programming	13.5	26	.45	0.0126
97760	Orthotic management and training	14	18	.45	0.0257
93016	Cardiovascular stress test	15	19	.45	0.0240

(42) Special Radiation Treatment (CPT Code 77470)

We identified CPT code 77470 through the high expenditures by specialty screen. We proposed the RUC-recommended work RVU of 2.03. However, we believe the description of service and vignette describe different and unrelated treatments being performed by the physician and clinical staff for a typical patient, and this presents a disparity between the work RVUs and PE RVUs. We solicited comment on information that would clarify this apparent disparity to help determine appropriate PE inputs. In addition, we solicited comment to determine if creating two G-codes, one that describes the work portion of this service, and one that describes the PE portion, may be a potentially more accurate method of valuing and paying for the service or services described by this code.

Comment: Some commenters maintained that the clinical labor and physician work component are related and are necessarily reported together. Commenters did not approve of CMS suggestion of breaking the work and PE components of this service into two separate G-codes in future rulemaking, stating that the CPT descriptor is accurate and represents the typical patient. Some commenters sought greater explanation for why CMS believes that the work and PE portions of this service are unrelated; commenters question if it is because the vignettes offered for the work and PE describe treatments for two separate diagnoses. Commenters also questioned if CMS is assuming that the ''devices'' mentioned in the description of clinical labor activities overlap with Radiation Treatment Devices codes which are also being evaluated in this rule. A commenter stated that if CMS is suggesting that there should be multiple CPT codes for every possible diagnosis for the use of this code, then that suggestion is problematic.

Response: According to the description of work provided for this service, the physician performs cognitive work such as planning, consideration of test results, and therapeutic treatment contingency planning that is in addition to what he or she would typically be performing for most radiation treatments. Meanwhile, the radiation therapist handles the treatment devices, performs tasks such as positioning the patient, and helps facilitate the scan of the patient. We believe that this may describe activities that are fundamentally disconnected. To illustrate our concern, we offer the example that this is akin to a physician removing a mole from a patient's hand while the clinical staff places a cast on the patient's foot; we see no compelling clinical evidence to indicate that the two tasks are related. In addition, the disparate diagnoses described by the vignettes further calls into question the degree to which the work and PE components are interrelated. While we agree that there should not separate coding for each possible diagnosis for a particular service, in trying to accurately assess relative value, we believe that the work and PE components should be valued under unified assumptions about the typical service. We are finalizing the RUC-recommended work RVU and PE inputs as proposed; however, we continue to have serious concerns about the validity of this coding.

(43) Interstitial Radiation Source Codes (CPT Codes 77778 and 77790)

In the CY 2016 PFS final rule with comment period, we established an interim final value for CPT code 77790 without a work RVU, consistent with the RUC's recommendation. We did not use the RUC-recommended work RVU to establish the interim final values for CPT code 77778. We stated that the specialty society survey included a work time that was significantly higher than the RUC-recommended work time without a commensurate change in the work RVU. For CY 2016, we established the 25th percentile work RVU survey result of 8.00 as interim final for CPT code 77778 and 0 work RVUs for CPT code 77790.

Comment on the CY 2016 PFS final rule with comment period: Commenters agreed that the preservice survey times and the RUC-recommended survey times were inconsistent and explained that this inconsistency resulted from the RUC's use of preservice packages in developing recommendations. In addition, commenters stated that because the work associated with CPT code 77790 (including pre-time supervision, handling, and loading of radiation seeds into needles) was bundled into CPT code 77778, that the additional work should be reflected in the RVU for CPT code 77778. Commenters encouraged us to accept the RUC-recommended work RVU of 8.78 and requested that CPT code 77778 be referred to the refinement panel.

Response in the CY 2017 PFS proposed rule: We did not refer CPT code 77778 to the CY 2016 multispecialty refinement panel because commenters did not provide new clinical information. We continued to believe that, based on the reduction in total work time, an RVU of 8.00 accurately reflected the work involved in furnishing CPT code 77778.

In the CY 2017 proposed rule, we proposed a work RVU of 8.00 for CPT code 77778 and 0 work RVUs for CPT code 77790. We also sought comment on whether we should use time values based on preservice packages if the recommended work value was based on time values that were significantly different than those ultimately recommended.

The following is a summary of the comments we received regarding our proposed valuations for CPT codes 77778 and 77790:

Comment: Some commenters stated that CMS underestimates the additional work inherent in furnishing CPT code 77778, considering that it is being bundled with CPT code 77790.

Commenters did not agree with our decision not to accept the RUC-recommended work RVU of 8.78 and to propose for CY 2017 a work RVU of 8.00, considering the disparity between the survey total time and the RUC-recommended total time. According to the RUC, the survey respondents had accurately estimated the work RVU based on magnitude estimation while overestimating the relatively low intensity pre-service time involved in performing this service, and this explains the disparity between the survey time and the RUC-recommended total time. One commenter noted that the RUC significantly reduced the pre-time because it did not include work in supervising the ordering of the isotope. Several commenters stated that CMS routinely accepts and uses pre-service time packages as recommended by the RUC.

Response: We continue to question how the same survey respondents that significantly overestimated the total time based on the RUC's analysis could nonetheless accurately estimate the overall work. We are also concerned about the specialty society's perspective that the RUC does not consider the work of supervising the ordering of the isotope as part of the service, given the survey respondents clearly considered such work to be described by the code. We believe that it is important that a particular code clearly describes the work involved in furnishing a service. While we appreciate the usefulness of pre-time packages generally, for this particular code, we believe that in this case the drastic time difference from the survey time value to the RUC-recommended time value that the pre-time package produces is problematic, especially since there does not appear to be consensus regarding which services are included in the code, or which might be perceived to be separately reportable.

In general we are concerned with using recommended time values that are disconnected from recommended work RVUs, including in cases where the recommended work RVU may include elements of work that are not reflected in the assumptions in time, as appears to be the case for this code. We reiterate that we believe the statute directs us to establish work RVUs that reflect the relative resource costs in time and intensity, so we believe that there should be an identifiable relationship between time and work RVUs.

To align the time and work associated with this code, we proposed a reduction of the work RVU from 8.78 to 8.00 as we proposed. However, upon consideration of comments, we were persuaded that

the RUC-recommended work RVUs for this service are appropriate, particularly because the work includes the supervision, handling, and loading of radiation seeds, and it reflects the bundling with CPT code 77790.

While we are not finalizing a change in the time associated with this code since we proposed to use the RUC recommended value based on the pre-service package, we seek additional information regarding the best approach to valuing work when there is a clear disconnect between assumptions regarding time described by a code and the time recommended by the RUC. We understand that pre-service time packages can be a helpful tool in assigning estimates of time to particular codes relative to others on the PFS and that these times may be significantly different than those derived from survey results. However, since the RUC has repeatedly stated that its recommendations reflect the typical resources involved in furnishing PFS services, we believe it would be important for us to be able to identify cases where the recommended time values reflect the application of particular policies rather than the best estimate of the actual time involved in furnishing procedures.

(44) Colon Transit Imaging (78264, 78265, 78266)

In establishing CY 2016 interim final values, we accepted the RUC recommended work RVUs for CPT codes 78265 and 78266. We believed that the RUC-recommended RVU of 0.80 overestimated the work involved in furnishing CPT code 78264 and as a result, we established an interim final work RVU of 0.74 based on a crosswalk to CPT code 78226 (hepatobiliary system imaging, including gallbladder when present), due to similar intraservice times and intensities.

Comment on the CY 2016 PFS final rule with comment period: Commenters did not support our interim final work RVU for CPT code 78264. Commenters disagreed with our assessment of CPT code 78264 as having a higher work RVU and shorter intraservice time relative to the other codes in the family. One commenter stated that a difference of two minutes in intraservice time was insignificant and should not be used as a rationale for revaluing. Another commenter stated that we should have maintained the RUC-recommended crosswalk of CPT code 78264 to CPT code 78227 (Hepatobiliary system imaging, including gallbladder when present; with pharmacologic intervention, including quantitative measurement(s) when performed) due to similarities in service, work and intensity. Based on these concerns, commenters requested that CPT code 78264 be referred to the refinement panel.

Response in the CY 2017 PFS proposed rule: CPT code 78264 was referred to the CY 2016 multi-specialty refinement panel for further review. We calculated the refinement panel results as the median of each vote. That result for CPT code 78264 was 0.79 RVUs.

In the CY 2017 proposed rule, we proposed a value of 0.79 for CPT code 78264.

The following is a summary of the comments we received regarding our proposed valuation of the Colon Transit Imaging codes:

Comment: A commenter recommended that we reexamine the data associated with these codes to ensure the accuracy of the final values.

Response: We thank the commenter for this input. We continue to believe that the proposed valuation on CPT code 78264 most accurately describes the work, time and intensity associated with this service; therefore, we are finalizing the work RVU as proposed.

(45) Cytopathology Fluids, Washings or Brushings and Cytopathology Smears, Screening, and Interpretation (CPT Codes 88104, 88106, 88108, 88112, 88160, 88161, and 88162)

In the CY 2016 PFS final rule with comment period, we made a series of refinements to the recommended direct PE inputs for this family of codes. We removed the equipment time for the solvent recycling system (EP038) and the associated clinical labor described by the tasks ''Recycle xylene from stainer'' and ''Order, restock, and distribute specimen containers and or slides with requisition forms'' due to our belief that these were forms of indirect PE. This refinement applied to all seven codes in the family. We also noticed what appeared to be an error in the quantity of non-sterile gloves (SB022), impermeable staff gowns (SB027), and eye shields (SM016) assigned to CPT codes 88108 and 88112. The recommended value of these supplies was a quantity of 0.2, which we believed was intended to be a quantity of 2. We therefore refined the value of these supplies to 2 for CPT codes 88108 and 88112.

Comment on the CY 2016 PFS final rule with comment period: Several commenters disagreed with our characterization of the solvent recycling system and its associated clinical labor tasks as indirect PE. Commenters stated that the solvent recycling system costs are direct expenses since they are based on the amount of recycled solvent allocated to each specimen, with solvents allocated to specific specimens based on batch size. They indicated that the related clinical labor tasks are direct PE as they are also based on the amount of recycled solvent allocated to each specimen. The time for these tasks varies based on the batch size, which varies by procedure.

Response in the CY 2017 PFS proposed rule: We maintained our previously stated belief that these are forms of indirect PE, as they are not allocated to any individual service. Under the established PE methodology, direct PE inputs are defined as clinical labor, medical supplies, or medical equipment that are individually allocable to a particular patient for a particular service. We continue to believe that a solvent recycling system would be in general use for a lab practice, and that the associated clinical labor tasks for ordering and restocking specimen containers can be more accurately described as administrative activities. We proposed to maintain these refinements from the previous rulemaking cycle for CPT codes 88104–88162.

Comment on the CY 2016 PFS final rule with comment period: A commenter indicated that we did not account for the batch size when considering the supply quantities for CPT codes 88108 and 88112. The commenter indicated that the practice expense inputs should be assumed to have a batch size of five for these two codes, and therefore, no edits should be made. The commenter requested that we restore the quantity of 0.2 for the gloves, gowns, and eye shields associated with these procedures. This did not apply to the other codes on the submitted spreadsheet, which had a batch size of one.

Response in the CY 2017 PFS proposed rule: We appreciated the assistance of the commenter in clarifying the batch size for these procedures. As a result, we proposed to refine the supply quantity of the non-sterile gloves (SB022), impermeable staff gowns (SB027), and eye shields (SM016) back to the RUC-recommended value of 0.2 for CPT codes 88108 and 88112.

The following is a summary of the comments we received regarding our proposed valuation of the Cytopathology Fluids and Cytopathology Smears codes:

Comment: A few commenters continued to disagree that the proposed refinements to the direct PE inputs were forms of indirect PE. Commenters stated that these tasks are direct expenses, as they are variable based on the volume

of these services, with the clinical labor and equipment time directly attributable to the quantity of specimens typically provided from a typical laboratory. Commenters also stated that these activities were not captured in the questions asked on the indirect practice expense cost survey.

Response: We continue to believe that these are administrative tasks that are more accurately classified as forms of indirect PE because they are not allocable to an individual service. Whether these tasks are variable based on the volume of the services is unrelated to this classification. For example, some services may require additional time for administrative staff to record electronic health records or restock inventory than other services, but in all cases these are defined as indirect PE under the established methodology, as they are administrative tasks that are not allocated to any individual service. We disagree that the validity of the practice expense data rests on whether or not particular questions were asked on the survey. We note that we understand medical practice and technology often change over time and the PE survey data is used to capture the relative difference in practice expenses incurred by various specialties as opposed to representing a summation of all individual items that incur an expense. Therefore, we do not believe that inclusion or exclusion of particular items means that the underlying data are invalid for purposes of measuring relativity.

Comment: A commenter agreed with the changes to the RUC-recommended supply quantity of 0.2 for the non-sterile gloves (SB022), impermeable staff gowns (SB027), and eye shields (SM016) in CPT codes 88108 and 88112.

Response: We appreciate the support from the commenter.

After consideration of comments, we are finalizing the proposed direct PE inputs for CPT codes 88104, 88106, 88108, 88112, 88160, 88161, and 88162.

(46) Flow Cytometry Interpretation (CPT Codes 88184, 88185, 88187, 88188, and 88189)

The Flow Cytometry Interpretation family of codes is split into a pair of codes used to describe the technical component of flow cytometry (CPT codes 88184 and 88185) that do not have a work component, and a trio of codes (CPT codes 88187, 88188, and 88189) that do not have direct practice expense inputs, as they are professional component only services. CPT codes 88184 and 88185 were reviewed by the RUC in April 2014, and their CMS refined values were included in the CY 2016 PFS final rule with comment period. The full family of codes was reviewed again at the January 2016 RUC meeting, and new recommendations were submitted to CMS as part of the CY 2017 PFS rulemaking cycle.

We proposed the RUC-recommended work RVU of 0.74 for CPT code 88187, and the RUC-recommended work RVU of 1.70 for CPT code 88189. For CPT code 88188, we proposed a work RVU of 1.20 instead of the RUC-recommended work RVU of 1.40. We arrived at this value by noticing that there were no comparable codes with no global period in the RUC database with intraservice time and total time of 30 minutes that had a work RVU higher than 1.20. The RUC-recommended work RVU of 1.40 would go beyond the current maximum value and establish a new high, which is not consistent with our estimation of the overall intensity of this service relative to the others. As a result, we believe it is more accurate to crosswalk CPT code 88188 to the work value of the code with the current highest value, which is CPT code 88120 (Cytopathology, in situ hybridization (for example, FISH), urinary tract specimen with morphometric analysis, 3–5 molecular probes) at a work RVU of 1.20. We believe that CPT code 88120 is crosswalk comparable code since it shares the identical intraservice time and total time of 30 minutes with CPT code 88188.

We also noted that the survey increment between CPT codes 88187 and 88188 at the RUC-recommended 25th percentile was 0.40 (between work RVUs of 1.00 and 1.40), and this increment of 0.40 when added to CPT code 88187's work RVU of 0.74 would arrive at a value of 1.14. In addition, the total time for CPT code 88188 decreases from 43 minutes to 30 minutes, which is a ratio of 0.70, and when this time ratio is multiplied by CPT code 88188's previous work value of 1.69, the result would be a new work RVU of 1.18. With this information in mind, we proposed a work RVU of 1.20 for CPT code 88188 as a result of a direct crosswalk to CPT code 88120.

For CPT codes 88184 and 88185, which describe the technical component of flow cytometry, we proposed to use the RUC-recommended inputs with a series of refinements. However, we believe that the coding for these two procedures may inhibit accurate valuation. CPT code 88184 describes the first marker for flow cytometry, while CPT code 88185 is an add-on code that describes each additional marker. We believe that it may be more accurate to have a single CPT code that describes the technical component of flow cytometry on a per patient case basis, as these two procedures are always performed together and it is difficult to determine the clinical labor, supplies, and equipment used in the typical case under the current coding structure. We solicited comments regarding the public interest in consolidating these two procedures into a single code used to describe the technical component of flow cytometry.

Absent such a change in coding, we proposed to refine the clinical labor time for ''Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling'' from 15 minutes to 13 minutes for CPT code 88184. We maintained that 13 minutes for this activity, which is the current time value, would be typical for the procedure, as CPT code 88182 also uses 13 minutes for the identical clinical labor task. We also proposed to refine the L054A clinical labor for ''Load specimen into flow cytometer, run specimen, monitor data acquisition, and data modeling, and unload flow cytometer'' from 10 minutes to 7 minutes using the same rationale, a comparison to CPT code 88182.

We proposed to maintain the clinical labor for ''Print out histograms, assemble materials with paperwork to pathologists Review histograms and gating with pathologist'' for CPT code 88184 at 2 minutes, as opposed to the RUC-recommended 5 minutes. A clinical labor time of 2 minutes is standard for this activity; we disagree with the RUC rationale that reviewing histograms and gating with the pathologist in this procedure is not similar to other codes. We also note that the review of histograms with a pathologist is not even described by CPT code 88184, which again refers to the technical component of flow cytometry, not the professional component. We also proposed to refine the L033A clinical labor time for ''Clean room/equipment following procedure'' from 2 minutes to 1 minute for CPT code 88184. We have established 1 minute in previous rulemaking (80 FR 70902) as the standard time for this clinical labor activity in the laboratory setting.

We proposed to maintain our removal of the clinical labor time for ''Enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation'' for both CPT code 88182 and CPT code 88184. As we stated in the CY 2016 PFS final rule with comment period (80 FR 70979), we have not recognized the laboratory information system as an equipment

item that can be allocated to an individual service. We continue to believe that this is a form of indirect PE, and therefore, we do not recognize the laboratory information system as a direct PE input, and we do not consider this task as typically performed by clinical labor on a per-service basis.

We proposed to maintain the quantity of the ''lysing reagent'' supply (SL089) at 2 ml for CPT code 88185, as opposed to the RUC-recommended quantity of 3 ml. In our discussions with pathology specialists who perform flow cytometry, we were informed that the use of 50–55 ml of the lysing reagent would be typical for an entire patient case. The RUC recommendation similarly suggested a quantity of 46 ml or 48 ml per patient case. We were also told that the most typical number of markers used for flow cytometry is 24, consisting of 1 service of CPT code 88184 and 23 services of CPT code 88185. An investigation of our claims data confirmed this information, indicating that 24 markers is the most frequent per patient case for flow cytometry, and the use of more than 20 markers is typical. We believe that this data supports our refinement of the lysing reagent from a quantity of 3 ml to a quantity of 2 ml for CPT code 88185, which is also the current value for the procedure and the RUC-recommended value from the previous set of recommendations. For the typical case of 24 markers, our value would produce a total lysing reagent quantity of 51 ml (5 ml from the single service of CPT code 88184 and 46 ml from the 23 services of CPT code 88185), which matches with the amount required for a total per patient case. If we were to adopt the RUC recommendation, the total lysing reagent quantity would be 74 ml, which is well in excess of what we believe to be typical for these procedures.

We also proposed to refine the quantity of the ''antibody, flow cytometry'' supply (SL186) from quantity 1.6 to quantity 1, which is also the current value for the supply and the RUC-recommended value from the previous set of recommendations. We do not agree that more than one antibody would be typically used for each marker. We are reaffirming the previous RUC recommendation, and maintaining the current quantity of 1 antibody for each marker.

We did not agree with the recommended additional time for the ''printer, dye sublimation (photo, color)'' equipment (ED031). We proposed to maintain the equipment time at 2 minutes for CPT code 88184, and at 1 minute for CPT code 88185. As we stated in the CY 2016 PFS final rule with comment period (80 FR 70979), we proposed to assign equipment time for the dye sublimation printer to match the clinical labor time for ''Print out histograms, assemble materials with paperwork to pathologists.'' We do not believe that it would be typical for the printer to be in use longer than it takes to accomplish this clinical labor task.

The following is a summary of the comments we received regarding our proposed valuation of the Flow Cytometry Interpretation codes. Due to the large number of comments we received for this code family, we will first summarize the comments related to the coding structure of CPT codes 88184 and 88185, followed by the comments related to specific work RVUs, and finally the comments related to the direct PE inputs.

Comment: Many commenters disagreed with the potential concept of consolidating CPT codes 88184 and 88185 into a single code used to describe the technical component of flow cytometry. Commenters stated that the resources required for the first marker and for each subsequent marker differ, and with flow cytometry, there is no ''typical case.'' Because the number of markers differ for different disease states, such as HIV, Lyme disease, and acute leukemias, the current coding structure is designed to reflect different valuations of the professional component codes, based on the number of markers that must be interpreted. Many commenters stressed that this makes one code for the technical component of flow cytometry infeasible, and strongly advised against it. One commenter was also concerned that a coding structure change may exacerbate the undervaluation of these services, which have been recently reviewed twice by the RUC and resulted in substantial decreases in the practice expense relative values.

A few commenters supported the possibility of combining CPT codes 88184 and 88185 into a single code. One commenter stated that the current coding structure does not incentivize the use of less reagents, and actually penalizes labs that appropriately test fewer markers. According to this commenter, moving to a single code structure would be consistent with the vast majority of lab tests, would simplify billing processes, and may make development of more cost-effective panels financially desirable. The commenter supported further examination of a single CPT code and urged that current payment rates should be frozen while such examination occurs. Another commenter suggested a slightly different coding structure, one which would collapse the codes into a series of case rate codes that reflect the procedures: screening, classification, and monitoring. There was support from one additional commenter for a three code proposal designed to track this workflow.

Response: We appreciate the detailed responses from the commenters about the proper coding structure used to describe the technical component of flow cytometry. We do not intend to finalize any recommendations regarding the coding structure at this time, but we will consider this information for future proposals regarding these services.

Comment: Many commenters made general comments about decreases to the proposed rates for either the professional or the technical component of the flow cytometry codes. Commenters stated that there was no justification for the reduction in payment rates, and that the decreases would hamper laboratories' ability to offer the flow cytometry services. One commenter stated that the payment cuts were not realistic and would result in flow cytometry not being financially feasible in the less expensive physician-office setting. Another commenter indicated that further reductions to these codes would result in an inability to maintain the level of professional services required to reduce medical errors.

Response: We share the concern of the commenters in ensuring that payment for Medicare services is based on an accurate assessment of the relative resource costs involved in furnishing the service. With regards to the technical component of flow cytometry, most of the decrease in code valuation is taking place due to a decrease in the quantity of the lysing reagent supply (SL089). The RUC has agreed that there was previously an excess of this supply in CPT codes 88184–88185, and has recommended a decrease of approximately 78 percent in this supply quantity, from 336 ml to 74 ml, in the typical case of 24 markers. Due to the resource-based nature of the RVU system, this substantial reduction in supply costs will be reflected in the RVUs for these procedures. We note that since CY 2016 the phase-in of significant reductions in RVUs has been in effect; 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, those decreases are limited to a 19 percent reduction in total RVUs. We note that the phase-in mechanism allows reductions to be transitioned in over time rather than instituting large decreases in a single

rule cycle. Please see section II.H for more information regarding the phase-in of significant RVU reductions.

Comment: Many commenters disagreed with the proposed work RVU of 1.20 for CPT code 88188. Several commenters took issue with the CMS statement that there were no comparable codes with no global period in the RUC database with intra-service time and total time of 30 minutes that had a work RVU higher than 1.20. These commenters indicated that there were at least 10 such codes valued over 1.20 RVUs in the 2016 RUC database (1 XXX and 9 ZZZ add-on global codes), ranging in work value from 1.38 to 2.40 RVUs, with a median of 1.67. The commenters suggested that these codes supported the higher RUC-recommended work RVU of 1.40 for CPT code 88188.

Response: We continue to believe that there are no comparable codes with the same global period with intraservice time and total time of 30 minutes that have a work RVU higher than 30 minutes. When we used the phrase ''no global period'' to refer to CPT code 88188, we were not referring to add-on codes with a global period of ZZZ. We have stated on numerous occasions that we believe the resources required to furnish add-on codes constitute a separate category, and we typically only compare add-on codes to other add-on codes. We do not believe that it is appropriate to compare the work RVU of add-on codes with 30 minutes of intraservice time to the work RVU of CPT code 88188, which is not an add-on code.

With regards to non-add on codes, Table 21 lists all 13 codes in the RUC database with 30 minutes of intraservice time, fewer than 40 minutes of total time, and a global period of XXX:

TABLE 21: WORK RVU OF CODES WITH COMPARABLE TIME VALUES TO CPT CODE 88188

HCPCS	Descriptor	Work RVU
77331	Special radiation dosimetry.	0.87
78195	Lymph system imaging.	1.20
78456	Acute venous thrombus image.	1.00
86079	Phys blood bank serv authrj.	0.94
88120	Cytp urne 3–5 probes ea spec.	1.20
88187	Flowcytometry/read 2–8.	0.74
88365	Insitu hybridization (fish).	0.88
88368	Insitu hybridization manual.	0.88
88374	M/phmtrc alys ishquant/semiq.	0.93
93750	Interrogation vad in person.	0.92
95251	Gluc monitor cont phys i&r.	0.85
97004	Ot re-evaluation	0.60
97606	Neg press wound tx >50 cm.	0.60

As we stated previously, there are no codes with a work RVU higher than 1.20, which is where we proposed to value CPT code 88188. We acknowledge that there are global XXX codes with 30 minutes of intraservice time that have a work RVU greater than 1.20. However, all of these codes have at least 40 minutes of total time, which is 33 percent higher at a minimum than the total time for CPT code 88188. We believe that a crosswalk to CPT code 88120, which shares the identical time values as CPT 88188, is a more appropriate choice than codes that have substantially higher total time. In the particular case of CPT code 88188, we continue to believe that establishing a new maximum work value above 1.20 would not be consistent with our estimation of the overall intensity of this service relative to the others on the PFS.

Comment: Some commenters disagreed with the proposed work RVU of CPT code 88188 based on the work increments between the codes in the family. These commenters stated that the original recommended work values had almost identical increments between the three services (0.60 between CPT codes 88187 and 88188, and 0.63 between CPT codes 88188 and 88189); however the median survey results indicated a much greater physician work increment between CPT codes 88188 and 88189. According to commenters, the final RUC recommendations were based on the expertise of the RUC to establish the work increment between CPT codes 88187 and 88188 (0.74) higher than the increment between CPT codes 88188 and 88189 (0.30). In other words, the recommended work increment between CPT code 88187 (work RVU = 0.74) and CPT code 88188 (work RVU = 1.40) was significantly larger than the work increment between CPT code 88188 (work RVU = 1.40) and CPT code 88189 (work RVU = 1.70). The commenters stated that the survey results and expert opinion justified this smaller increment between the final two codes, and the RUC-recommended work RVU of 1.40 for CPT code 88188.

Response: We disagree that the survey data justifies a smaller increment between the final two codes. While this is true for the 25th percentile survey results, the exact opposite is true for the survey median results, in which the increment between CPT codes 88187 and 88188 is 0.35 and the increment between CPT codes 88188 and 88189 is 0.70. In addition, in the current pre-reviewed version of these codes, the increment between CPT codes 88187 and 88188 is 0.33, while the increment between CPT codes 88188 and 88189 is 0.54. We believe that this suggests the survey data on the work increments is conflicting, not conclusive, and that the RUC-recommended increments are a departure from the previous incremental structure of this code family, in which the second two codes had a larger increment than the first two codes. We do not agree that the work increments at the survey 25th percentile are a sufficient justification for adopting the recommended work RVU for CPT code 88188 due to the additional data regarding work increments between these codes detailed above.

Comment: Several commenters stated that over the last decade, flow cytometric analyses have changed through new technological advances that have led to an increased interpretative sophistication. It is now typical for the physician to analyze substantially more data than in the past. According to commenters, with the advent of 5, 6, 8, and 10 color flow cytometry the intensity and complexity of these services has significantly increased. Commenters stated that this increased intensity and complexity is reflected in the RUC recommendation for this service, based on new physician work associated with technological changes, time, and intensity.

Response: We appreciate this additional information about the professional interpretation of flow cytometry from the commenters. However, we note that the RUC-recommended intensity of CPT codes 88187 and 88189 has actually decreased compared to the current pre-reviewed version of these codes. We believe that this indicates that the same new technological advances also allow practitioners to analyze data faster and with fewer errors, which is reflected in the decreased work RVUs and time values in the RUC recommendations. The only one of the three codes with a RUC-recommended increase in intensity is CPT code 88188. This increased intensity in the second code creates an anomalous relationship within the

family, as the RUC-recommended intensity for CPT code 88188 is equal to the intensity for CPT code 88189, in contrast to the current pre-reviewed version of these codes where the three codes have a linear increase in intensity (IWPUT = 0.39, 0.43, 0.50). We do not understand why the professional interpretation of 9 to 15 markers would have an equal intensity to interpreting 16 or more markers. Logic would suggest that CPT code 88188 should have a lower intensity than CPT code 88189, which is indeed the case at our proposed work RVU of 1.20. The proposed value also re-establishes a linear increase in intensity between the three codes as additional markers are interpreted (IWPUT = 0.37, 0.40, 0.47). We believe that this intensity data offers additional support for our proposed work RVU.

Comment: One commenter disagreed with the CMS crosswalk to the work RVU of CPT code 88120, which the commenter suggested was completely different in step by step work effort, intensity, and complexity. The commenter stated that CPT code 88120 typically only involves identifying and quantifying a limited subset molecular probes (for example, FISH probes for chromosomes 3, 7, 17 and 9p21 loss), using two to four color signal enumeration to detect aneuploidy staining of nuclei on slides from isolated cell preparations, usually from morphologically well-characterized specimens. In contrast, the commenter stated that for CPT code 88188 the pathologist is required to integrate multi-parameter diagnostic information on different cell populations (both abnormal and normal), by assessing cell scatter (size and shape) along with signal intensity and pattern of staining of cell surface markers with antibody reagents using four to six (or more) color fluorescent antibody probes. The pathologist must perform successive, iterative analyses of 2- and 3-dimensional plots and histograms and re-gating of identified cell populations (based on size, shape, relative staining patterns, signal intensity, etc.) to characterize cell lineage and render a final diagnosis and interpretation. Due to this clinical rationale, the commenter indicated that the work and complexity of CPT code 88188 was substantially greater than CPT code 88120.

Response: We disagree with the commenter that CPT code 88120 is an inappropriate crosswalk code for CPT code 88188. These codes are both recently-reviewed pathology codes with identical intraservice time and total time values within the Cytopathology listing of the CPT manual. We also note that many of the activities listed by the commenter are not detailed in the intraservice work description for CPT code 88188, and may not be needed in the typical case.

The following comments address the proposed direct PE inputs for the Flow Cytometry family of codes.

Comment: Many commenters disagreed with the proposed time of 13 minutes for the clinical labor activity ''Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling.'' Commenters stated that the CMS comparison to CPT code 88182 was not appropriate, as that code uses older/simpler technology, with CPT code 88184 using 4–6 or more color channels while CPT code 88182 uses 1–2 channels. Commenters stressed that these clinical labor tasks are unique to this flow cytometry service, and they should not be assumed to take the identical time as other services. Other commenters stated that three instruments must be run consecutively, and the task includes quality control calibration, taking a minimum of 13 to 16 minutes in dedicated technical staff time. Another commenter indicated that the time required to complete these activities is continually increasing as more regulatory requirements are added, and that the recently added flow cytometry requirement for individual antibody lot/shipment testing increased this time exponentially.

Response: We disagree with the commenters that the identical clinical labor activity would take longer to perform for CPT code 88184 than it would for CPT code 88182. Both of these procedures use the same equipment to perform this task, a flow cytometer (EP014) and a centrifuge (EP007). We do not agree that there is additional clinical labor time required for using additional color channels in CPT code 88184, as the same equipment is being used to perform the same clinical labor task as in CPT code 88182. We did not receive data from the commenters suggesting that regulatory requirements are increasing the time required to perform this clinical labor task, nor was this reflected in the RUC recommendations, which continued to recommend the same unchanged time for this task.

Comment: Many commenters objected to the proposed clinical labor time of 7 minutes for the ''Load specimen into flow cytometer, run specimen, monitor data acquisition, and data modeling, and unload flow cytometer'' activity for CPT code 88184. Commenters stated that the CMS comparison to the clinical labor time used for this same activity in CPT code 88182 was not appropriate as CPT code 88184 uses 4–6 color channel instruments and up, while 88182 uses only 1–2 channels. According to the commenters, the time it takes for data capture, data modeling, data acquisition, and computational analysis is exponentially longer for CPT code 88184 than for CPT code 88182, since additional colors result in more complicated profiles which are more difficult and time consuming to evaluate. Another commenter stated that 7 minutes was wholly inadequate to perform all of these tasks, and that analysis of a specimen can take 12 to 15 minutes, depending on the complexity of the case.

Response: We continue to disagree with the commenters that the identical clinical labor activity would take longer to perform for CPT code 88184 than it would for CPT code 88182. As we stated in response to the previous comment, we do not agree that there is additional clinical labor time required for using additional color channels in CPT code 88184, as the same equipment is being used to perform the same clinical labor task as in CPT code 88182. For the same reason, we do not agree that this clinical labor activity takes 12 to 15 minutes to perform, since the identical task only requires 7 minutes for CPT code 88182.

Comment: Many commenters opposed the proposed value of 2 minutes for the clinical labor activity ''Print out histograms, assemble materials with paperwork to pathologists Review histograms and gating with pathologist'' for CPT code 88184. Commenters stated that it was not reasonable to expect that a flow cytometry technologist could print out histograms, assemble the documents and deliver them to a pathologist, and review the histograms with a pathologist, all in the span of a mere 120 seconds. Commenters were concerned that flow cytometry technologists cannot produce a high-quality product and ensure its accuracy and completeness for presentation to a pathologist in the proposed time. One commenter noted that although their specific procedure for these steps was largely electronic, their workflow analysis corroborated the RUC's conclusion because it showed that it took 5 minutes for staff to complete the equivalent activities. Several other commenters stated that if the time the cyotechnologist takes to determine exactly which histograms to print is subtracted, then they could agree with the proposed 2 minutes. Commenters also stated that printing is not performed all at one time, with 25–30 pages of information and data printed over a 5 minute time span, and one

commenter indicated that the process was ''largely electronic'' with clinical staff not using the equipment for the full duration that it is in use.

Response: We appreciate the support from several of the commenters. In responding to the comments for this clinical labor activity and the equipment time for the dye sublimation printer (ED031), it became clear that the clinical labor time for printing was not the same as the equipment time that the printer was in use. Based on the information from the commenters that printing is not performed all at one time, we are assigning the full 5 minutes of equipment time for the dye sublimation printer; however, we are maintaining our proposed 2 minutes of clinical labor time for ''Print out histograms, assemble materials with paperwork to pathologists Review histograms and gating with pathologist'', as commenters have informed us that the clinical staff do not use the equipment for the full duration that it is in use.

Comment: Several commenters disagreed with the proposed clinical labor time of 1 minute for ''Clean room/equipment following procedure'' for CPT code 88184. The commenters stated that this time is allocated over entire patient case, and that it is typical and critical to clean the equipment between patient cases. The commenters also supplied details about the cleaning process, regarding how the laboratory technician cleans the equipment and workspace by decontaminating the equipment and work bench surfaces, as well as carrying out waste management after the procedure.

Response: We appreciate the additional information from the commenters regarding the cleaning of the room. However, the commenters did not provide a rationale as to why CPT code 88184 requires additional clinical labor above the standard value of 1 minute for room cleaning in lab procedures. We continue to believe that the standard clinical labor time is the most accurate valuation for this clinical labor task.

Comment: Many commenters requested that CMS restore the clinical labor time for the ''Enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation'' activity. Commenters stated that this data entry is manually entered and must be performed for each individual patient case. Several commenters indicated that entering test-specific data takes between five and ten minutes, and entry of client information and demographics and specimen information takes additional time that cannot be short-changed. Commenters emphasized that these are extremely important tasks that require technical skills, and assigning zero minutes to this critical task was illogical for a service like flow cytometry. One commenter stated that the current RUC-recommended value of four minutes was already a gross underestimation of the time required to complete these activities for the majority of testing, and suggested that these activities commonly take more than ten minutes to perform.

Response: We agree with the commenters that entering patient data into information systems is an important task, and we agree that it would take more than zero minutes to perform. However, the commenters did not address our rationale for removing this clinical labor time from CPT codes 88184 and 88185, which is that this task is indirect PE. As we stated in the CY 2016 final rule with comment period (80 FR 70979), we have not recognized the laboratory information system as an equipment item that can be allocated to an individual service. We continue to believe that this is indirect PE, and therefore, we do not recognize the laboratory information system as a direct PE input, and we do not consider this task as typically performed by clinical labor on a per-service basis.

Comment: One commenter requested the inclusion of additional cytotechnologist time of 10 minutes for CPT code 88184 and 2 minutes for CPT code 88185, as well as an additional desktop computer with monitor (ED021) equipment times of 10 minutes for 88184 and 2 minutes for 88185. This additional time was intended to reflect the time spent using the flow cytometry analytics software (EQ380).

Response: We agree with the RUC recommendations that the clinical labor and equipment time associated with the flow cytometry analytics software is already accounted for in the recommended clinical labor inputs. As the recommendations indicate, this time is included as part of the clinical labor activities ''Accession specimen'', ''Instrument start-up, quality control functions'', ''Load specimen into flow cytometer, run specimen'' and ''Print out histograms, assemble materials with paperwork to pathologists.''

Comment: Many commenters disagreed with the proposed supply quantity of 2 for the lysing reagent (SL089) in CPT code 88185. Commenters stated that although they acknowledged that the current Medicare data showed that a patient case of 24 markers is typical, this result ignored other relevant pieces of information. The commenters indicated that an analysis of the 2014 Medicare 5% Sample Carrier Database showed that over 50 percent of individual providers typically bill fewer than 20 markers per patient case, and that since these providers are generally smaller and see fewer annual cases, the proposed supply quantity of 2 would potentially drive these providers to consider ceasing their flow cytometry services. The commenter also stated that these codes are often billed as part of either the Hospital IPPS or OPPS, which should be factored into the typical number of markers billed per case. The commenter also stated that the most common professional component of flow cytometry, CPT code 88189, would be associated with patient cases that bill for fewer than 24 markers, from 16 to 24.

Response: We reiterate that we establish payment rates based on the typical case, which the commenters agreed was 24 total markers. We have historically established payment rates based on the typical service and do not believe that it would be appropriate or serve the purpose of relativity to deviate from that practice in this case. We also do not believe that the payment for these codes under the IPPS or OPPS is a directly relevant factor in defining the typical case under the Physician Fee Schedule. We believe that the patient population and typical case under the IPPS would not necessarily be the same as the typical case under the PFS. Finally, we agree that CPT code 88189 would be associated with patient cases that bill for fewer than 24 markers, as the code descriptor states that it refers to the performance of 16 or more markers. However, we do not believe that this affects the number of markers in the typical case, which the commenters agreed was 24 for the typical patient.

Comment: A commenter stated that that it opposed putting a number or cap on markers because there is a wide range of possible markers required to achieve patient diagnosis.

Response: We agree with the commenter, and we are not establishing a cap or determining a fixed number of markers to use for these procedures. As stated previously, however, we are required to establish payment rates based on the typical case, which our internal data and commenter feedback has agreed is 24 markers.

Comment: Other commenters disagreed with the CMS proposal for the lysing reagent based on the supply quantity needed to perform the procedure. A commenter stated that the 46–48 mL quantity detailed by CMS in

the proposed rule was based on a RUC recommendation; however, the RUC's amount was based on an average of 16 markers, not 24 markers. Although the commenter agreed that 24 markers reflected a common case, the commenter stated that it was necessary to consider the amount of lysing agent for a 24 marker case, not to assume that the 46–48 mL amount based upon 16 markers also applies to 24 markers. Another commenter stated that a laboratory using ammonia chloride needs at least 2.5 ml of lysing reagent for each time that CPT code 88185 is performed.

Response: We did not base our proposal for this supply quantity upon the RUC recommendation. As we stated in the proposed rule, we were informed that the use of 50–55 ml of the lysing reagent would be typical for an entire patient case based on our discussions with pathology specialists who perform flow cytometry. For the typical case of 24 markers, our value would produce a total lysing reagent quantity of 51 ml (5 ml from the single service of CPT code 88184 and 46 ml from the 23 services of CPT code 88185), which matches with the amount required for a total per patient case. Since commenters agreed that 24 markers was the typical patient case, we continue to believe that our proposed quantity of 2 ml is the most accurate value for CPT code 88185.

Comment: Many commenters objected to the proposed supply quantity of 1 for the flow cytometry antibody (SL186) in CPT codes 88184 and 88185. Commenters stated that although it is standard practice to use a single antibody multiple times during the analysis, each antibody or marker can only be billed once per analysis. According to commenters, multiple use of such antibodies are not reportable or billable, but are critical to the overall analysis and interpretation of results and are part of the total cost for each procedure performed. Some commenters explained that the recommended quantity of 1.6 antibodies per billed marker was based on averaging together two separate analyses: a survey of 59 professionals performing flow cytometry that found 1.52 antibodies required per marker, and a customer survey that found 1.87 antibodies per marker. A different commenter stated that its member laboratories found that under the current four-color process, 1.36 antibodies per marker is necessary. Another commenter stated that while one antibody is generally used per marker, the required use of controls for many of these markers for analysis or quality control means that this value is greater than 1 antibody per marker reported.

Response: We appreciate the additional data presented regarding the clinical use of the flow cytometry antibody supply. However, we continue to have reservations regarding the information that we have received regarding the 1.6 quantity for this supply. Different commenters recommended different quantities of this supply required to furnish the procedure, ranging from 1 to 1.36 to 1.52 to 1.6 to 1.87. We are hesitant to increase the quantity of this supply given the wide-ranging information that we received from commenters. We are also concerned that although commenters referenced studies that found different supply quantities for SL186, commenters did not submit the data associated with these studies for our review. We would be more open to the idea of increasing the supply quantity to 1.6 if this data were supported by clinical data or study. We also note that one commenter stated that one antibody is ''generally used'' per marker, which supports our contention that the proposed value of 1 antibody for CPT codes 88184 and 88185 would be typical. As a result, we are maintaining a supply quantity of 1 for the flow cytometry antibody supply, which is also the current value for the supply and the RUC-recommended value from the previous set of recommendations.

Comment: Several commenters disagreed with the proposed equipment time for the dye sublimation printer (ED031). Commenters stated that printing is not performed all at one time, with 25–30 pages of information and data printed over a 5 minute time span. Commenters indicated that this time cannot be linked directly to one particular clinical labor task line, and the printer cannot be used for any other task during these 5 minutes even while it is not actively printing.

Response: We appreciated the additional information from the commenters regarding the use of the dye sublimation printer. Due to the presentation of this new information detailing how the equipment time for the printer is disassociated from any clinical labor tasks, we will increase the equipment time to the RUC-recommended 5 minutes for CPT code 88184 and 2 minutes for CPT code 88185.

After consideration of comments received, we are finalizing the proposed work RVUs for CPT code 88187, 88188, and 88189. We are also finalizing the proposed direct PE inputs, with the refinement to the dye sublimation printer detailed above.

(47) Microslide Consultation (CPT Codes 88321, 88323, and 88325)

CPT codes 88321, 88323, and 88325 were reviewed by the RUC in April 2014 for their direct PE inputs only, and the CMS refined values were included in the CY 2016 PFS final rule with comment period. The family of codes was reviewed again at the January 2016 RUC meeting for both work values and direct PE inputs, and new recommendations were submitted to CMS as part of the CY 2017 PFS rulemaking cycle.

In the CY 2016 PFS final rule with comment period, we finalized our proposal to remove many of the inputs for clinical labor, supplies, and equipment for CPT code 88325. The descriptor for this code did not state that slide preparation was taking place, and therefore, we refined the labor, supplies, and equipment inputs to align with the inputs recommended for CPT code 88321, which also does not include the preparation of slides. After further discussion with pathologists and consideration of comments received, we have been persuaded that slide preparation does take place in conjunction with the service described by CPT code 88325. In the RUC-recommended direct PE inputs from the January 2016 meeting, the labor, supplies, and equipment inputs related to slide preparation were added once again to CPT code 88325. We proposed to accept these restorations related to slide preparation without refinement.

Regarding the clinical labor direct PE inputs, we proposed to assign 1 minute of L037B clinical labor for ''Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist'' for CPT codes 88323 and 88325. We are maintaining this at the current value for CPT code 88323, and adding this 1 minute to CPT code 88325 based on our new understanding that slide preparation is undertaken as part of the service described by this code. We proposed to remove the clinical labor for ''Assemble and deliver slides with paperwork to pathologists'' from all three codes, as we believe this clinical labor is redundant with the labor assigned for ''Complete workload recording logs.'' We similarly proposed to remove the clinical labor for ''Clean equipment while performing service'' from CPT codes 88323 and 88325, as we believe it to be redundant with the clinical labor assigned for ''Clean room/equipment following procedure.''

We proposed to maintain the quantity of the ''stain, hematoxylin'' supply

(SL135) at 16 ml for CPT codes 88323 and 88325, as opposed to the RUC-recommended quantity of 32 ml. The RUC recommendation stated that the hematoxylin supply does not include eosin and should not be redundant; the stains are not mixed together, but are instead sequential. The recommendation also made a comparison to the use of the hematoxylin supply quantity in CPT code 88305. However, we note that CPT code 88305 does not include 8 ml of eosin stain (SL201), but instead 8 gm of eosin solution (SL063), and these are not the same supply. Therefore we do not agree that a direct comparison of the supply quantities is the most accurate way to value these procedures. For CPT codes 88323 and 88325, we continue to note that the prior supply inputs for these procedures had quantity 2.4 of the eosin solution (SL063) and quantity 4.8 of the hematoxylin stain (SL135); in other words, a 1:2 ratio between the eosin and hematoxylin. We proposed to maintain that 1:2 ratio with 8 ml of the eosin stain (SL201) and 16 ml of the hematoxylin stain (SL135).

We also proposed to update the use of the eosin solution (sometimes listed as ''eosin y'') in our supply database. We believe that the eosin solution supply (SL063), which is measured in grams, reflects an older process of creating eosin stains by hand. This is in contrast to the eosin stain supply (SL201), which is measured in milliliters, and can be ordered in a state that is ready for staining immediately. We do not believe that the use of eosin solution would reflect typical lab practice today, with the readily availability for purchase of inexpensive eosin staining materials. We also note that in the CY 2016 PFS final rule with comment period, we removed 8 gm of the eosin solution and replaced it with 8 ml of the eosin stain, and this substitution was accepted without further change in the most recent set of RUC recommendations. As a result, we proposed to update the price of the eosin stain supply from $0.044 per ml to $0.068 per ml to reflect the current cost of the supply. We also proposed to use CPT codes 88323 and 88325 as a model, and replace the use of eosin solution with an equal quantity of eosin stain for the rest of the codes that make use of this supply. This applies to 15 other CPT codes: 88302 (Level II—Surgical pathology, gross and microscopic examination), 88304 (Level III—Surgical pathology, gross and microscopic examination), 88305 (Level IV—Surgical pathology, gross and microscopic examination), 88307 (Level V—Surgical pathology, gross and microscopic examination), 88309 (Level VI—Surgical pathology, gross and microscopic examination), 88364 (In situ hybridization (*e.g.,* FISH), per specimen; each additional single probe stain procedure), 88365 (In situ hybridization (*e.g.,* FISH), per specimen; initial single probe stain procedure), 88366 (In situ hybridization (*e.g.,* FISH), per specimen; each multiplex probe stain procedure), 88367 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; initial single probe stain procedure), 88368 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; initial single probe stain procedure), 88369 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each additional single probe stain procedure), 88373 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each additional single probe stain procedure), 88374 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure), 88377 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure), and G0416 (Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method).

The following is a summary of the comments we received regarding our proposed valuation of the Microslide Consultation codes.

Comment: One commenter supported the restoration of the direct PE inputs related to slide preparation in CPT code 88325 and requested that CMS update the PE data files for CY 2016 to reflect these changes.

Response: We appreciate the support from the commenter. The proposed rates for CY 2017 reflected these changes to the direct PE inputs. However, the RVUs for CY 2016 were unaffected by this proposal, as has been our longstanding practice for interim final codes.

Comment: Several commenters requested that CMS add an additional 1 minute for the clinical labor activity ''Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist'' in CPT code 88321. Commenters stated that this clinical labor task was accidently left off of the April 2014 RUC recommendation for CPT code 88321, and that it was a necessary task that was not redundant with other clinical labor activities.

Response: We agree with the commenters that 1 minute of clinical labor time for this task is an appropriate addition for CPT 88321 to be consistent with the identical clinical labor task taking place in other codes in the family.

After consideration of comments received, we are finalizing our proposed work RVUs for CPT code 88321, 88323, and 88325. We are also finalizing the proposed direct PE inputs, with the addition of 1 minute of clinical labor time as detailed above for CPT code 88321. We note as well that we are finalizing the replacement of eosin solution with eosin stain, as detailed in the PE section of this final rule (see section II.A. of this final rule).

(48) Immunohistochemistry (CPT Codes 88341, 88342, 88344, and 88350)

In the CY 2014 PFS final rule with comment period (78 FR 74341), we assigned a status indicator of I (Not valid for Medicare purposes) to CPT codes 88342 and 88343 and instead created two G-codes, G0461 and G0462, to report immunohistochemistry services. We did this, in part, to avoid creating incentives for overutilization.

For CY 2015, the CPT coding was revised with the creation of two new CPT codes, 88341 and 88344, the revision of CPT code 88342 and the deletion of CPT code 88343. In the past for similar procedures in this family, the RUC recommended a work RVU for the add-on code (CPT code 88364) that was 60 percent of the work RVU for the base code (CPT code 88365). In the CY 2015 PFS final rule with comment period, we stated that the relative resources involved in furnishing an add-on service in this family would be reflected appropriately using the same 60 percent metric and subsequently established an interim final work RVU of 0.42 for CPT code 88341, which was 60 percent of the work RVU of 0.70 for the base CPT code 88342. In the CY 2016 PFS proposed rule, we revised the add-on codes from 60 percent to 76 percent of the base code and subsequently proposed a work RVU of 0.53 for CPT code 88341. However, we inadvertently published work RVUs for CPT code 88341 in Addendum B on the CMS Web site without explicitly discussing it in the preamble text. In the CY 2016 PFS final rule with comment period, we maintained the CY 2015 work RVU of 0.53 for CPT code 88341 as interim final for CY 2016 and requested public comment. Also, in the CY 2016 PFS final rule with comment period, we

established an interim final work RVU of 0.70 for CPT codes 88342 and 88344.

Comment on the CY 2016 PFS final rule with comment period: Several commenters objected to a standard discount for the physician work involved in pathology add-on services and urged us to accept the RUC-recommend work RVU of 0.65 for CPT code 88341.

Response in the CY 2017 PFS proposed rule: We responded to the comments by stating our appreciation of the commenters' concerns regarding a standard discount; however, we believed that it was reasonable to estimate work RVUs for a base and an add-on code, and to recognize efficiencies between them, by looking at how similar efficiencies are reflected in work RVUs for other PFS services. Also we noted that the intravascular codes for which we initially established our base/add-on code relationship for CPT codes 88346 and 88350 were deleted in CY 2016 and replaced with two new codes; CPT codes 37252 and 37253. The relationship between CPT codes 37252 and 37253 represents a 20 percent discount for the add-on code as the base CPT code 37252 has a work RVU of 1.80 and CPT code 37253 has a work RVU of 1.44. As CPT codes 37252 and 37253 replaced the codes on which our discounts for base and add-on codes were based (please see the CY 2016 PFS final rule with comment period (80 FR 70972) for a detailed discussion), we believed it would be appropriate to maintain the same 20 percent relationship for CPT codes 88346 and 88350. Therefore, for CY 2017, we proposed a work RVU of 0.56 for CPT code 88341, which represents 80 percent of the work RVU of 0.70 for the base code. For CY 2016, we finalized a work RVU of 0.56 for CPT code 88350 which, represented 76 percent of the work RVU of 0.74 for the base code. To maintain consistency within this code family, for CY 2017 we proposed to revalue CPT code 88350 using the 20 percent discount discussed above. To value CPT code 88350, we multiplied the work RVU of 0.74 for CPT code 88346 by 80 percent, and then subtracted the product from 0.74, resulting in a work RVU of 0.59 for CPT code 88350. For CY 2017, we proposed a work RVU of 0.59 for CPT code 88350.

The following is a summary of the comments we received regarding our proposed valuations for the Immunohistochemistry family:

Comments: Several commenters stated concerns regarding the level of reimbursement these pathology codes would receive if CMS reduced the work RVUs as proposed. The commenters stated the reduced reimbursement would force pathologists to decrease the number of technical staff, which would interfere with pathologists' ability to perform these services accurately and timely.

The RUC stated the CY 2017 proposed work RVUs for CPT codes 88341 and 88350 do not represent the work involved in furnishing the procedure and present a rank order anomaly for other services. The RUC also stated that the services furnished by CPT codes 37252 and 37253, which we used to establish the relationship between the base code and the add-on code, are not medically comparable services to CPT codes 88341 and 88350. Additionally, the RUC stated each pathology service has individual intensities and complexities. Specifically, for additional immunohistochemistry services represented by add-on CPT codes 88341 and 88350, each antibody is evaluated separately on different slides and each additional service is separate and distinct.

Lastly, the RUC stated its approach of evaluating the actual work associated with each unique base and each unique add-on service is far more accurate, rational, and responsive to the specific circumstances than holding codes equal to a fixed discount from the base code. Applying ratio comparisons and fixed discounts to arrive at a work relative value will continue to create inter-specialty rank order anomalies of physician work RVUs.

Another commenter noted there were RUC surveys that evaluated physician work differentials between the base codes and the add-on codes for pathology services. The commenter offered CPT codes 88333 (Pathology consultation during surgery; cytologic examination (*e.g.,* touch prep, squash prep), initial site) and 88334 (Pathology consultation during surgery; cytologic examination (*e.g.,* touch prep, squash prep), each additional site (List separately in addition to code for primary procedure)) and CPT codes 88331 (Pathology consultation during surgery; first tissue block, with frozen section(s), single specimen) and 88332 (Pathology consultation during surgery; each additional tissue block with frozen section(s) (List separately in addition to code for primary procedure) as examples for consideration.

Response: We appreciate commenters' concern regarding the level of reimbursement and will continue to consider input from the medical community on this issue through evaluation of CPT coding changes and associated RUC recommendations, as well as feedback received through public comments, as we value these services through future notice and comment rulemaking. We also note that the PFS is a relative value system and, as such, values services across all specialties. We believe it is important that there are accurate comparisons between codes in different families.

As discussed in detail in previous proposed and final rules, we continue to believe the metric we use to value add-on codes relative to their base codes is appropriate and representative of the work involved and note that there is no rank order anomaly within this particular code family. In response to the commenter's statement that there should be no comparison of intravascular ultrasound services to any pathology service, we continue to believe any difference in work RVUs for codes describing different kinds of services should reflect the relative differences in time and intensity involved in furnishing the services. Therefore, we believe that it is imperative that we can compare the assumptions regarding overall work between any two codes, regardless of their characteristics.

We appreciate commenters' concerns regarding a standard discount, and we do not consider the use of a particular increment to establish a new standard. Instead, we reiterate that we believe that it is reasonable to estimate work RVUs for a base and an add-on code, and to recognize efficiencies between them, by looking at how similar efficiencies are reflected in work RVUs for other PFS services. We appreciate the commenters' concerns regarding the time ratio methodologies and have responded to these concerns about our methodology in section II.L of this final rule.

Therefore, for CY 2017 we are finalizing a work RVU of 0.56, 0.70, 0.70, and 0.59 for CPT codes 88341, 88342, 88344 and 88350, respectively.

(49) Morphometric Analysis (CPT Codes 88364, 88365, 88367, 88368, 88369 and 88373)

For CY 2015, the CPT Editorial Panel revised the code descriptors for the in situ hybridization procedures, CPT codes 88365, 88367 and 88368, to specify ''each separately identifiable probe per block.'' Additionally, three new add-on codes (CPT codes 88364, 88369 and 88373) were created to specify ''each additional separately identifiable probe per slide.'' Some of the add-on codes in this family had RUC-recommended work RVUs that were 60 percent of the work RVU of the base procedure. We believed this accurately reflected the resources used in furnishing these add-on codes and

subsequently established interim final work RVUs of 0.53 for CPT code 88364 (60 percent of the work RVU of CPT code 88365); 0.53 for CPT code 88369 (60 percent of the work RVU of CPT code 88368); and 0.43 for CPT code 88373 (60 percent of the work RVU of CPT code 88367).

For CY 2016, the RUC re-reviewed these services due to the specialty society's initially low survey response rate. In our review of these codes, we noticed that the latest RUC recommendation was identical to the RUC recommendation provided for CY 2015. Therefore, we proposed to retain the CY 2015 work RVUs and work time for CPT codes 88367 and 88368 for CY 2016. For CPT code 88365 we finalized a work RVU of 0.88 for CY 2016. For CPT codes 88364 and 88369, we increased the work RVUs for both of these add-on codes from 0.53 to 0.67, which reflected 76 percent of the work RVUs of the base procedures for these services. However, we inadvertently omitted the rationale for this revision to the work RVUs in the preamble to CY 2016 proposed rule. Consequently, we maintained the CY 2015 interim final values of the work RVU of 0.67 for CPT codes 88464 and 88369 and sought comment on these values for CY 2016. For CPT code 88373 we finalized a work RVU of 0.43.

Comment on the CY 2016 PFS final rule with comment period: A few commenters stated their objection to our use of a standard discount for pathology add-on services and for suggesting that each service is separate and unique. Commenters also stated there should be no comparison of intravascular ultrasound services to morphometric analysis, immunohistochemistry, immunofluorescence, or any pathology service.

Response in the CY 2017 PFS proposed rule: In reviewing the RUC recommended base/add-on relationships between several pathology codes, we continue to believe the base/add-on code time relationships for pathology services are appropriate and have not been presented with any compelling evidence that conflicts with the RUC-recommended relationships. However, as we stated above, the intravascular codes we initially examined in revaluing CPT codes 88364 and 88369 were deleted in CY 2016 and replaced with CPT codes 37252 and 37253. For the reasons stated above we continue to believe this 20 percent discount relationship between the base and add-on code accurately reflects the work involved in furnishing these services. Therefore, for CY 2017, we are proposing a work RVU of 0.70 for CPT codes 88364 and 88369 which represents a 20 percent discount from the base code. As the relationship between the base code and add-on code now represents a 20 percent difference we are proposing to revalue CPT code 88373 at 0.58 work RVUs.

In the CY 2017 proposed rule, we proposed a work RVU of 0.58 for CPT code 88373.

The following is a summary of the comments we received regarding our proposed valuation of the Morphometric Analysis codes:

Comments: The RUC stated appreciation for the proposed increase in work RVUs for CPT codes 88364 and 88369 although it stated the increase still does not represent the proper work RVU for the work involved and presents a rank order anomaly relative to other services. The RUC, along with other commenters, stated the services described by CPT codes 37252 and 37253 are not comparable medical services to those furnished by CPT codes 88364 and 88369, and there should be no comparison of intravascular ultrasound services to any pathology services.

The RUC also stated that although some medical procedures and services may present efficiencies between base and add-on services, this is not the case for CPT codes 88364 and 88369, as each pathology service is individual so that any rational comparison of the physician work of intravascular ultrasound services with pathology services is impossible. The RUC also stated that no pathology add-on service can be presumed to have a discount in physician work from the base service.

Another commenter stated for CPT code 88373, it is irrational to assume that second and subsequent services designated by convention as ''add-on'' services require a reduction in resources relative to the corresponding initial service.

Another commenter noted that in the CY 2017 proposed rule, CMS incorrectly stated it was utilizing a RUC recommendation specific to these codes. According to the CY 2015 Final Rule (79 FR 67548), the codes on which CMS based its discount were CPT codes 88334, 88335, 88177, and 88172. The commenter states the distinction between the codes cited in the CY 2015 final rule, CPT codes 88334, 88335, 88177, 88172, and the new add-on codes, CPT codes 88364, 88369 and 88373, is that the discount factor is specific to services for which a diagnosis has already been furnished. For the new codes to which CMS applied this discount, no such corresponding interpretative diagnosis has been made.

The same commenter stated for morphometric codes, the pathologist is reviewing a second, unique and distinct probe with an entirely different signal than that of its base code, and the work involved with these add-on services requires the same level of intensity and time as their base codes.

The commenter also stated that pathology consultation and cytopathology evaluation codes were clinically different and are not valid proxies to identify efficiencies for the new add-on codes.

Response: We do not agree that there are rank order anomalies within this code family, and we note that this code family was valued within itself and not in relation to other services within the PFS. In response to the commenter's statement that there should be no comparison of intravascular ultrasound services to any pathology service as discussed above, we continue to believe it is valid to compare services across the PFS when determining appropriate values.

We also continue to believe that it is reasonable to recognize efficiencies between them a base and an add-on code. In reviewing the RUC-recommended base/add-on relationships between several pathology codes, we continue to believe the base/add-on code time relationships for pathology services are appropriate and have not been presented with any persuasive evidence or rationale that conflicts with the RUC-recommended relationships.

We agree with the commenter that the designation ''add-on'' does not automatically imply a reduction; however, in the case of these similar pathology services, we continue to believe using the same valuation metrics is valid. Therefore, for CY 2017, we are finalizing a work RVU of 0.70, 0.73, 0.88, 0.70 and 0.58 for CPT codes 88364, 88367, 88368, 88369 and 88373, respectively.

(50) Liver Elastography (CPT Code 91200)

For CY 2016, we received a RUC recommendation of 0.27 work RVUs for CPT code 91200. After careful review of the recommendation, we established the RUC-recommended work RVU and direct PE inputs as interim final for CY 2016.

Comment on the CY 2016 PFS final rule with comment period: A few commenters requested that we reconsider the level of payment assigned to this service when furnished in a nonfacility setting, stating that the

code met the definition for the potentially misvalued code list as there is a significant difference in payment between sites of service. The commenters also asked us to reconsider the assigned 50 percent utilization rate for the FibroScan equipment in this procedure as the current utilization rate would translate to over 50 procedures per week. Instead, the commenters suggested the typical number of procedures done per week ranges between 15 and 25 and requested we adopt a 25 percent utilization rate which corresponds to that number of procedures.

Response in the CY 2017 PFS proposed rule: We refer commenters to the CY 2016 final rule with comment period (80 FR 71057–71058) where we discussed and addressed the comparison of the PFS payment amount to the OPPS payment amount for CPT 91200. For the commenter's statement about the utilization rate, we have previously addressed the accuracy of these default assumptions as they apply to particular equipment resources and particular services. In the CY 2008 PFS proposed rule (72 FR 38132), we discussed the 50 percent utilization assumption and acknowledged that the default 50 percent usage assumption is unlikely to capture the actual usage rates for all equipment. However, we stated that we did not believe that we had strong empirical evidence to support any alternative approaches. We indicated that we would continue to monitor the appropriateness of the equipment utilization assumption, and evaluate whether changes should be proposed in light of the data available. The commenters did not provide any verifiable data suggesting a lower utilization rate. Therefore, for CY 2017 we proposed a work RVU of 0.27 for CPT code 91200, consistent with the CY 2016 interim final value, and we continued to explore and solicit comments regarding publically available data sources to identify the most accurate equipment utilization rate assumptions possible. We also noted that following the publication of the CY 2016 PFS final rule with comment period (80 FR 70886) there was an inconsistency in the Work Time file published on the CMS Web site. For CPT code 91200 the RUC recommended 16 minutes total service time whereas our file reflected 18 minutes total time for the service. For CY 2017, we proposed to update the Work Time file to reflect the RUC's recommendation, which is 16 minutes for CPT code 91200.

The following is a summary of the comments we received regarding our proposed valuation of CPT code 91200.

Comment: Many commenters disagreed with the proposed valuation of CPT code 91200, suggesting that the $34 payment rate in the nonfacility setting for CY 2016 underestimated the resource cost of the procedure. Commenters stated that this code is a first-line method used to assess fibrosis scores in patients with chronic liver disease, especially those with chronic Hepatitis C, and that the current reimbursement was not sufficient to cover the cost of providing the service. Some commenters compared the use of the Fibroscan device in CPT code 91200 to more expensive and more invasive liver biopsies, or compared the cost of the procedure to the treatment provided in hospital-based payment systems. Commenters urged CMS to increase the valuation of CPT code 91200 to encourage providers to adopt the use of the Fibroscan device.

Response: We remind commenters that we are obligated by statute to set payment rates based on the resources used to furnish the procedure, and that as a result pricing for codes on the PFS does not necessarily mirror pricing for codes under different payment systems. We also note that we proposed the RUC-recommended work RVU and direct PE inputs for CPT code 91200 without alteration.

Comment: Many of the commenters also addressed the pricing of the Fibroscan equipment (ER101). Commenters provided CMS a range of different prices for this equipment item, individually suggesting that the equipment costs $120k, $130k, $140k, and $150k. One commenter supplied an individual invoice for the Fibroscan, including the device itself along with a CAP option, an S probe, a printer, and shipping/maintenance costs.

Response: We appreciate the submission of additional information regarding the proper pricing of the Fibroscan. We encourage more commenters to include invoices with their comment submissions if they believe that existing supplies or equipment items are undervalued, as we have had longstanding reservations about establishing pricing based on single invoices. In the specific case of the Fibroscan equipment, we agree that the price should be increased based on the submitted invoice. We are pricing ER101 at $183,390 based on a combination of the cost of the Fibroscan itself ($131,950), the CAP option ($22,955), the S probe ($27,950), and the printer ($495). We note that we do not typically pay for shipping costs or maintenance costs, as equipment maintenance costs are built into the equipment cost per minute formula. We are also changing the name of ER101 from ''Fibroscan'' to ''Fibroscan with printer'' to reflect the fact that this pricing incorporates a printer.

After consideration of comments received, we are finalizing our proposed work RVUs and direct PE inputs, with the price increase to the Fibroscan with printer equipment.

(51) Closure of Paravalvular Leak (CPT Codes 93590, 93591, and 93592)

The CPT Editorial Panel developed three new codes (two base codes and one add-on code) to describe paravalvular leak closure procedures that were previously reported using an unlisted code. The RUC recommended a work RVU of 17.97 for CPT code 93591. We proposed a work RVU of 14.50 for CPT code 93591, a direct crosswalk from CPT code 37227. We stated in the CY 2017 proposed rule that we believe that a direct crosswalk to CPT code 37227 accurately reflected the time and intensity described in CPT code 93591 since CPT code 37227 also described a transcatheter procedure with similar service times.

To maintain relativity among the codes in this family, we proposed refinements to the recommended work RVUs for CPT code 93590. The RUC noted that the additional work associated with CPT code 93590 compared to CPT code 93591 was due to the addition of a transseptal puncture to access the mitral valve. The RUC identified a work RVU of 3.73 for a transseptal puncture. Therefore, for CPT code 93590, we proposed a work RVU of 18.23 by using our proposed work RVU of 14.50 for CPT code 93591 and adding the value of a transseptal puncture (3.73).

CPT code 93592 is an add-on code used to report placement of additional occlusion devices for percutaneous transcatheter paravalvular leak closure, performed in conjunction with either an initial mitral or aortic paravalvular leak closure. The RUC recommended a work RVU of 8.00 for this code. In the proposed rule, we stated that we considered applying the relative increment between CPT codes 93590 and 93591; however, we believed that a direct crosswalk to CPT code 35572, with a work RVU of 6.81, more accurately reflected the time and intensity of furnishing the service. Therefore, for CPT code 93592, we proposed a work RVU of 6.81.

Comment: For CPT code 93591, commenters opposed CMS' assertion that a cardiovascular intervention

performed in an immobile leg is comparable in intensity and patient risk to an intervention performed in a beating, moving heart. Commenters suggested that CMS' proposed crosswalk to CPT code 37227 was not appropriate since CPT code 37227 is generally performed in an outpatient setting, while CPT code 93591 is generally performed in a facility setting due to the intensity and risk associated with the procedure. Subsequently, commenters suggested that CMS finalize the RUC-recommended work RVU of 17.97 for CPT code 93591.

For CPT code 93590, commenters, including the RUC, supported CMS' proposed use of the same building block methodology used in the RUC recommendations, by proposing to apply a work RVU of 3.73 to the base code value of 93591. However, commenters suggested that CMS apply the value of a transeptal puncture to the RUC-recommended value for CPT code 93591, and therefore, finalize the RUC-recommended work RVU of 21.70 for CPT code 93590.

For CPT code 93592, commenters, including the RUC, disagreed with CMS' proposed comparison of CPT code 93592 to CPT code 35572 (Harvest of femoropopliteal vein, 1 segment, for vascular reconstruction procedure (*e.g.*, aortic valve services)). Commenters stated that CMS's proposed crosswalk is inappropriate and does not recognize the intensity and skill level needed to place a device to close a paravalvular leak in a moving, beating heart, frequently in patients with heart failure. Commenters stated that CPT code 35572 was only similar to CPT code 93592 in that both procedures are cardiovascular in nature. Commenters also stated that surgical harvest of the lower extremity vein is not clinically similar to the transcatheter percutaneous structural heart therapies.

Response: We thank the commenters for their feedback on our proposal. After consideration of the comments received, we are finalizing the RUC-recommended work RVUs for each of the codes in this family. Therefore, we are finalizing a work RVU of 21.70 for CPT code 93590, a work RVU of 17.97 for CPT code 93591, and a work RVU of 8.00 for CPT code 93592.

(52) Electroencephalogram (EEG) (CPT Codes 95812, 95813, and 95957)

In February 2016, the RUC submitted recommendations for work and direct PE inputs for CPT codes 95812, 95813, and 95957. We proposed to use the RUC-recommended physician work and direct PE inputs for CPT code 95957 and to use the RUC-recommended work RVUs for CPT codes 95812 and 95813.

In the CY 2016 PFS final rule with comment period (80 FR 70886), we finalized direct PE input refinements for several clinical labor times for CPT codes 95812 and 95813. The RUC's February 2016 direct PE summary of recommendations indicated that the specialty society expert panel disagreed with CMS' refinements to clinical labor time for these two codes. The RUC recommended 62 minutes for clinical labor task ''perform procedure'' for CPT code 95812 and 96 minutes for the same clinical labor task for CPT code 95813, similar to the values recommended by the RUC in April 2014.

We proposed to maintain the CMS-refined CY 2016 PE inputs for clinical labor task ''perform procedure'' for CPT codes 95812 (50 minutes) and 95813 (80 minutes), since the RUC's PE summary of recommendations stated that CPT code 95812 required 50 minutes of clinical labor time for EEG recording, and CPT code 95813 required 80 minutes of clinical labor time for the same clinical labor task.

We did not receive any comments on our proposals for this family of codes. Therefore, for CY 2017, we are finalizing our proposed direct PE inputs for these codes without modifications. We are also finalizing for CY 2017 work RVUs of 1.08 for CPT code 95812, 1.63 for CPT code 95813, 1.98 for CPT code 95957.

(53) Analysis of Neurostimulator Pulse Generator System (CPT Codes 95971, 95972)

CPT codes 95971 and 95972 were established as interim final following the CY 2016 final rule with comment period. For CY 2017, we proposed to maintain their work RVUs and direct PE inputs.

Comment: A commenter expressed support for the proposal to maintain the current work and PE RVUs, stating that these codes were revalued in 2015 and there was no reason to make any changes.

Response: We appreciate the support from the commenter.

After consideration of comments received, we are finalizing our proposed work RVUs and proposed direct PE inputs for CPT codes 95971 and 95972.

(54) Patient, Caregiver-focused Health Risk Assessment (CPT Codes 96160 and 96161)

In October 2015, the CPT Editorial Panel created two new PE-only CPT codes, 96160 (Administration of patient-focused health risk assessment instrument (*e.g.,* health hazard appraisal) with scoring and documentation, per standardized instrument) and 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). For CPT code 96160, we proposed the RUC-recommended direct PE inputs. For CPT code 96161, the service is furnished to a patient who may not be a Medicare beneficiary, and therefore, we did not believe the code would be eligible for Medicare payment. We proposed to assign a procedure status of I (Not valid for Medicare purposes) for CPT code 96161.

We noted that we believed that CPT code 96160 describes a service that is frequently reasonable and necessary in the treatment of illness or injury, such as when there has been a change in health status. However, when the service described by CPT code 96160 is explicitly included in another service being furnished, such as the Annual Wellness Visit (AWV), this code should not be billed separately, much like other codes that describe services included in codes with broader descriptions. We also noted that this service should not be billed separately if furnished as a preventive service as it would describe a non-covered service. However, we also solicited comment on whether this service may be better categorized as an add-on code and welcomed stakeholder input regarding whether or not there are circumstances when this service might be furnished as a stand-alone service.

Comment: Many commenters recommended that CMS should recognize and make separate payment for CPT code 96160, as proposed, as well as 96161 using the RUC-recommended values. Several of these commenters argued that the medical community has recognized that health risk assessment of caregivers is an integral part of ongoing medical care for patients with particular needs. These commenters offered several examples where such an assessment is integral to treating patients, such as:

- Assessment of maternal depression in the active care of infants,
- Assessment of parental mental health as part of evaluating a child's functioning,
- Assessment of caretaker conditions as indicated where atypical parent/child interactions are observed during care,
- Assessment of caregivers as part of care management for adults whose physical or cognitive status renders them incapable of independent living and dependent on another adult caregiver. Some examples might be intellectually disabled adults, seriously

disabled military veterans and adults with significant musculoskeletal or central nervous system impairments.

Because commenters noted that these assessments were generally administered during E/M services, they were receptive to making both CPT codes 96160 and 96161 add-on codes to E/M services.

Response: After considering comments, we believe that CPT codes 96160 and 96161 describe services that, in particular cases, can be necessary components of services furnished to Medicare beneficiaries. While we recognize that in many cases we have previously assigned non-payment indicators to codes that describe interactions with caregivers, we also note that we have also recognized that in current medical practice, practitioner interaction with caregivers is an integral part of treatment for some patients. Accordingly, the descriptions for several payable codes under the PFS include direct interactions between practitioners and caregivers.

In developing our proposal regarding the payment disposition of this code, we noted that it singularly described a service administered to a caregiver. However, based on public comments, including the receptivity to our assignment of add-on code status, we understand that in actual practice, this service is integrated with E/M visits under particular circumstances. Consequently, we believe the appropriate payment status for the code should be determined by looking at the overall service as described by the two codes together. We agree with commenters, then, that there are circumstances where this service is an essential part of a service to a Medicare beneficiary. Therefore, we are assigning an active payment status to both codes for CY 2017. We are also establishing use of the RUC recommended values for these codes. We are also assigning 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.

(55) Reflectance Confocal Microscopy (CPT Codes 96931, 96932, 96933, 96934, 96935, and 96936)

For CY 2015, the CPT Editorial Panel established six new Category I codes to describe reflectance confocal microscopy (RCM) for imaging of skin. For CPT codes 96931 and 96933, the specialty society and the RUC agreed that the physician work required for both codes were identical, and therefore, should be valued the same. The RUC recommended a work RVU of 0.80 for CPT codes 96931 and 96933 based on the 25th percentile of the survey. Based on the similarity of the services being performed in CPT codes 96931 and 96933 and the identical intra-service times of 96931, 96933 and 88305, the key reference code from the survey, we believe a direct crosswalk from CPT code 88305 to CPT codes 96931 and 96933 would more accurately reflect the work involved in furnishing the procedure. Therefore, for CY 2017, we proposed a work RVU of 0.75 for CPT codes 96931 and 96933. In addition, we proposed removing 3 minutes of preservice time from CPT codes 96931 and 96933 since it is not included in CPT code 88305 and as a result, we did not believe it was appropriate in CPT codes 96931 and 96933.

For CPT codes 96934 and 96936, the specialty society and the RUC agreed that the physician work required for both codes were identical, and therefore, should be valued the same. In its recommendation, the RUC stated that it believed the survey respondents somewhat overestimated the work for CPT code 96934 with the 25th percentile yielding a work RVU of 0.79. Consequently, the RUC reviewed the survey results from CPT code 96936 and agreed that the 25th percentile work RVU of 0.76 accurately accounted for the work involved for the service. Therefore, the RUC recommended a work RVU of 0.76 for CPT codes 96934 and 96936.

We believe that the incremental difference between the RUC-recommended values for the base and add-on codes accurately captures the difference in work between the code pairs. However, because we valued the base codes differently than the RUC, we proposed values for the add-on codes that maintain the RUC's 0.04 increment instead of the RUC-recommended values. Therefore we proposed a work RVU of 0.71 for CPT codes 96934 and 96936.

We also proposed to reduce the preservice clinical labor for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by physician'' for CPT codes 96934 and 93936 as this work is performed in the two base CPT codes 93931 and 93933. We proposed to reduce the service period clinical labor for ''Prepare and position patient/monitor patient/set up IV'' from 2 to 1 minute for CPT codes 93934 and 93936 since we believed that less positioning time is needed with subsequent lesions. We proposed to refine the service period clinical labor for ''Other Clinical Activity—Review imaging with interpreting physician'' to zero minutes for CPT codes 96933 and 96936 as these are interpretation and report only codes and not image acquisition.

Comment: Several commenters, including the RUC, objected to the proposed valuations for CPT codes 96931, 96933, 96934, and 96936. The RUC disagreed with pre-service time being removed from a survey code simply due to a key reference code not also having pre-service time. The RUC stated CPT codes 96931 and 96933 are distinct procedures from CPT codes 88305 and the CMS proposal to remove 3 minutes of pre-time from the base RCM codes was grounded on faulty logic. The RUC stated its agreement with the specialty society that 3 minutes of preservice time was necessary for the physician to review clinical history and referral information. The RUC further stated with the 3 minutes of pre-service time in its recommendation for the RCM base codes were appropriately in line with top key reference CPT code 88305 and urged CMS to accept the survey 25th percentile work RVUs for CPT codes 96931, 96933, 96934, and 96936. Other commenters stated there were very significant differences in the technologies used and the work involved between the procedures of CPT code 88305, the key reference code, and CPT codes 96931 and 96933, with CPT codes 96931 and 96933 being more complex procedures.

One commenter stated CMS incorrectly removed technician time for ''Other Clinical Activity—Review imaging with interpreting physician'' for CPT codes 96933 and 96936 noting the technician still must review the imaging with the interpreting physician and urged CMS to accept the RUC recommendations.

Response: After consideration of comments received, we agree with the commenters and will finalize the RUC-recommended work RVUs of 0.80, 0.80, 0.76, and 0.76 for CPT codes 96931, 96933, 96934 and 96936; respectively. We will also restore the 3 minutes of preservice time to CPT codes 96931 and 96933.

(56) Evaluative Procedures for Physical Therapy and Occupational Therapy (CPT Codes 97161, 97162, 97163, 97164, 97165, 97166, 97167, 97168)

For CY 2017, the CPT Editorial Panel deleted four CPT codes (97001, 97002, 97003, and 97004) and created eight new CPT codes (97161–97168) to describe the evaluative procedures furnished by physical therapists and

occupational therapists. There are three new codes, stratified by complexity, to replace a single CPT code 97001, for physical therapy (PT) evaluation, and three new codes, also stratified by complexity, to replace a single code CPT code 97003, for occupational therapy (OT) evaluation, and one new code each to replace the re-evaluation codes for physical and occupational therapy, CPT codes 97002 and 97004. Table 23 includes the long descriptors and the required components of each of the eight new CPT codes for the PT and OT services.

The CPT Editorial Panel's creation of the new codes for PT and OT evaluative procedures grew out of a CPT workgroup that was originally convened in January 2012 when contemplating major revision of the Physical Medicine and Rehabilitation CPT section of codes in response to our nomination of therapy codes as potentially misvalued codes, including CPT code 97001 (and, as a result, all four codes in the family) in the CY 2012 PFS proposed rule.

In reviewing the eight new CPT codes for evaluative procedures, the HCPAC forwarded recommendations for work RVUs and direct PE inputs for each code. Currently, CPT codes 97001 and 97003 both have a work RVU of 1.20, and CPT codes 97002 and 97004 both have a work RVU of 0.60. These CPT codes have reflected the same work RVUs since CY 1998 when we accepted the HCPAC values during CY 1998 rulemaking.

i. Valuation of Evaluation Codes

In the CY 2017 PFS proposed rule, we noted that the HCPAC submitted work RVU recommendations for each of the six new PT and OT evaluation codes. These recommendations are intended to be work neutral relative to the valuation for the previous single evaluation code for PT and OT, respectively. However, that assessment for each family of codes is dependent on the accuracy of the utilization forecast for the different complexity levels within the PT or OT family. As used in this section, work neutrality is distinct from the budget neutrality that is applied broadly in the PFS. Specifically, work neutrality is intended to reflect that despite changes in coding, the overall amount of work RVUs for a set of services is held constant from one year to the next. For example, if a service is reported using a single code with a work RVU of 2.0 for one year but that same service would be reported using two codes, one for ''simple'' and another for ''complex'' in the subsequent year valued at 1.0 and 3.0 respectively, work neutrality could only be attained if exactly half the services were reported using each of the two new codes. If more than half of the services were reported using the ''simple'' code, then there would be fewer overall work RVUs. If more than half of the services were reported using the ''complex'' code, then there would be more overall work RVUs. Therefore, work neutrality can only be assessed with an understanding of the relative frequency of how often particular codes will be reported.

The HCPAC recommended a work RVU of 0.75 for CPT code 97161, a work RVU of 1.18 for CPT code 97162, and a work RVU of 1.5 for CPT code 97163. The PT specialty society projected that the moderate complexity evaluation code would be reported 50 percent of the time because it is the typical evaluation, and the CPT codes for the low and high complexity evaluations are each expected to be billed 25 percent of the time. The HCPAC-recommended work RVU of 1.18 for CPT code 97162 represents the survey median with 30 minutes of intraservice time, 10 minutes of preservice time, and 15 minutes postservice time. The HCPAC notes this work value is appropriately ranked between levels 2 and 3 of the E/M office visit codes for new patients.

The HCPAC recommended a work RVU of 0.88 for CPT code 97165, a work RVU of 1.20 for CPT code 97166, and a work RVU of 1.70 for CPT code 97167. For the OT codes, work neutrality would be achieved only with a projected utilization in which the low complexity evaluation is billed 50 percent of the time; the moderate complexity evaluation is billed 40 percent of the time, and the high complexity evaluation only billed 10 percent of the time. For purposes of calculating work neutrality, the HCPAC recommended assuming that the low complexity code will be most frequently reported even though the HCPAC-recommended work RVU of 1.20 and 45 minutes of intraservice time for moderate complexity code is identical to that of the current OT evaluation code. The HCPAC believes that the work RVU of 1.20 is appropriately ranked between 99202 and 99203, levels 2 and 3 for E/M office visits for new outpatients.

ii. Valuation of Evaluation Codes and Discussion of PAMA

In our review of the HCPAC recommendations, we noted the work neutrality and the inherent reliance on the utilization assumptions. We considered the three complexity levels for the PT evaluations and the three complexity levels for the OT evaluations; and we also considered the evaluation services described by the codes as a whole. The varying work RVUs and the dependence on utilization for each complexity level to ensure work neutrality in the PT and OT code families make it difficult for us evaluate the HCPAC's recommended values or to predict with a high degree of certainty whether physical and occupational therapists will actually bill for these services at the same rate forecast by their respective specialty societies.

We were concerned that the coding stratification in the PT and OT evaluation codes may result in upcoding incentives, especially while physical and occupational therapists gain familiarity and expertise in the differential coding of the new PT and OT evaluation codes that now include the typical face-to-face times and new required components that are not enumerated in the current codes. We were also concerned that stratified payment rates may provide, in some cases, a payment incentive to therapists to upcode to a higher complexity level than was actually furnished to receive a higher payment.

We understood that there may be multiple reasons for the CPT Editorial Panel to stratify coding for OT and PT evaluation codes based on complexity. We also noted that the codes will be used by payers in addition to Medicare, and other payers may have direct interest in making such differential payment based on complexity of OT and PT evaluation. Given our concerns regarding appropriate valuation, work neutrality, and potential upcoding, however, we did not believe that making different payment based on the reported complexity for these services is, at current, advantageous for Medicare or Medicare beneficiaries.

Given the advantages inherent and public interest in using CPT codes once they become part of the code set, we proposed to adopt the new CPT codes for use in Medicare for CY 2017. However, given our concerns about appropriate pricing and payment for the stratified services, we proposed to price the services described by these stratified codes as a group instead of individually. To do that, we proposed to utilize the authority in section 220(f) of the Protecting Access to Medicare Act (PAMA), which revised section 1848(c)(2)(C) of the Act to authorize the Secretary to determine RVUs for groups of services, rather than determining RVUs at the individual service level. We believed that using this authority instead of proposing to make payment based on Medicare G-codes will preserve consistency in the code set

across payers, thus lessening burden on providers, while retaining flexibilities that are beneficial to Medicare.

We proposed a work RVU of 1.20 for both the PT and the OT evaluation groups of services. We proposed this work RVU because we believed it best represents the typical PT and OT evaluation. This is the value recommended by the HCPAC for the OT moderate complexity evaluation and nearly the same work RVU for corresponding PT evaluation (1.18). Additionally, a work RVU of 1.20 is the long-standing value for the current evaluation codes, CPT codes 97001 and 97003, and thus, assures work neutrality without reliance on particular assumptions about utilization, which we believed was the intent of the HCPAC recommendation.

Because we proposed to use the same work RVU for the six evaluation codes, we are not addressing any additional concerns about the utilization assumptions recommended to us. Because we proposed the same work values for each code in the family, there will be no ratesetting impact to work neutrality. As such, we are not revising the utilization crosswalks as projected by the respective therapy specialties to achieve work neutrality. However, were we to value each code in the PT or OT evaluation families individually, we would seek objective data from stakeholders to support the utilization crosswalks, particularly those for the OT family in which the low-level complexity evaluation is depicted as typical and the high complexity is projected to be billed infrequently at 10 percent of the overall number of OT evaluations.

We proposed to use the direct PE inputs forwarded by the HCPAC (with the refinements described below) for the moderate complexity PT and OT evaluations in the development of PE RVUs for the PT and OT codes as a group of services. For the PT codes, we proposed to use the recommended inputs for the moderate complexity code for the direct PE inputs of all three codes based on its assumption as the typical service. Our proposed direct PE inputs reflect the recommended values minus 2 minutes of physical therapist assistant (PTA) time in the service period because we believe that PTA tasks to administer certain assessment tools are appropriately included as part of the physical therapist's work and the time of the PTA to explain and score self-reported outcome measures is not separately included in the clinical labor of other codes. We proposed to include the recommended four sheets of laser paper without an association to a specific equipment item, but we solicited comment regarding the paper's use.

For the OT evaluation codes, we considered proposing to use the direct PE inputs for the low complexity evaluation because the OT specialty organization believes it represents the typical OT evaluation service with a projected 50 percent utilization rate. However, we proposed to use the moderate-level direct inputs instead, because the direct PE for this level is based on a vignette that is valued with the same intraservice time, 45 minutes, as the current code, CPT code 97003. Consequently, we proposed to use the recommended direct PE inputs for the moderate complexity code for use in developing PE RVUs for this group of services.

Our proposed direct PE inputs reflect the recommended values minus 2 minutes of occupational therapist assistant (OTA) time in the service period because we believe that OTA tasks to administer certain assessment tools are appropriately included as part of the occupational therapist's work and the time of the OTA to explain and score self-reported outcome measures is not separately included in the clinical labor of other codes. We also rounded up the recommended 6.8 minutes to 7 minutes to represent the time the OTA assists the occupational therapist during the intraservice time period. For the Vision Kit equipment item, our proposed price reflects the submitted invoice that clearly defined a kit.

iii. Valuation of Re-evaluation Codes

The recommendations the HCPAC sent to us for the PT and OT re-evaluation codes are not work neutral. For the new PT re-evaluation code, CPT code 97164, the HCPAC recommended a work RVU of 0.75 compared to the work RVU of 0.60 for CPT code 97002. This recommended work RVU falls between the 25th percentile of the survey and the survey's median value and was based on a direct crosswalk to CPT code 95992 for canalith repositioning with 20 minutes intraservice time and 10 minutes immediate postservice time. The HCPAC supported this 0.15 work RVU increase based on an anomalous relationship between PT services and E/M office visit codes for established patients, noting that physician E/M codes have historically been used as a relative comparison. The HCPAC stated its recommendation of a work RVU of 0.75 for CPT code 97164 appropriately ranks it between the key reference codes for this service, CPT codes 99212 and 99213, levels 2 and 3 E/M office-visit codes for established patients.

The HCPAC provided a work RVU of 0.80 for the OT re-evaluation code, CPT code 97168, based on the 25th percentile of the survey, which represents an increase over the current work RVU of 0.60 for CPT code 97004. This work value includes 30 minutes of intraservice time, 5 minutes preservice time, and 10 minutes immediate postservice time. The HCPAC noted that the increase in work compared to the PT re-evaluation code (0.75) is because the occupational therapist spends more time observing and assessing the patient and, in general, the OT patient typically has more functional and cognitive disabilities. The HCPAC recommendation notes that the 0.80 work RVU recommendation appropriately ranks it between the level 1 and 2 E/M office-visit codes for new patients.

The HCPAC's recommended increases to work RVUs for the PT and OT re-evaluation codes are not work neutral. We are unclear why the HCPAC did not maintain work neutrality for the OT and PT re-evaluation codes since maintaining work neutrality was important to the establishment of the six new evaluation codes. We proposed to maintain the overall work RVUs for these services by proposing a work RVU of 0.60 for CPT codes 97164 and 97168, consistent with the work RVUs for the deleted re-evaluation codes. We solicited comments from stakeholders on whether there are reasons that the re-evaluation codes should be revalued without regard to work neutrality.

We proposed the HCPAC-recommended direct PE inputs for CPT code 97164 with a reduction in time for the PTA by 1 minute (from 5 to 4) in the service period—the line for ''Other Clinical Activity''—because the time to explain and score the self-reported outcome measure (for example, Oswestry) is not separately included in the clinical labor of other codes.

We proposed the HCPAC-recommended direct PE inputs for CPT code 97168 with a reduction in time for the OTA by 1 minute (from 3 to 2) in the service period—the line for ''Other Clinical Activity''—for the same reason we proposed to reduce the corresponding line for PTAs—because the time to explain and score any patient-self-administered functional and other standardized outcome measure is not separately included in the clinical labor of other codes.

Because the new CPT code descriptors contain new coding requirements for each complexity level, we solicited comment from the PT and

OT specialty organizations, as well as other stakeholders to clarify how therapists will be educated to distinguish the required complexity level components and the selection of the number of elements that impact the plan of care. For example, for the OT codes, we invited comment on how to define performance deficits, what process the occupational therapist uses to identify the number of these performance deficits that result in activity limitations, and performance factors needed for each complexity level. For the PT codes, we sought more information about how the physical therapist differentiates the number of personal factors that actually affect the plan of care. We were also interested in understanding more about how the physical therapist selects the number of elements from any of the body structures and functions, activity limitations, and participation restrictions to make sure there is no duplication during the physical therapist's examination of body systems.

The following is summary of the comments we received:

Comment: Several commenters disagreed with our proposal to accept the new CPT codes for PT and OT evaluations and re-evaluations and urged us to keep the current four-code set. A few of these commenters noted our proposal to accept the stratified code sets for PT and OT evaluations would increase the administrative burden associated with documentation and education training of therapists, billers and coders. Other commenters believed that CMS should first implement the new complexity-defined CPT code set on a demonstration or pilot project basis before we apply it nationally. One commenter proposed that, rather than accepting the new CPT eight-code set with varying descriptors for each PT and OT complexity level, we adopt just two codes that both the PT and OT disciplines could use: a code for PT/OT evaluation and another for PT/OT re-evaluation. Another commenter told us that ''implementation of the complex scheme for determining the evaluation level will excessively complicate patient evaluations where clinicians will require more mental effort to meet the demands of the documentation with less time and attention directed at treating the patient.'' One commenter suggested that instead of implementing the stratified code sets, CMS should develop an alternative coding and payment model for therapy services and recommended that we create a value-based payment program, consistent with the Triple Aim of health care, which includes reliable and valid outcome and quality measures to demonstrate the outcome and value of therapy.

Response: We thank the commenters for voicing their concerns about our adoption of the new CPT codes for PT and OT evaluative procedures and their alternative coding suggestions. However, we note that we do not have the authority to change CPT code descriptors or use deleted codes without creating G-codes to do so. We also note that adopting a demonstration or pilot program is not a typical CMS payment policy response to the creation of new CPT codes or code sets. After considering these comments, we continue to believe that our proposal to adopt the eight new CPT codes for use in Medicare for CY 2017, rather than retain the current coding structure by creating G-codes, is the best option given the advantages inherent and public interest in using the CPT codes once they become part of the code set. As such, we are finalizing our proposal to adopt new CPT codes 97161–97168 for PT and OT evaluations and re-evaluations.

Comment: Many commenters objected to our proposal to use the PAMA authority to price the services described by the stratified sets of PT and OT evaluation codes as a group instead of individually and asked us to accept or consider the HCPAC work RVU values for each of these six evaluation services. Some commenters expressed concern that we ignored the HCPAC recommendations and proposed to maintain the work RVU of 1.20, since the codes have not been reviewed for this purposes in nearly 20 years. Other commenters stated that CMS, by valuing the PT and OT evaluation complexity levels with the same work RVUs, was failing to appropriately align cost and quality as mandated in the ACA and MACRA.

Because we proposed the same values, a few commenters were concerned that we failed to discuss the difference in the PT and OT evaluation services. These commenters told us that the HCPAC recommendations included higher work RVUs for the OT services because they reflected greater intraservice times from the surveys, and these times led, in part, to the HCPAC's belief that the typical patient receiving OT services is more complex and intense to treat than the patient receiving PT services. The HCPAC and the OT specialty society urged us to consider the increase in work RVUs for the OT evaluative services, indicating in their comments that while the HCPAC recommendations for the PT evaluations were work-neutral, those for the OT evaluations were not. The HCPAC requested that we consider the difference in PT services versus OT services.

Some commenters presumed that our proposal to value the work the same for each evaluation complexity level was temporary. Another commenter expressed hope that we did not intend to equally value the PT high complexity evaluation the same as the low complexity one in perpetuity. Several commenters requested that CMS describe our future plans to revisit these code sets and asked that the future proposal for these payment amounts be subject to public comment. One of these commenters that favored keeping the current code structure urged us not to adopt the new CPT codes until we are ready to differentiate payments based on the complexity of the provided service.

Some commenters told us that our lack of payment stratification for the three PT and three OT evaluation codes would likely prompt coding and billing behavioral change by some therapists and other providers of therapy services. One of these commenters claimed that assigning the same work RVU to each evaluation complexity level would cause some providers not to adhere to the new coding stratification which could result in inaccurate data on the levels being reported. Another commenter stated that the lack of payment stratification to reflect the therapist's time and expertise at each complexity level could signal to therapists that the accurate coding of evaluations is of diminished interest to CMS. Other commenters stated that the failure to recognize payment stratification between the complexity levels would be detrimental to patient care and the practice of therapy, for example, by reducing incentives for therapists to thoroughly evaluate patients with multiple and complex conditions who fall into the high complexity evaluation.

Response: After a review of the comments, we continue to believe that using the PAMA RVU authority to value the PT and OT evaluation codes as a group of services is appropriate. Given our concerns about appropriate pricing and payment for the PT and OT stratified evaluation services as described in the CY 2017 proposed rule, we are finalizing our proposal to use the PAMA authority to value services as groups rather than individually—valuing each complexity level at 1.2 work RVUs for the PT and OT family of evaluation codes for CY 2017. We believe this policy has advantages for the Medicare program. It limits the incentives for and consequences of

upcoding by therapists and providers, especially as therapists become more familiar with the new set of codes. Additionally, the policy assures work neutrality for these PT and OT code families while allowing us to collect and analyze utilization data of the complexity levels for possible future rulemaking.

We understand commenters' concerns about the possibility that the absence of payment stratification in the complexity levels of the PT and OT evaluations could have an effect on some therapists' coding behavior in for these services in CY 2017. However, we are also concerned with the implication that financial incentives are the primary drivers for accurate coding for a significant number of therapists, and if that is the case, we believe that implementing stratified coding would likely encourage upcoding since that is consistent with the financial incentives. We believe that the implementation of these new PT and OT code sets carries with it an inherent change for the therapists furnishing the services since there will be three complexity levels to replace just one and each new code contains newly defined necessary components. We also believe that it is premature to predict how therapists will code and bill the new complexity levels before therapists gain familiarity with the new codes.

Comment: We received several comments on utilization assumptions inherent to the HCPAC recommendations. Several commenters questioned why we did not treat the HCPAC-recommended utilization assumptions for the PT and OT complexity-stratified evaluation code sets as we have historically treated other codes sets that come to us from the HCPAC or RUC; that is, using the utilization assumptions provided in the recommendations. The HCPAC explained that if the assumptions are overestimated, the HCPAC or RUC will examine and determine whether to recommend reductions.

We received several comments from stakeholders in response to our statement in the proposed rule that we would request additional objective data to support the utilization crosswalks, especially for the OT codes, if we were to value the codes individually for the PT and OT evaluation complexity levels. In its comments, the OT specialty society explained that their frequency estimations of the three complexity levels were based on the most recent utilization frequency data from the 2014 Medicare utilization from the five percent sample file. The OT specialty society also stated that it defined the complexity levels using certain groups of diagnoses and patient types. The PT specialty society stated that because its survey process included a broad cross-section of therapists working in the various Medicare settings, it believed its utilization projections for the low, moderate and high complexity evaluation were representative. Many commenters told us because some therapists may not initially code the complexity levels correctly, that we would need to consider an entire year of utilization data to ensure its accuracy.

Response: We appreciate the views expressed and the information that the commenters forwarded to us. However, we continue to have concerns that therapists, particularly occupational therapists, will not bill with the same utilization frequencies forecast by their specialty societies for the low, moderate, and high complexity evaluations as described in the CY 2017 proposed rule. In other words, we are concerned with the possibility that we would establish rates (including for purposes of PFS budget neutrality) that rely on the national organizations' assessment of what ought to be billed, but Medicare spending and subsequent PFS budget neutrality assumptions will reflect actual billing given the financial incentives inherent in stratified payment. Should we propose to value the evaluation codes individually in future rulemaking, we would seek additional objective data at that time. We agree that an entire year of data is likely needed to appropriately analyze the utilization of these evaluation services. We appreciate that our historical practice regarding significant revision of CPT coding scheme has required us to make significant assumptions regarding utilization for new codes. We note that in many cases, we have not accepted the assumptions recommended by specialty societies and the RUC and that we were not pricing groups of services together in the past.

Comment: Several commenters expressed concern about the new PT and OT CPT code descriptors, specifically, that each descriptor includes minimal coding requirements. Several commenters expressed skepticism that therapists will be able to report the new codes accurately—one of these commenters believes the new codes rely on subjective clinical reasoning and decision making that will lead to further significant coding and audit concerns for CMS. Several commenters told us that they believe the true complexity of evaluating patients cannot be solely based on personal factors, comorbidities, performance deficits, or time requirements. One of these commenters noted that some patients with multiple comorbidities and body structures involved are not complicated, while others with few comorbidities and body structures involved are deceptively very complex, difficult to diagnose and treat. Another commenter specifically recommended that each PT and OT evaluation complexity level should have the same timeframes, as well as the same component requirements. A few commenters voiced concern about how CMS and our contractors will note these multiple required components of each CPT code. One commenter noted that an evaluation may have characteristics that fall between two complexity levels and told us that it should be up to the clinician to determine which level is most appropriate. A few commenters noted that the new detailed requirements that dictate the level of each code's definition may cause confusion for physical and occupational therapists, especially as they begin to navigate the new codes.

Response: We appreciate the commenters' concerns about new code descriptors that detail the minimal required components for each of the eight new PT and OT evaluative procedures. We realize that it may take time to train therapists about the various required components of each new PT and OT evaluative procedure code and we have addressed this training in the comment and response below. We also appreciate the commenters' concern that the evaluative process is likely more complex than the component parts comprising each code's new coding requirements; however, as noted in the CY 2017 proposed rule, we proposed to adopt the new CPT codes for PT and OT evaluative procedures rather than propose a different coding structure using G-codes. We would like to clarify for the commenters that were concerned about ''time requirements'' in the new PT and OT CPT code descriptors for evaluative procedures that these ''typical times'' are included as a frame of reference and do not represent a minimum coding requirement. Just as the typical times included for each E/M code represent the physician face-to-face time with the patient, the typical times in the new PT and OT CPT codes represent the typical face-to-face time of the physical or occupational therapist with the patient. Regarding the commenter's concern about evaluations that fall between two complexity levels, we would note general coding principles applicable to all codes—that the therapist should select the evaluation complexity level that best

represents the furnished service and for which the medical necessity is clearly documented.

Comment: Many commenters requested that we delay documentation requirements for the new PT and OT evaluative procedure codes; several commenters requested a one year reprieve from application of medical review and audit requirements; and a few commenters requested that we delay the implementation of the new CPT codes until CY 2018. Most of these delay requests, commenters told us, were related to the time needed to educate therapists about the new codes. Most of these commenters who asked us not to implement new documentation requirements also supported payment stratification of the complexity levels for the PT and OT evaluation complexity levels. Concerned about the proposed lack of payment stratification, the PT specialty society noted in its comments that it asked CPT to postpone the codes for CPT 2017, but CPT denied the request. In its comments, the PT society, along with a few other stakeholders, also asked CMS to delay implementing the new CPT codes for CY 2017 ''if there is any way possible that does not disrupt patient care.''

A few commenters say they will need a delay of six months, at a minimum, to train therapists, since all new descriptors include various required elements and the typical time for each PT and OT complexity level and the re-evaluation codes. The majority of commenters, though, indicated they would need a year for their educational efforts to be successful. In addition to therapists, a few commenters told us they would have to educate coders and billers in the use of the new CPT codes. A few commenters noted the time to implement these new codes into their billing systems was too short.

The PT and OT specialty societies each told us about their plans to educate their therapist members and nonmembers to ensure coding accuracy. Each therapy association has already begun this training, some of which will include webinars, self-paced online courses, frequently asked questions, documentation resources, published articles, etc.

Some commenters asked CMS to work with various stakeholders and to either establish guidelines or assist in educating therapists about the new codes through Open Door Forums, MLN articles, etc. Additionally, they also wanted to work with CMS on LCDs established by contractors. One commenter stated that CMS must provide clear guidance regarding the selection of the appropriate level of evaluation services provided by physical and occupational therapists and the associated documentation requirements to ensure consistency and appropriate reporting of these services.

Several commenters asked us to consider a one-year reprieve from the payment consequences of medical review and audit requirements that address lack of documentation to support the complexity level of the code billed.

Response: We understand that implementing the new code sets for PT and OT evaluative procedures will require time for therapists to be educated in their proper use. We would like to remind those requesting we assist in writing guidelines that the CPT manual PM&R subsections for PT and OT Evaluations contain official CPT guidelines. We understand the many requests for delay of new documentation requirements during the initial year of their use. As such, for CY 2017, we will delay changes to our current manual instructions for documentation for evaluations and re-evaluations in the Medicare Benefits Policy Manual (MBPM), chapter 15, section 220.3.

We understand and appreciate that the PT and OT specialty societies are already underway in their educational efforts of therapists, as it has been our past experience with the implementation of other CPT codes and code sets that the leading educational role is assumed by the specialty societies responsible for the code changes.

Comment: We received many comments objecting to our proposal to maintain a work RVU of 0.60 for the re-evaluation codes. Many commenters—including therapy specialty societies and organization representing therapy providers and private practice physical and occupational therapists, among other stakeholders—disagreed with our proposal to maintain the work RVUs for the PT and OT re-evaluation codes and expressed their disappointment that we did not consider or accept the HCPAC recommendations for increased work RVUs of 0.75 for PT (CPT code 97164) and 0.8 for OT (CPT code 97168).

One commenter supported increasing the work RVUs, but suggested that the PT and OT re-evaluation codes should be equally valued for the relative work, PE and MP RVUs. This same commenter contended that because the patients treated by the PT and OT disciplines for hand rehabilitation are the same; that is, have the same functional and cognitive deficits, the same time and expertise of both physical and occupational therapists is required to perform a thorough re-evaluation. The commenter recommended that both re-evaluations reflect the 30-minute typical time that is inherent to the OT re-evaluation code.

Several commenters reminded us that the work RVU recommendations forwarded to us were not considered work neutral because the HCPAC accepted the PT and OT specialty societies' beliefs as compelling evidence that the practice of PT and OT have each significantly changed over the past two decades.

Some commenters reasoned that we should accept the HCPAC-recommended work RVUs for these codes, in part, because the PT and OT specialty societies completed the RUC–HCPAC defined survey process, including time and intensity of the services.

Comments from the HCPAC, the PT and OT specialty societies, and a few other stakeholders provided the rationale that the practice of PT and OT has significantly changed since 1997, including the work of physical therapists and occupational therapists. Some of their rationale included: (a) advances in technology has created opportunities for additional types of treatment approaches; and, (b) the work RVUs for the PT and OT re-evaluation codes have not kept pace with the relativity of increases in work RVUs of comparable E/M codes that have historically been used as comparison: In 1997 the 0.60 work RVUs for CPT codes 97002 and 97004 was 90 percent of that for CPT code 99213; today, it is just 62 percent. Other rationales included ones often cited by commenters requesting increases in RVUs, including increased patient acuity and administrative and reporting burdens.

Response: We appreciate the commenters' remarks and the rationale forwarded in response to our request for comments. After a careful consideration of the comments, we agree that modification of our proposal, to recognize the change in practice since 1997 for the work of physical and occupational therapists, is appropriate. Because we believe that PT and OT have similar work, though, we are finalizing the value of both codes at the same work RVUs by assigning a work RVU of 0.75—the HCPAC-recommended work RVU for the PT re-evaluation and the PT low complexity evaluation.

We would like to take this opportunity to remind physical and occupational therapists about our manual instructions regarding the reporting of a both the evaluation and re-evaluation codes (MBPM, Chapter 15, section 220). Of note, to be separately payable, the re-evaluation requires a

significant change in the patient's condition or functional status that was not anticipated in the plan of care. The MBPM full definitions follow in Table 22.

TABLE 22—FULL DEFINITIONS FOR MBPM

Therapy service	Definition
EVALUATION	EVALUATION is a separately payable comprehensive service provided by a clinician, as defined above, that requires professional skills to make clinical judgments about conditions for which services are indicated based on objective measurements and subjective evaluations of patient performance and functional abilities. Evaluation is warranted for example, for a new diagnosis or when a condition is treated in a new setting. These evaluative judgments are essential to development of the plan of care, including goals and the selection of interventions.
RE-EVALUATION	RE–EVALUATION provides additional objective information not included in other documentation. Re-evaluation is separately payable and is periodically indicated during an episode of care when the professional assessment of a clinician indicates a significant improvement, or decline, or change in the patient's condition or functional status that was not anticipated in the plan of care. Although some state regulations and state practice acts require re-evaluation at specific times, for Medicare payment, re-evaluations must also meet Medicare coverage guidelines.

Comment: We received a few comments regarding our PE proposals in the CY 2017 proposed rule for the PT and OT evaluation and re-evaluation codes. In its comments, the PT specialty society, in response to our PE proposal, explained, per our request, the use of the 4 sheets of paper as supply items in the PT evaluation and re-evaluation codes. The OT specialty society noted that they accepted the PE refinements we proposed in the proposed rule.

Response: We appreciate the comments from both the PT and OT specialty societies. We will finalize the PE input changes as proposed and include them in the calculation of the final PE RVUs of the PT and OT evaluation and re-evaluation codes.

After considering the comments, in summary, we are finalizing our proposals to (a) accept the new CPT codes 97161–97168 for PT and OT evaluative procedures and (b) use the PAMA smoothing authority to value the PT and OT complexity level evaluations as groups of services rather than individually by assigning a work RVU of 1.2 to each complexity level. We are modifying our proposal for the valuation of the PT and OT re-evaluation codes and are finalizing a work RVU of 0.75 for each code. Lastly, we are finalizing the PE inputs as proposed.

iv. Always Therapy Codes

It is important to note that CMS defines the codes for these evaluative services as ''always therapy.'' This means that they always represent therapy services regardless of who performs them and always require a therapy modifier, GP or GO, to signify that the services are furnished under a PT or OT plan of care, respectively. These codes will also be subject to the therapy MPPR and to statutory therapy caps.

TABLE 23—CPT LONG DESCRIPTORS FOR PHYSICAL MEDICINE AND REHABILITATION

New CPT code	CPT long descriptors for physical medicine and rehabilitation
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. Typically, 20 minutes are spent face-to-face with the patient and/or family.
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. Typically, 30 minutes are spent face-to-face with the patient and/or family.
97163	Physical therapy evaluation: high complexity, requiring these components: • A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; • An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; • A clinical presentation with unstable and unpredictable characteristics; and • Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.

TABLE 23—CPT LONG DESCRIPTORS FOR PHYSICAL MEDICINE AND REHABILITATION—Continued

New CPT code	CPT long descriptors for physical medicine and rehabilitation
97164	Re-evaluation of physical therapy established plan of care, requiring these components: • An examination including a review of history and use of standardized tests and measures is required; and • Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
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 (eg, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.
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 (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.
97167	Occupational therapy evaluation, high complexity, requiring these components: • An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; • An assessment(s) that identify 5 or more performance deficits (i.e., relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and • A clinical decision-making is of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.
97168	Re-evaluation of occupational therapy established plan of care, requiring these components: • An assessment of changes in patient functional or medical status with revised plan of care; • An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and • A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.

v. Potentially Misvalued Therapy Codes

Since 2010, in addition to the codes for evaluative services, CMS has periodically added codes that represent therapy services to the list of potentially misvalued codes. The current list of ten therapy codes was based on the statutory category ''codes that account for the majority of spending under the physician fee schedule,'' as specified in section 1848(c)(2)(K)(ii)(VII) of the Act. We understand that the therapy specialty organizations have pursued the development of coding changes through the CPT process for these modality and procedure services. While we understand that, in some cases, it may take several years to develop appropriate coding revisions, we are, in the meantime, seeking information regarding appropriate valuation for the existing codes. See Table 24.

Comment: We received multiple comments on our nomination of the ten therapy codes to the potentially misvalued code list. The PT and OT specialty societies each expressed concern that we issued the potentially misvalued code list knowing that they are currently working with the AMA

Relativity Assessment Workgroup (RAW) to survey and submit CPT changes to certain intervention codes in the PM&R family, including some codes on the misvalued code list. Nonetheless, the PT specialty society told us that it will work with the RUC (as the appropriate venue) this fall to survey and value the codes; but asked to meet with us in early 2017 to discuss their progress. The OT specialty society stated that it has already begun work with AMA to expedite valuation surveys for relevant codes, but also noted its intent to resume work with the RAW to replace some of the codes on the misvalued code list, including CPT code 97535, as soon as the misvalued code survey process is complete. In addition, the OT specialty society noted its belief that CMS staff attendance at the RAW condoned their timeline for proceeding with various PM&R code revisions.

A few commenters believe the codes on the potentially misvalued code list are already valued correctly as the PE inputs for many therapy codes, including those defined by 15-minute intervals, have already been adjusted by the PEAC/RUC/HCPAC to account for efficiencies when billed with other therapy codes. Several commenters cautioned that any review must also consider that all of these codes are already subject to a 50 percent MPPR reduction. One commenter believes the work of CPT code 97140 is undervalued compared to other codes since it requires the more skilled therapist using manual techniques to touch the patient.

Response: We will include a valuation discussion during CY 2018 rulemaking of those codes for which we receive RUC recommendations by/at its February 2017 meeting.

TABLE 24—POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH HIGH EXPENDITURE BY SPECIALTY SCREEN

HCPCS code	Short descriptor
97032	Electrical stimulation.
97035	Ultrasound therapy.
97110	Therapeutic exercises.
97112	Neuromuscular reeducation.
97113	Aquatic therapy/exercises.
97116	Gait training therapy.
97140	Manual therapy 1/regions.
97530	Therapeutic activities.
97535	Self care mngment training.
G0283	Elec stim other than wound.

(57) Valuation of Services Where Moderate Sedation is an Inherent Part of the Procedure and Valuation of Moderate Sedation Services (CPT Codes 99151, 99152, 99153, 99155, 99156, and 99157; and HCPCS Code G0500)

In the CY 2015 PFS proposed rule (79 FR 40349), we noted that it appeared that practice patterns for endoscopic procedures were changing. Anesthesia services are increasingly being separately reported for endoscopic procedures, meaning that resource costs associated with sedation were no longer incurred by the practitioner reporting the procedure. Subsequently, in the CY 2016 PFS proposed rule (80 FR 41707), we solicited public comment and recommendations on approaches to address the appropriate valuation of moderate sedation related to the approximately 400 diagnostic and therapeutic procedures for which the CPT Editorial Panel has determined that moderate sedation is an inherent part of furnishing the service. The CPT Editorial Panel created separate codes for reporting moderate sedation services (see Table 25).

TABLE 25—MODERATE SEDATION CODES AND DESCRIPTORS

CPT/HCPCS code	Descriptor
99151	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient younger than 5 years of age.
99152	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient age 5 years or older.
99153	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; each additional 15 minutes of intra-service time (List separately in addition to code for primary service).
99155	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intra-service time, patient younger than 5 years of age.
99156	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intra-service time, patient age 5 years or older.
99157	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; each additional 15 minutes intra-service time (List separately in addition to code for primary service).

For the newly created moderate sedation CPT codes, we proposed to use the RUC-recommended work RVUs for CPT codes 99151, 99152, 99155, and 99157. We stated in the CY 2017 proposed rule that CPT codes 99151 and 99152 make a distinction between moderate sedation services furnished to patients younger than 5 years of age and patients 5 years or older, with CPT codes 99155 and 99156 making a similar distinction. The RUC recommendations included a work RVU increment of 0.25 between CPT codes 99151 and 99152. For CPT code 99156, we proposed a work RVU of 1.65 to maintain the 0.25 increment relative to CPT code 99155 (a RUC-recommended work RVU of 1.90) and maintain relativity among the CPT codes in this family. We proposed to use the RUC-recommended direct PE inputs for all six codes.

We stated in the CY 2017 proposed rule that when moderate sedation is reported for Medicare beneficiaries, we expect that it would most frequently be reported using the code that describes moderate sedation furnished by the same person who also performs the primary procedure for patients 5 years

of age or older. Under the new coding structure, these moderate sedation services would be reported using CPT code 99152, for which we proposed a work RVU of 0.25, consistent with the RUC recommendations for this code. Stakeholders presented information that illustrated that the specialty group survey data regarding the work involved in furnishing moderate sedation described by CPT code 99152 showed a significant bimodal distribution between procedural services furnished by gastroenterologists (GI) and those services furnished by other specialties. The GI societies' survey data reported a median valuation of 0.10 work RVUs for moderate sedation furnished by the same person furnishing the base procedure. Given the significant volume of moderate sedation furnished by GI practitioners and the significant difference in RVUs reported in the survey data, we proposed to make payment using a GI endoscopy-specific moderate sedation code (HCPCS code G0500) that would be used in lieu of the new CPT moderate sedation coding for use with other services.

- G0500: moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service (excluding biliary procedures) that sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time; patient age 5 years or older.

We proposed to value HCPCS code G0500 at 0.10 work RVUs based on the median survey result for GI respondents in the survey data. We proposed that when moderate sedation services are furnished by the same practitioner reporting the GI endoscopy procedure, practitioners would report the sedation services using HCPCS code G0500 instead of CPT code 99152. In all other cases, we proposed that practitioners would report moderate sedation using one of the new moderate sedation CPT codes consistent with CPT guidance. This would include the full range of codes for those furnishing moderate sedation with the remaining (non-GI endoscopy) base procedures, as well as for the other circumstances during which moderate sedation is furnished along with a GI endoscopy (for example, to a patient under 5 years of age or for a biliary procedure, the endoscopist furnishing moderate sedation should not use HCPCS code G0500, but instead use the appropriate CPT code.

In addition to proposing work RVUs for the new codes used to separately report moderate sedation, we stated in the proposed rule that the RUC provided recommendations that valued the procedural services without moderate sedation. However, the RUC recommended removing fewer RVUs from the procedures than it recommended for valuing the moderate sedation services that were removed from the procedure codes. In other words, the RUC recommended that overall payments for these procedures should be increased now that practitioners would be required to report the sedation services that were previously included as inherent parts of the procedures. We stated in the proposed rule that we believe that if we were to use the RUC recommendations for revaluation of the procedural services without refinement, the RVUs currently attributable to the redundant payment for sedation services when anesthesia is separately reported would be used exclusively to increase overall payment for these services. We refer readers to section II.D.5. of this final rule, which includes a more extensive discussion of our general principle that overall resource costs for procedures that include moderate sedation do not inherently change based solely on changes in coding.

To account for the separate billing of moderate sedation services, we proposed to maintain current values for the procedure codes less the work RVUs associated with the most frequently reported corresponding moderate sedation code so that practitioners furnishing the moderate sedation services previously considered to be inherent in the procedure would have no change in overall work RVUs. Since we proposed 0.10 work RVUs for moderate sedation for the GI endoscopy procedures, we proposed a corresponding 0.10 reduction in work RVUs for these same procedures. For all other Appendix G procedures that currently include moderate sedation as an inherent part of the procedure, we proposed to remove 0.25 work RVUs from the current values.

We received 22 comments from medical professionals, ambulatory surgical centers (ASCs), manufacturers, and professional medical specialty societies representing radiation oncology, brachytherapy, colon and rectal surgeons, certified registered nurse anesthetists (CRNAs), pediatrics, cardiology, thorasic surgery, general surgery, gastroenterology, emergency medicine, interventional radiology, and vascular surgery. Commenters were generally supportive of CMS' proposals related to valuation of the new moderate sedation codes. A few commenters disagreed with our proposed refinements for one of the new moderate sedation CPT codes. While most commenters were supportive of CMS' proposal to use a methodology to revalue the procedural services without moderate sedation, some commenters suggested that we should revalue certain procedures differently (for example, apply a lower work RVU reduction or make no reduction). A few commenters were opposed to separate reporting of moderate sedation and suggested alternatives for CMS to consider. Our responses to commenters' specific issues are included below.

Comment: Many commenters expressed support for CMS' proposal to accept the RUC's recommendations for new moderate sedation CPT codes 99151, 99152, 99153, 99155, and 99157. Several commenters, including the RUC and medical specialty societies, disagreed with CMS' proposal to value CPT code 99156 at 1.65 work RVUs. Commenters requested that CMS finalize the RUC-recommended work RVU of 1.84 (the 25th percentile survey result). Commenters stated that there were clinical differences in the typical patients that receive services that would be reported using CPT code 99156, disagreeing with CMS' proposal to reduce the work RVU for CPT code 99156 to maintain relativity among the code pairs in this family. Commenters suggested that CPT code 99156 would be used to report moderate sedation services that are currently reported using CPT code 99149. Commenters stated that CPT code 99149 was typically performed in the emergency department (approximately 58 percent of the time), indicating that the typical patient is either acutely ill or injured, and that moderate sedation services are typically performed without support staff, which commenters suggested further justified a work RVU of 1.84 for CPT code 99156.

Response: The code descriptors for each of the new moderate sedation CPT codes make distinctions between the ages of the patients and the clinical staff involved in furnishing the moderate sedation services. The typical patient vignettes used in the specialty societies' surveys did not indicate clinical differences between patients receiving moderate sedation services reported using CPT code 99156 compared to services reported with CPT code 99155. Additionally, the typical patient vignettes for CPT codes 99151 and 99152 did not indicate clinical differences in the patients. We continue to believe that the work RVU increment of 0.25 should be maintained between CPT codes 99155 and 99156 since these

codes have the same younger than age 5/older than age 5 dynamic as described by CPT codes 99151 and 99152.

Therefore, for CY 2017, we are finalizing work RVUs for the moderate sedation codes as follows:

- Work RVU of 0.50 for CPT code 99151;
- Work RVU of 0.25 for CPT code 99152;
- Work RVU of 1.90 for CPT code 99155;
- Work RVU of 1.65 for CPT code 99156; and
- Work RVU of 1.25 for CPT code 99157.

We note that CPT code 99153 is a PE-only code and we are finalizing the proposed PE inputs for CPT code 99153, as well as finalizing the proposed PE inputs for all other codes in this family without modification.

Comment: While many commenters supported use of a methodological approach to revaluing Appendix G procedural services, some commenters disagreed with CMS' proposed refinements to the RUC's recommended methodology. Commenters suggested that the RUC's approach was consistent with how the services were originally valued and was budget neutral within these services. The RUC, along with several commenters representing specialty medical societies, requested that CMS use the same RUC-approved two-tier methodology for removing work RVUs associated with the work of moderate sedation from Appendix G services based on whether the code was assigned to one of two preservice time packages used by the RUC in developing recommendations. Using the same two-tier methodology, the RUC suggested removal of 0.10 work RVUs for some GI services and 0.19 work RVUs from other GI services, depending on the RUC's assignment of pre-service time.

Response: We understand that some stakeholders would prefer that we use the RUC's recommendations so that the RVUs currently attributable to the redundant payment for sedation services when anesthesia is separately reported would be used exclusively to increase overall payment for these services. We also understand that the RUC assumes that the amount of pre-service time for particular services may reflect a different level of preparation required for sedation services. However, we continue to believe that the overall resource costs for the procedures including moderate sedation do not inherently change based solely on changes in coding, so we do not believe that our assignment of overall work RVUs should increase in cases where the moderate sedation is performed by the proceduralists, as previously assumed. Therefore, we believe that a different amount of work RVUs should be removed from the Appendix G services only in cases where the typical moderate sedation code also has a different amount of assigned work RVUs, such as the case with codes that would be reported with G0500. In other words, we believe that there should be a direct relationship, for each code, between the work RVUs attributable to moderate sedation, regardless of whether it is automatically included in payment for a given procedure (at current) or separately reported (as proposed).

Comment: A few commenters expressed concerns that the proposed revaluation methodology would disturb the relativity of many of the Appendix G codes, along with the increasing administrative burden by requiring separate reporting of the procedural and moderate sedation services. Other commenters suggested that CMS consider alternatives including only addressing revaluation of Appendix G services where moderate sedation is no longer inherent or only those procedural services reported with separate anesthesia services the majority of the time.

Response: We appreciate the concerns of commenters regarding both the issues of relativity within families of codes, as well as concerns regarding administrative burden. However, we believe that it serves relativity to maintain the overall work RVUs for each of the services when reported with moderate sedation, which would be typical for many of these codes. While we understand the value in reducing the number of codes required to be reported for payment under the PFS, we also believe that it is important that the coding be granular enough to allow us to identify which services are furnished to Medicare beneficiaries by which practitioners. It is also clear to us that the accuracy of the assumption of moderate sedation as inherent for particular procedures may change over time, as we have seen reflected in the claims data. We do not believe that a shifting set of services where moderate sedation values are alternatively included or not included in the valuation of particular codes based on annual analysis of claims data would be likely to be administratively easier for practitioners.

Comment: A few commenters requested that CMS not finalize its proposal to reduce the work RVUs for certain procedures. Some commenters indicated that certain codes identified in Appendix G were valued before Appendix G was established, or the work of moderate sedation was not included in the valuation of certain procedures.

Response: We appreciate the commenters' feedback regarding our proposals. We remind stakeholders that the potentially misvalued code process is intended to improve the accuracy of the RVUs assigned to particular codes. We welcome feedback from interested individuals, stakeholders, and specialty societies regarding the valuation of specific codes for consideration in future rulemaking.

Comment: A few commenters stated that CMS did not provide a rationale to support that moderate sedation furnished with GI endoscopy services required less work than moderate sedation furnished with other Appendix G procedures.

Response: Our proposal was based on the GI societies' survey data included in the RUC recommendations that reported a median valuation of 0.10 work RVUs for moderate sedation furnished by the same person furnishing the base procedure.

Comment: A few commenters suggested that creation of HCPCS code G0500 would cause confusion among practitioners since the new CPT codes developed to report moderate sedation do not differentiate between GI and non-GI procedures. One commenter stated that HCPCS code G0500 is time based, and therefore, to report the code, at least 50 percent of the time (7.5 minutes) is required, but the GI subset of data that CMS accepted to create the HCPCS code G0500 indicates an intraservice time of 5 minutes. The commenter went on to state that it would appear that a majority of the GI endoscopists would never be able to report HCPCS code G0500.

Response: We expect that practitioners will report the appropriate CPT or HCPCS code that most accurately describes the services performed during a patient encounter, including those services performed concurrently and in support of a procedural service consistent with CPT guidance. We note that the commenter refers to the time for moderate sedation in the survey data, while the time thresholds for the moderate sedation codes are intended to match the intraservice time of the procedure itself. We reviewed the intraservice time assumptions for the procedure codes, and only one includes an intraservice time as low as 7.5 minutes and none lower. Table 26 identifies the GI endoscopic services for which HCPCS code G0500 will be used to report moderate sedation services (available in the ''downloads'' section of the PFS

Web site at *http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*).

Comment: Several commenters disagreed with CMS' proposal to revalue Appendix G esophageal dilation, biliary endoscopy, and ERCP procedures minus 0.25 work RVUs instead of minus 0.10 work RVUs, similar to other endoscopy services identified in Appendix G. Commenters requested that CMS only reduce these procedural services with a 0.10 work RVU reduction, and allow reporting of moderate sedation using HCPCS code G0500, similar to other endoscopy procedures identified in Appendix G.

Response: While we continue to believe that the moderate sedation work for Appendix G esophageal dilation, biliary endoscopy, and ERCP procedures is more extensive than for other endoscopy procedures identified in Appendix G, for CY 2017, after considering the comments, we are finalizing a revaluation of certain esophageal dilation, biliary endoscopy, and ERCP procedures minus 0.10 work RVUs instead of the 0.25 work RVU reduction as proposed (see Table 26 for additional information). We will continue to monitor claims data related to separately billed anesthesia services performed in conjunction with these procedures to inform future rulemaking related to the valuation of these codes.

We are also modifying the code descriptor for HCPCS code G0500 to reflect these changes. Therefore, we are finalizing the descriptor for HCPCS code G0500 as:

- G0500: Moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service that sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time; patient age 5 years or older. (additional time may be reported with 99153, as appropriate).

Comment: Some commenters requested that CMS provide practitioners and providers with instructions on use of the newly created moderate sedation codes, allow for additional time to implement the coding changes, and provide MACs appropriate claims processing instructions specific to these codes.

Response: We plan to issue appropriate claims processing instructions to the local MACs. We do not believe that an implementation delay is necessary since the new CPT and HCPCS codes will be effective January 1, 2017 and available for use by practitioners and providers at that time.

In summary, after consideration of the comments, we are finalizing our proposed modifications to maintain the current values for the procedure codes less the work RVUs associated with the most frequently reported corresponding moderate sedation code. Practitioners furnishing the moderate sedation services previously considered to be inherent in the procedure will have no change in overall work RVUs. Since we are finalizing a work RVU of 0.10 (HCPCS code G0500) for moderate sedation for the GI endoscopy procedures, we are finalizing a corresponding 0.10 reduction in work RVUs for the corresponding procedural services. For all other Appendix G procedures that currently include moderate sedation as an inherent part of the procedure, we are finalizing a 0.25 work RVU reduction from the current values.

Table 26 lists the CY 2016 work RVUs for each applicable service and our proposed and final CY 2017 refined work RVUs using the finalized revaluation methodology described above. Additionally, the table identifies the GI endoscopic services for which HCPCS code G0500 will be used to report moderate sedation services (available in the ''downloads'' section of the PFS Web site at *http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*).

TABLE 26—VALUATIONS FOR SERVICES MINUS MODERATE SEDATION

CPT code	CY 2016 work RVU	CY 2017 proposed work RVU	CY 2017 final work RVU	Use HCPCS code G0500 to report moderate sedation (Y/N)
10030	3.00	2.75	2.75	N
19298	6.00	5.75	5.75	N
20982	7.27	7.02	7.02	N
20983	7.13	6.88	6.88	N
22510	8.15	7.90	7.90	N
22511	7.58	7.33	7.33	N
22512	4.00	4.00	4.00	N
22513	8.90	8.65	8.65	N
22514	8.24	7.99	7.99	N
22515	4.00	4.00	4.00	N
22526	6.10	5.85	5.85	N
22527	3.03	3.03	3.03	N
31615	2.09	1.84	1.84	N
31622	2.78	2.53	2.53	N
31623	2.88	2.63	2.63	N
31624	2.88	2.63	2.63	N
31625	3.36	3.11	3.11	N
31626	4.16	3.91	3.91	N
31627	2.00	2.00	2.00	N
31628	3.80	3.55	3.55	N
31629	4.00	3.75	3.75	N
31632	1.03	1.03	1.03	N
31633	1.32	1.32	1.32	N
31634	4.00	3.75	3.75	N
31635	3.67	3.42	3.42	N
31645	3.16	2.91	2.91	N

TABLE 26—VALUATIONS FOR SERVICES MINUS MODERATE SEDATION—Continued

CPT code	CY 2016 work RVU	CY 2017 proposed work RVU	CY 2017 final work RVU	Use HCPCS code G0500 to report moderate sedation (Y/N)
31646	2.72	2.47	2.47	N
31647	4.40	4.15	4.15	N
31648	4.20	3.95	3.95	N
31649	1.44	1.44	1.44	N
31651	1.58	1.58	1.58	N
31652	4.71	4.46	4.46	N
31653	5.21	4.96	4.96	N
31654	1.40	1.40	1.40	N
31660	4.25	4.00	4.00	N
31661	4.50	4.25	4.25	N
31725	1.96	1.71	1.71	N
32405	1.93	1.68	1.68	N
32550	4.17	3.92	3.92	N
32551	3.29	3.04	3.04	N
32553	3.80	3.55	3.55	N
33010	2.24	1.99	1.99	N
33011	2.24	1.99	1.99	N
33206	7.39	7.14	7.14	N
33207	8.05	7.80	7.80	N
33208	8.77	8.52	8.52	N
33210	3.30	3.05	3.05	N
33211	3.39	3.14	3.14	N
33212	5.26	5.01	5.01	N
33213	5.53	5.28	5.28	N
33214	7.84	7.59	7.59	N
33216	5.87	5.62	5.62	N
33217	5.84	5.59	5.59	N
33218	6.07	5.82	5.82	N
33220	6.15	5.90	5.90	N
33221	5.80	5.55	5.55	N
33222	5.10	4.85	4.85	N
33223	6.55	6.30	6.30	N
33227	5.50	5.25	5.25	N
33228	5.77	5.52	5.52	N
33229	6.04	5.79	5.79	N
33230	6.32	6.07	6.07	N
33231	6.59	6.34	6.34	N
33233	3.39	3.14	3.14	N
33234	7.91	7.66	7.66	N
33235	10.15	9.90	9.90	N
33240	6.05	5.80	5.80	N
33241	3.29	3.04	3.04	N
33244	13.99	13.74	13.74	N
33249	15.17	14.92	14.92	N
33262	6.06	5.81	5.81	N
33263	6.33	6.08	6.08	N
33264	6.60	6.35	6.35	N
33282	3.50	3.25	3.25	N
33284	3.00	2.75	2.75	N
33990	8.15	7.90	7.90	N
33991	11.88	11.63	11.63	N
33992	4.00	3.75	3.75	N
33993	3.51	3.26	3.26	N
35471	10.05	9.80	9.80	N
35472	6.90	6.65	6.65	N
35475	6.60	6.35	6.35	N
35476	5.10	4.85	4.85	N
36010	2.43	2.18	2.18	N
36140	2.01	1.76	1.76	N
36147	3.72	3.47	3.47	N
36148	1.00	1.00	1.00	N
36200	3.02	2.77	2.77	N
36221	4.17	3.92	3.92	N
36222	5.53	5.28	5.28	N
36223	6.00	5.75	5.75	N
36224	6.50	6.25	6.25	N
36225	6.00	5.75	5.75	N
36226	6.50	6.25	6.25	N

TABLE 26—VALUATIONS FOR SERVICES MINUS MODERATE SEDATION—Continued

CPT code	CY 2016 work RVU	CY 2017 proposed work RVU	CY 2017 final work RVU	Use HCPCS code G0500 to report moderate sedation (Y/N)
36227	2.09	2.09	2.09	N
36228	4.25	4.25	4.25	N
36245	4.90	4.65	4.65	N
36246	5.27	5.02	5.02	N
36247	6.29	6.04	6.04	N
36248	1.01	1.01	1.01	N
36251	5.35	5.10	5.10	N
36252	6.99	6.74	6.74	N
36253	7.55	7.30	7.30	N
36254	8.15	7.90	7.90	N
36481	6.98	6.73	6.73	N
36555	2.68	2.43	2.43	N
36557	5.14	4.89	4.89	N
36558	4.84	4.59	4.59	N
36560	6.29	6.04	6.04	N
36561	6.04	5.79	5.79	N
36563	6.24	5.99	5.99	N
36565	6.04	5.79	5.79	N
36566	6.54	6.29	6.29	N
36568	1.92	1.67	1.67	N
36570	5.36	5.11	5.11	N
36571	5.34	5.09	5.09	N
36576	3.24	2.99	2.99	N
36578	3.54	3.29	3.29	N
36581	3.48	3.23	3.23	N
36582	5.24	4.99	4.99	N
36583	5.29	5.04	5.04	N
36585	4.84	4.59	4.59	N
36590	3.35	3.10	3.10	N
36870	5.20	4.95	4.95	N
37183	7.99	7.74	7.74	N
37184	8.66	8.41	8.41	N
37185	3.28	3.28	3.28	N
37186	4.92	4.92	4.92	N
37187	8.03	7.78	7.78	N
37188	5.71	5.46	5.46	N
37191	4.71	4.46	4.46	N
37192	7.35	7.10	7.10	N
37193	7.35	7.10	7.10	N
37197	6.29	6.04	6.04	N
37211	8.00	7.75	7.75	N
37212	7.06	6.81	6.81	N
37213	5.00	4.75	4.75	N
37214	2.74	2.49	2.49	N
37215	18.00	17.75	17.75	N
37216	0.00	0.00	0.00	N
37218	15.00	14.75	14.75	N
37220	8.15	7.90	7.90	N
37221	10.00	9.75	9.75	N
37222	3.73	3.73	3.73	N
37223	4.25	4.25	4.25	N
37224	9.00	8.75	8.75	N
37225	12.00	11.75	11.75	N
37226	10.49	10.24	10.24	N
37227	14.50	14.25	14.25	N
37228	11.00	10.75	10.75	N
37229	14.05	13.80	13.80	N
37230	13.80	13.55	13.55	N
37231	15.00	14.75	14.75	N
37232	4.00	4.00	4.00	N
37233	6.50	6.50	6.50	N
37234	5.50	5.50	5.50	N
37235	7.80	7.80	7.80	N
37236	9.00	8.75	8.75	N
37237	4.25	4.25	4.25	N
37238	6.29	6.04	6.04	N
37239	2.97	2.97	2.97	N
37241	9.00	8.75	8.75	N

TABLE 26—VALUATIONS FOR SERVICES MINUS MODERATE SEDATION—Continued

CPT code	CY 2016 work RVU	CY 2017 proposed work RVU	CY 2017 final work RVU	Use HCPCS code G0500 to report moderate sedation (Y/N)
37242	10.05	9.80	9.80	N
37243	11.99	11.74	11.74	N
37244	14.00	13.75	13.75	N
37252	1.80	1.80	1.80	N
37253	1.44	1.44	1.44	N
43200	1.52	1.42	1.42	Y
43201	1.82	1.72	1.72	Y
43202	1.82	1.72	1.72	Y
43204	2.43	2.33	2.33	Y
43205	2.54	2.44	2.44	Y
43206	2.39	2.29	2.29	Y
43211	4.30	4.20	4.20	Y
43212	3.50	3.40	3.40	Y
43213	4.73	4.63	4.63	Y
43214	3.50	3.40	3.40	Y
43215	2.54	2.44	2.44	Y
43216	2.40	2.30	2.30	Y
43217	2.90	2.80	2.80	Y
43220	2.10	2.00	2.00	Y
43226	2.34	2.24	2.24	Y
43227	2.99	2.89	2.89	Y
43229	3.59	3.49	3.49	Y
43231	2.90	2.80	2.80	Y
43232	3.69	3.59	3.59	Y
43233	4.17	4.07	4.07	Y
43235	2.19	2.09	2.09	Y
43236	2.49	2.39	2.39	Y
43237	3.57	3.47	3.47	Y
43238	4.26	4.16	4.16	Y
43239	2.49	2.39	2.39	Y
43240	7.25	7.15	7.15	Y
43241	2.59	2.49	2.49	Y
43242	4.83	4.73	4.73	Y
43243	4.37	4.27	4.27	Y
43244	4.50	4.40	4.40	Y
43245	3.18	3.08	3.08	Y
43246	3.66	3.56	3.56	Y
43247	3.21	3.11	3.11	Y
43248	3.01	2.91	2.91	Y
43249	2.77	2.67	2.67	Y
43250	3.07	2.97	2.97	Y
43251	3.57	3.47	3.47	Y
43252	3.06	2.96	2.96	Y
43253	4.83	4.73	4.73	Y
43254	4.97	4.87	4.87	Y
43255	3.66	3.56	3.56	Y
43257	4.25	4.15	4.15	Y
43259	4.14	4.04	4.04	Y
43260	5.95	5.70	5.85	Y
43261	6.25	6.00	6.15	Y
43262	6.60	6.35	6.50	Y
43263	6.60	6.35	6.50	Y
43264	6.73	6.48	6.63	Y
43265	8.03	7.78	7.93	Y
43266	4.17	3.92	3.92	N
43270	4.26	4.01	4.01	N
43273	2.24	2.24	2.24	N
43274	8.58	8.33	8.48	Y
43275	6.96	6.71	6.86	Y
43276	8.94	8.69	8.84	Y
43277	7.00	6.75	6.90	Y
43278	8.02	7.77	7.92	Y
43450	1.38	1.13	1.28	Y
43453	1.51	1.26	1.41	Y
44360	2.59	2.49	2.49	Y
44361	2.87	2.77	2.77	Y
44363	3.49	3.39	3.39	Y
44364	3.73	3.63	3.63	Y

TABLE 26—VALUATIONS FOR SERVICES MINUS MODERATE SEDATION—Continued

CPT code	CY 2016 work RVU	CY 2017 proposed work RVU	CY 2017 final work RVU	Use HCPCS code G0500 to report moderate sedation (Y/N)
44365	3.31	3.21	3.21	Y
44366	4.40	4.30	4.30	Y
44369	4.51	4.41	4.41	Y
44370	4.79	4.69	4.69	Y
44372	4.40	4.30	4.30	Y
44373	3.49	3.39	3.39	Y
44376	5.25	5.15	5.15	Y
44377	5.52	5.42	5.42	Y
44378	7.12	7.02	7.02	Y
44379	7.46	7.36	7.36	Y
44380	0.97	0.87	0.87	Y
44381	1.48	1.38	1.38	Y
44382	1.27	1.17	1.17	Y
44384	2.95	2.85	2.85	Y
44385	1.30	1.20	1.20	Y
44386	1.60	1.50	1.50	Y
44388	2.82	2.72	2.72	Y
44388–53	1.41	1.36	1.36	Y
44389	3.12	3.02	3.02	Y
44390	3.84	3.74	3.74	Y
44391	4.22	4.12	4.12	Y
44392	3.63	3.53	3.53	Y
44394	4.13	4.03	4.03	Y
44401	4.44	4.34	4.34	Y
44402	4.80	4.70	4.70	Y
44403	5.60	5.50	5.50	Y
44404	3.12	3.02	3.02	Y
44405	3.33	3.23	3.23	Y
44406	4.20	4.10	4.10	Y
44407	5.06	4.96	4.96	Y
44408	4.24	4.14	4.14	Y
44500	0.49	0.39	0.39	Y
45303	1.50	1.40	1.40	Y
45305	1.25	1.15	1.15	Y
45307	1.70	1.60	1.60	Y
45308	1.40	1.30	1.30	Y
45309	1.50	1.40	1.40	Y
45315	1.80	1.70	1.70	Y
45317	2.00	1.90	1.90	Y
45320	1.78	1.68	1.68	Y
45321	1.75	1.65	1.65	Y
45327	2.00	1.90	1.90	Y
45332	1.86	1.76	1.76	Y
45333	1.65	1.55	1.55	Y
45334	2.10	2.00	2.00	Y
45335	1.14	1.04	1.04	Y
45337	2.20	2.10	2.10	Y
45338	2.15	2.05	2.05	Y
45340	1.35	1.25	1.25	Y
45341	2.22	2.12	2.12	Y
45342	3.08	2.98	2.98	Y
45346	2.91	2.81	2.81	Y
45347	2.82	2.72	2.72	Y
45349	3.62	3.52	3.52	Y
45350	1.78	1.68	1.68	Y
45378	3.36	3.26	3.26	Y
45378–53	1.68	1.63	1.63	Y
45379	4.38	4.28	4.28	Y
45380	3.66	3.56	3.56	Y
45381	3.66	3.56	3.56	Y
45382	4.76	4.66	4.66	Y
45384	4.17	4.07	4.07	Y
45385	4.67	4.57	4.57	Y
45386	3.87	3.77	3.77	Y
45388	4.98	4.88	4.88	Y
45389	5.34	5.24	5.24	Y
45390	6.14	6.04	6.04	Y
45391	4.74	4.64	4.64	Y

TABLE 26—VALUATIONS FOR SERVICES MINUS MODERATE SEDATION—Continued

CPT code	CY 2016 work RVU	CY 2017 proposed work RVU	CY 2017 final work RVU	Use HCPCS code G0500 to report moderate sedation (Y/N)
45392	5.60	5.50	5.50	Y
45393	4.78	4.68	4.68	Y
45398	4.30	4.20	4.20	Y
47000	1.90	1.65	1.65	N
47382	15.22	14.97	14.97	N
47383	9.13	8.88	8.88	N
47532	4.25	4.25	4.25	N
47533	6.00	5.38	5.38	N
47534	8.03	7.60	7.60	N
47535	4.50	3.95	3.95	N
47536	2.88	2.61	2.61	N
47538	6.60	4.75	4.75	N
47539	9.00	8.75	8.75	N
47540	10.75	9.03	9.03	N
47541	5.61	5.38	6.75	N
47542	2.50	2.85	2.85	N
47543	3.07	3.00	3.00	N
47544	4.29	3.28	3.28	N
49405	4.25	4.00	4.00	N
49406	4.25	4.00	4.00	N
49407	4.50	4.25	4.25	N
49411	3.82	3.57	3.57	N
49418	4.21	3.96	3.96	N
49440	4.18	3.93	3.93	N
49441	4.77	4.52	4.52	N
49442	4.00	3.75	3.75	N
49446	3.31	3.06	3.06	N
50200	2.63	2.38	2.38	N
50382	5.50	5.25	5.25	N
50384	5.00	4.75	4.75	N
50385	4.44	4.19	4.19	N
50386	3.30	3.05	3.05	N
50387	2.00	1.75	1.75	N
50430	3.15	2.90	2.90	N
50432	4.25	4.00	4.00	N
50433	5.30	5.05	5.05	N
50434	4.00	3.75	3.75	N
50592	6.80	6.55	6.55	N
50593	9.13	8.88	8.88	N
50606	3.16	3.16	3.16	N
50693	4.21	3.96	3.96	N
50694	5.50	5.25	5.25	N
50695	7.05	6.80	6.80	N
50705	4.03	4.03	4.03	N
50706	3.80	3.80	3.80	N
57155	5.40	5.15	5.15	N
66720	5.00	4.75	4.75	N
69300	6.69	6.44	6.44	N
77371	0.00	0.00	0.00	N
77600	1.56	1.31	1.31	N
77605	2.09	1.84	1.84	N
77610	1.56	1.31	1.31	N
77615	2.09	1.84	1.84	N
92920	10.10	9.85	9.85	N
92921	0.00	0.00	0.00	N
92924	11.99	11.74	11.74	N
92925	0.00	0.00	0.00	N
92928	11.21	10.96	10.96	N
92929	0.00	0.00	0.00	N
92933	12.54	12.29	12.29	N
92934	0.00	0.00	0.00	N
92937	11.20	10.95	10.95	N
92938	0.00	0.00	0.00	N
92941	12.56	12.31	12.31	N
92943	12.56	12.31	12.31	N
92944	0.00	0.00	0.00	N
92953	0.23	0.01	0.01	N
92960	2.25	2.00	2.00	N

TABLE 26—VALUATIONS FOR SERVICES MINUS MODERATE SEDATION—Continued

CPT code	CY 2016 work RVU	CY 2017 proposed work RVU	CY 2017 final work RVU	Use HCPCS code G0500 to report moderate sedation (Y/N)
92961	4.59	4.34	4.34	N
92973	3.28	3.28	3.28	N
92974	3.00	3.00	3.00	N
92975	7.24	6.99	6.99	N
92978	0.00	0.00	0.00	N
92979	0.00	0.00	0.00	N
92986	22.85	22.60	22.60	N
92987	23.63	23.38	23.38	N
93312	2.55	2.30	2.30	N
93313	0.51	0.26	0.26	N
93314	2.10	1.85	1.85	N
93315	2.94	2.69	2.69	N
93316	0.85	0.60	0.60	N
93317	2.09	1.84	1.84	N
93318	2.40	2.15	2.15	N
93451	2.72	2.47	2.47	N
93452	4.75	4.50	4.50	N
93453	6.24	5.99	5.99	N
93454	4.79	4.54	4.54	N
93455	5.54	5.29	5.29	N
93456	6.15	5.90	5.90	N
93457	6.89	6.64	6.64	N
93458	5.85	5.60	5.60	N
93459	6.60	6.35	6.35	N
93460	7.35	7.10	7.10	N
93461	8.10	7.85	7.85	N
93462	3.73	3.73	3.73	N
93463	2.00	2.00	2.00	N
93464	1.80	1.80	1.80	N
93505	4.37	4.12	4.12	N
93530	4.22	3.97	3.97	N
93561	0.50	0.25	0.25	N
93562	0.16	0.01	0.01	N
93563	1.11	1.11	1.11	N
93564	1.13	1.13	1.13	N
93565	0.86	0.86	0.86	N
93566	0.86	0.86	0.86	N
93567	0.97	0.97	0.97	N
93568	0.88	0.88	0.88	N
93571	0.00	0.00	0.00	N
93572	0.00	0.00	0.00	N
93582	12.56	12.31	12.31	N
93583	14.00	13.75	13.75	N
93609	0.00	0.00	0.00	N
93613	6.99	6.99	6.99	N
93615	0.99	0.74	0.74	N
93616	1.49	1.24	1.24	N
93618	4.25	4.00	4.00	N
93619	7.31	7.06	7.06	N
93620	11.57	11.32	11.32	N
93621	0.00	0.00	0.00	N
93622	0.00	0.00	0.00	N
93624	4.80	4.55	4.55	N
93640	3.51	3.26	3.26	N
93641	5.92	5.67	5.67	N
93642	4.88	4.63	4.63	N
93644	3.29	3.04	3.04	N
93650	10.49	10.24	10.24	N
93653	15.00	14.75	14.75	N
93654	20.00	19.75	19.75	N
93655	7.50	7.50	7.50	N
93656	20.02	19.77	19.77	N
93657	7.50	7.50	7.50	N
94011	2.00	1.75	1.75	N
94012	3.10	2.85	2.85	N
94013	0.66	0.41	0.41	N
96440	2.37	2.12	2.12	N
G0105	3.36	3.26	3.26	Y

TABLE 26—VALUATIONS FOR SERVICES MINUS MODERATE SEDATION—Continued

CPT code	CY 2016 work RVU	CY 2017 proposed work RVU	CY 2017 final work RVU	Use HCPCS code G0500 to report moderate sedation (Y/N)
G0105–53	1.68	1.63	1.63	Y
G0121	3.36	3.26	3.26	Y
G0121–53	1.68	1.63	1.63	Y
G0341	6.98	6.98	6.98	N

(58) Prolonged Evaluation and Management Services (CPT Codes 99354, 99358, and 99359)

We previously received RUC recommendations for face-to-face and non-face-to-face prolonged E/M services. In response to the request for public comments in the CY 2016 PFS proposed rule about improving payment accuracy for cognitive services, commenters suggested that we consider making separate payment for CPT codes 99358 and 99359. As reflected in section II.E, we proposed to make separate payment for these services.

We also proposed values for services in this family of codes based on the RUC-recommended values, including for CPT code 99354, which would increase the current work RVU to 2.33. Likewise, we proposed to adopt the RUC-recommended work RVU of 2.10 for CPT code 99358 and 1.00 for CPT code 99359.

Comment: One commenter recommended that CMS develop separate payment for a modifier and new G-codes that would account for additional non-face-to-face time spent on circumstances that fell outside that of a typical level-4 patient.

Response: We appreciate the recommendation and will consider coding alternatives in future rulemaking.

Comment: Many commenters were very supportive of CMS' proposal to pay separately for CPT codes 99258 and 99359, and to increase the current work RVU for CPT code 99354.

Response: We thank commenters for their support, and are finalizing the values as proposed.

(59) Complex Chronic Care Management Services (CPT Codes 99487 and 99489)

We received RUC recommendations for CPT codes 99487 and 99489 following the October 2012 RUC meeting, however we considered these services bundled and did not make separate payment. For CY 2017, we proposed to change the procedure status for CPT codes 99487 and 99489 from B (bundled) to A (active), see II.E, and proposed to adopt the RUC-recommended work RVUs of 1.00 for CPT code 99487 and 0.50 for CPT code 99489, as well as direct PE inputs consistent with the RUC recommendations.

We received no comments on the valuation of CPT codes 99487 and 99489; therefore, we are finalizing as proposed.

(60) Prostate Biopsy, Any Method (HCPCS Code G0416)

The College of American Pathologists and the American Society of Cytopathology formed an expert panel to make recommendations at the October 2015 RUC meeting to determine an appropriate work RVU for HCPCS code G0416, as they believed that the survey results were invalid. The panel made several arguments to the RUC in recommending a higher work RVU under the RUC's ''compelling evidence'' standard. These arguments were: (1) That incorrect assumptions were made in previous valuations; (2) the value of HCPCS code G0416 remained constant while the code descriptors changed over the years; and (3) the ''anomalous relationship'' between HCPCS code G0416 and CPT code 88305 (Level IV—Surgical pathology, gross and microscopic examination). The expert panel recommended a work RVU of 4.00 based on a crosswalk from CPT code 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor). The RUC agreed with the recommendation of the expert panel.

We believed HCPCS code G0416 should not be valued as a direct crosswalk from CPT code 38240. Instead, since code G0416 describes services that would otherwise be reported using CPT code 88305 we believed that G0416 should be valued relative to CPT code 88305. To value HCPCS code G0416, we used the intra-service time ratio between HCPCS code G0416 and CPT code 88305 to arrive at a work RVU of 3.60. To further support this method, we noted that the IWPUT for HCPCS code G0416 with a work RVU of 3.60 is the same as CPT code 88305. Using the RUC-recommended RVU of 4.00 results in a higher IWPUT, and we did not believe there is a difference in work intensity between these codes. Therefore for CY 2017, we proposed a work RVU of 3.60 for HCPCS code G0416.

Comment: A few commenters, including the RUC, stated their objection to the methodology used in proposing a value for this HCPCS code along with the proposed work RVU. The RUC stated its disagreement with what it called a formulaic approach of multiplying time by intensity to arrive at a value for this code. The RUC, along with other commenters, also urged CMS to accept the compelling evidence that G0416 and 88305 have an anomalous relationship as a pathologist may examine 30–60 slides when furnishing HCPCS code G0416 whereas only one slide is examined with CPT code 88305. The commenters also noted that CMS had previously stated its belief that the typical number of specimens evaluated for prostate biopsies was between 10 and 12, and therefore, would value the typical G0416 at 9.00 RVUs (0.75 x 12), if the number of specimens were used rather than a time ratio.

Response: We continue to believe HCPCS code G0416 should not be valued as a direct crosswalk from CPT code 38240. CPT code 38240 involves the intense monitoring of a patient's reactions to a critical infusion of cellular material. This process does not allow the physician to leave the patient. We do not believe the time, effort, and intensity required of this procedure is similar to a physician reviewing slides. While examining slides, it is possible for the physician to stop, refer to references, complete other tasks, and return to the slides. Thus the service does not have analogous or comparable intensity.

We believe the vignette for CPT code 88305 typically involves, by definition, two blocks and resulting slides. Based upon that rationale, CMS values each block (and resulting slides) as worth a work RVU of 0.375. Valuing the RVUs on a per block basis, then a sextant

(typical 10–12 blocks or slides) would result in 5 times 0.375 to 6 times 0.375. Therefore, for CY 2017 we are finalizing a work RVU of 3.60 for HCPCS G0416.

(61) Resource-Intensive Services (HCPCS Code G0501)

As discussed in section II.E. of this final rule, we proposed to establish payment for services furnished to patients with mobility-related disabilities, through a new add-on G-code, to be billable with office/outpatient E/M and TCM codes. Based on our analysis of the resources typically involved in furnishing office visits to patients with these needs (especially including the typical additional practitioner and staff time), we believed that the physician work and time for HCPCS code G0501 was most accurately valued through a direct crosswalk from CPT code 99212 (Level 2 office or other outpatient visit for the evaluation and management of an established patient). Therefore, we proposed a work RVU of 0.48 and a physician time of 16 minutes for HCPCS code G0501. We sought comment on whether these work and time values accurately capture the additional physician work typically involved in furnishing services to patients with mobility impairments.

We believed that a direct crosswalk to the clinical staff time associated with CPT code 99212, which is 27 minutes of LN/LPN/MTA (L037D) accurately represented the additional clinical staff time required to furnish an outpatient office visit or TCM to a patient with a mobility-related disability. We also proposed to include as direct PE inputs 27 minutes for a stretcher (EF018) and a high/low table (EF028), and 27 minutes for new equipment inputs associated with the following: A patient lift system, wheelchair accessible scale, and padded leg support positioning system. These items were included in the CY 2017 proposed direct PE input database. We sought comments on whether these inputs are appropriate, and whether any additional inputs are typically used in treating patients with mobility impairments.

Comment: Many commenters supported the proposed valuation of G0501 and recommend we finalize as proposed, while others had questions or concerns about the crosswalk and the inputs.

Response: As noted in section II.E.6. of this final rule, we are not finalizing payment for HCPCS code G0501 for CY 2017. We will continue to welcome recommendations from stakeholders on methods for improving the payment accuracy of services for individuals with disabilities.

Comment: Several commenters noted that the Americans with Disabilities Act (ADA) provides federal tax credits for certain physicians to help cover the cost of specialized equipment for patients with mobility-related disabilities.

Response: We remind practitioners that there are existing IRS tax credits and deductions to assist business with complying with the ADA. More information on these tax credits is available at *https://www.ada.gov/taxcred.htm*.

(62) Behavioral Health Integration: Psychiatric Collaborative Care Model (HCPCS Codes G0502, G0503, and G0504) and General Behavioral Health Integration (HCPCS Code G0507)

For CY 2017, we proposed to establish and make separate Medicare payment using four new HCPCS G-codes, G0502 (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), G0503 (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), G0504 (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), and G0507 (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 time, per calendar month) for collaborative care and care management for beneficiaries with behavioral health conditions, as detailed in section II.E of this final rule. To value HCPCS codes G0502, G0503, and G0504, we proposed to base the portion of the work RVU that accounts for the work of the treating physician or other qualified health care professional on a direct crosswalk to the proposed work values for the complex CCM codes, CPT codes 99487 and 99489. To value the portion of the work RVU that accounts for the psychiatric consultant, we estimated 10 minutes of psychiatric consultant time per patient per month and a work RVU of 0.42, based on the per minute work RVUs for the highest volume codes typically billed by psychiatrists, since the resource costs of the consultant's work is being paid to the primary practitioner. Since the behavioral health care manager in the services described by HCPCS codes G0502, G0503, and G0504 should have specialized training in behavioral health, we proposed a new clinical labor type for the behavioral health care manager, L057B, at $0.57 per minute, based on the rates for genetic counselors in the direct PE input database. We solicited comment on all aspects of these proposed valuations.

Comment: Some commenters stated that the work of the psychiatric consultant should be valued at least the same as the primary care practitioner. Commenters noted that the crosswalk to CPT code 90836 was inaccurate, as the work of the psychiatric consultant would not be similar to psychotherapy but instead be similar to E/M services. Commenters recommended that CMS value the work of the psychiatric consultant through a crosswalk to a level-4 outpatient E/M, such as CPT codes 99204 or 99214.

Response: We thank commenters for their response and for providing CMS with additional perspectives on appropriate valuation of the work furnished by the psychiatric consultant. We note that for HCPCS codes G0502, G0503, and G0504, Medicare is making payment to the billing practitioner on the basis that he or she is incurring the costs associated with retaining the psychiatric consultant. In general, we consider such costs to be appropriately categorized under the PE RVUs, regardless of the degree of expertise for that particular contributor. Historically these costs have been included in the calculation of PE RVUs and incorporated as costs based on a national per minute payment rate for that kind of labor instead of varying based on which service is furnished. However, we recognize the unique nature of the services described by this code, especially with regard to the potential inclusion of the work of a physician as PE. We also recognize that the work of the psychiatrist under this model of care more closely resembles E/M work than that of psychotherapy, although not necessarily the work associated with a level-4 office visit. Therefore, for CY 2017, we are finalizing work RVUs for these services that reflect the per minute intensity of E/M services instead of psychotherapy for the portion of the overall work RVU attributable to the psychiatric consultant.

We welcome any information on the best way to account for the work, time, and practice expense resource costs associated with two physicians when one physician is typically incurring the resource costs of another. We are particularly interested in information regarding how CoCM might apply for beneficiaries receiving care in an institutional or inpatient setting.

We believe that the work associated with the billing practitioner would overall be greater than the work associated with the psychiatric consultant. The work of the billing practitioner includes services such as broader care management, direction of the care manager, and by ''incident to'' rules, the general supervision of other staff, while the psychiatric consultant primarily conducts review work. Therefore, in allocating differential portion of the work RVU to each practitioner, we believe the work RVU associated with the billing practitioner should be greater than the work RVU associated with the psychiatric consultant.

After considering these comments, we are finalizing total work RVUs of 1.70 for G0502, 1.53 for G0503, and 0.82 for G0504. These RVUs include 0.52 for the psychiatric consultant based on a crosswalk to the work per minute of a level three established patient office visit.

Comment: One commenter urged CMS to consider the forthcoming RUC recommendations.

Response: We thank the commenter for their suggestion and will evaluate the RUC's recommendation according to our established review process in future rulemaking.

Comment: A few commenters requested that CMS increase the facility setting PE RVUs, as patients in this setting are more complex, and therefore, the care manager would need to be more experienced. The extra costs in terms of clinical staff, commenters stated, would offset the decrease in other kinds of PE associated with the facility setting.

Response: The clinical labor costs for PFS are generally included in the nonfacility rate but not included in the facility rate under the PFS, because applicable payment for the clinical labor costs would be made under the appropriate institutional payment system, like the OPPS. Historically we have not developed separate work RVUs for the facility and the non-facility setting for the same codes. The only cases where we have differentiated work between an institutional and a non-institutional setting are when the HCPCS codes delineate between them, for example site specific codes describing E/M services furnished in an inpatient hospital setting versus those services furnished in an office setting. For this reason, we are not developing separate facility and non-facility work RVUs here.

Comment: With regard to G0503, a few commenters stated that the allocation of 60 minutes is inappropriate because a comprehensive follow up would take longer than 60 minutes.

Response: As these are temporary codes designed to facilitate one year of separate payment prior to receiving a RUC recommendations through CMS' standard process and we continue to believe that 60 minutes would be typical of the time involved, we will not be making adjustments to the time values at this time. We remind commenters that PFS direct PE inputs are used for calculation of rates that we believe reflect the typical case for a service, and are not intended to be instructive to providers as to what is permitted under the code or what should be furnished in any particular case. We also wish to remind commenters that we have longstanding interest in robust extant data sources regarding times, and as these services continue to be furnished to Medicare beneficiaries, we would encourage stakeholders to develop sets of such data that we could potentially use in valuation, among other things.

Comment: One commenter recommended that CMS pay separately for tools, such as multidimensional mental health monitoring tools, to assist practitioners in data analysis.

Response: The CoCM model does not make reference to any specific health monitoring tools; therefore, we will not be including those as direct PE inputs in our valuation of these services.

To value HCPCS code G0507, we proposed a work RVU of 0.61 based on a direct crosswalk from CPT code 99490 (Chronic care management services). We recognize that the services described by CPT code 99490 are distinct from those furnished under the CoCM and we believe that these also vary based on different kinds of BHI care. We note that there are relatively few existing codes that describe these kinds of services over a calendar month. We also believe that the resources associated with CPT code 99490 may vary based on the ways different practitioners furnish the service. Until we have more information about how the services described by G0507 are typically furnished, we believe valuation based on an estimate of the typical resources would be most appropriate. To account for the care manager minutes in the direct PE inputs for HCPCS code G0507, we proposed to use clinical labor type L045C, which is the labor type for social workers/psychologists and has a rate of $0.45 per minute.

Comment: Many commenters stated that 20 minutes of care manager time over the course of a month was an inaccurate representation of the resource costs incurred when furnishing BHI services, and that a longer duration was needed to fully reflect the time and resources associated with providing this care. A few commenters stated that CMS should create an add-on code for HCPCS code G0507 to account for any additional time.

Response: We proposed HCPCS code G0507 to make separate payment for other kinds of BHI and we are concerned that an increased time threshold may not be typical across the range of services captured by G0507 and may present an additional barrier to appropriate utilization for some models of care. We continue to be interested in information from stakeholders regarding other models of BHI, including those that have longer associated times than are accurately captured by HCPCS code G0507.

Comment: A few commenters recommended that CMS include the same clinical staff in HCPCS code G0507 as is included in HCPCS codes G0502, G0503, and G0504 because the complexity in care management would likely to be consistent across all four codes.

Response: We agree with commenters, and will finalize 20 minutes of behavioral health care manager, L057B, time for HCPCS code G0507.

After considering these comments, we are finalizing a total work RVU of 0.61 for G0507.

(63) Comprehensive Assessment and Care Planning for Patients With Cognitive Impairment (HCPCS Code G0505)

For CY 2017, we proposed to create and pay separately for new HCPCS code G0505 (Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history face-to-face obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home), see II.E for further discussion. Based on similarities between work intensity and time, we believe that the physician work and time for this code would be accurately valued by combining the work RVUs from CPT code 99204 (Level 4 office or other outpatient visit for the evaluation and

management of a new patient) and half the work RVUs for HCPCS code G0181 (Physician supervision of a patient receiving Medicare-covered services furnished by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved in the patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month, 30 minutes or more). Therefore, we proposed a work RVU of 3.30.

For direct PE inputs we proposed 70 total minutes of time for RN/LPN/MTA (L037D). We believed this was typical based on information from several specialty societies representing practitioners who typically furnish this service and report, it, when appropriate, using E/M codes. We solicited comment on these valuation assumptions and welcomed additional information on the work and direct PE associated with furnishing this service.

Comment: One commenter stated that to more accurately reflect the reality of the case complexity involved in assessment and care planning for patients with cognitive impairment, that the work RVU should be based on at least a Level 5 office visit with recognition that the work required is likely 1.5 times to two times greater than a Level 5 visit. Furthermore, the commenter stated that 120 minutes was a more appropriate time value. Many other commenters encouraged CMS to accept the RUC-recommended values for this code, presented at the April 2016 RUC meeting. The AMA RUC submitted the recommendation of a work RVU of 3.44 as part of its public comment.

Response: After reviewing values recommended by the RUC in its comment, we are persuaded that many elements of its valuation accurately capture the resource costs associated with the provision of this service. Therefore, we are finalizing the physician work and time values in consideration of these comments as recommended. We are finalizing a work RVU of 3.44 as recommended by the RUC. We are removing 2 minutes of the 6 recommended clinical staff time for the task ''Gather and review X-ray, lab, pathology reports and prepare for physician review; conduct initial phone call for preliminary assessment of cognitive function; identify caregiver and explain assessment'' as we believe 4 minutes is a more typical time associated with this task.

(64) Comprehensive Assessment and Care Planning for Patients Requiring Chronic Care Management (HCPCS Code G0506)

For CY 2017, we proposed to make payment for the resource costs of comprehensive assessment and care planning for patients requiring CCM services through HCPCS code G0506 as an add-on code to be billed with the initiating visit for CCM for patients that require extensive assessment and care planning (see section II.E). In valuing this code, we believed that a crosswalk to half the work and time values of HCPCS code G0181 (Physician supervision of a patient receiving Medicare-covered services provided by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved in the patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month, 30 minutes or more) accurately accounts for the time and intensity of the work associated with furnishing this service over and above the work accounted for as part of the separately billed initiating visit. Therefore, we proposed a work RVU of 0.87 and 29 minutes of physician time. We also proposed 36 minutes for a RN/LPN/MTA (L037D) as the only direct PE input for this service.

Comment: Many commenters supported the proposed work and PE values.

Response: We thank commenters for supporting physician work and PE inputs for G0506 and we are finalizing as proposed.

(65) Telehealth Consultation for a Patient Requiring Critical Care Services (HCPCS Codes G0508and G0509)

As discussed in section II.C, we proposed use of new HCPCS G-codes, G0508 (Telehealth consultation, critical care, physicians typically spend 60 minutes communicating with the patient via telehealth (initial) and G0509 (Telehealth consultation, critical care, physicians typically spend 50 minutes communicating with the patient via telehealth (subsequent)), to report telehealth consultations for a patient requiring critical care services, such as a stroke patient. We noted that due to limited coding granularity for high-intensity cognitive services, in the PFS, we did not believe there is an intuitive crosswalk code for ideal estimation of the work and time values for G0508. In general, we believed that the overall work for G0508 is not as great as 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) but that the service involves more work than HCPCS code G0427 (Telehealth consultation, emergency department or initial inpatient, typically 70 minutes or more communicating with the patient via telehealth). We believe that G0508 is most accurately valued by a crosswalk to the work RVU and physician intra-service time of CPT code 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor). Therefore, we proposed a work RVU of 4.0 and solicited comment on the accuracy of these assumptions. We did not believe that direct PE inputs would typically be involved with furnishing this service from the distant site. For G0509 we proposed a work RVU of 3.86 based on a crosswalk from G0427. We believed that G0427 has similar overall work intensity to G0509 and has a similar intraservice time. We also believed that no direct PE inputs would typically be associated with furnishing this service from the distant site.

Comment: Many commenters supported the proposal, saying the codes will improve patient outcomes and quality of care.

Response: We thank commenters for their support. We are finalizing the work RVUs for new HCPCS codes G0508 and G0509 as proposed.

Comment: A few commenters encouraged CMS to recognize critical care as a telehealth service rather than create G-codes to facilitate payment. Commenters also stated that the complex nature of patients requiring critical care services necessitates the codes be billed more than once per day.

Response: We continue to believe that the telehealth consultation model, including the limit on billing more than once per day, is more appropriate than the model used to describe the in-person critical care E/Ms. In general we believe that the complex nature of patients requiring critical care is described by in-person critical care E/Ms, which includes services that cannot be furnished via remote communication technology. Furthermore, we believe that the telehealth consultation model, including the limit on billing more than

once per day, appropriately captures the kind of work described as remote, critical consultations for critical care patients.

Comment: A few commenters suggested that CMS clarify that the consulting doctor could communicate with staff or family members if the patient was unable to communicate.

Response: We appreciate the comments and, in order to make it clear that the consultation could include conversations with other providers and caregivers if the patient is unable to communicate, we will finalize the following code descriptors:

- G0508: Telehealth consultation, critical care, physicians typically spend 60 minutes communicating with the patient and providers via telehealth (initial).
- G0509: Telehealth consultation, critical care, physicians typically spend 50 minutes communicating with the patient and providers via telehealth (subsequent).

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
00740	Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum.	0.00	0.00	0.00	No.
00810	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum.	0.00	0.00	0.00	No.
10035	Placement of soft tissue localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; first lesion.	1.70	1.70	1.70	No.
10036	Placement of soft tissue localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; each additional lesion.	0.85	0.85	0.85	No.
11730	Avulsion of nail plate, partial or complete, simple; single ...	1.10	1.05	1.05	No.
11732	Avulsion of nail plate, partial or complete, simple; each additional nail plate.	0.44	0.38	0.38	Yes.
20245	Biopsy, bone, open; deep (eg, humerus, ischium, femur) ..	8.95	6.00	6.00	No.
20550	Injection(s); single tendon sheath, or ligament, aponeurosis (eg, plantar ''fascia'').	0.75	0.75	0.75	No.
20552	Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s).	0.66	0.66	0.66	No.
20553	Injection(s); single or multiple trigger point(s), 3 or more muscles.	0.75	0.75	0.75	No.
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges) when performed to intervertebral disc space in conjunction with interbody arthrodesis, each interspace.	NEW	4.25	4.25	No.
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges) when performed to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect.	NEW	5.50	5.50	No.
22859	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect.	NEW	5.50	5.50	No.
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level.	NEW	13.50	13.50	No.
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level.	NEW	4.00	4.00	No.
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level.	NEW	7.03	7.03	No.
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level.	NEW	2.34	2.34	No.
26356	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (eg, no man's land); primary, without free graft, each tendon.	9.56	9.56	9.56	No.
26357	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (eg, no man's land); secondary, without free graft, each tendon.	10.53	11.00	11.00	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
26358	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (eg, no man's land); secondary, with free graft (includes obtaining graft), each tendon.	12.13	12.60	12.60	No.
27197	Closed treatment of posterior pelvic ring fracture(s), dislocation(s), diastasis or subluxation of the ilium, sacroiliac joint, and/or sacrum, with or without anterior pelvic ring fracture(s) and/or dislocation(s) of the pubic symphysis and/or superior/inferior rami, unilateral or bilateral; without manipulation.	NEW	1.53	1.53	Yes.
27198	Closed treatment of posterior pelvic ring fracture(s), dislocation(s), diastasis or subluxation of the ilium, sacroiliac joint, and/or sacrum, with or without anterior pelvic ring fracture(s) and/or dislocation(s) of the pubic symphysis and/or superior/inferior rami, unilateral or bilateral; with manipulation, requiring more than local anesthesia (i.e., general anesthesia, moderate sedation, spinal/epidural).	NEW	4.75	4.75	Yes.
28289	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint.	8.31	6.90	6.90	No.
28291	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant.	NEW	7.81	8.01	No.
28292	Correction, hallux valgus (bunion), with or without sesamoidectomy; Keller, McBride, or Mayo type procedure.	9.05	7.44	7.44	No.
28295	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal metatarsal osteotomy, any method.	NEW	8.25	8.57	No.
28296	Correction, hallux valgus (bunion), with or without sesamoidectomy; with metatarsal osteotomy (eg, Mitchell, Chevron, or concentric type procedures).	8.35	8.25	8.25	No.
28297	Correction, hallux valgus (bunion), with or without sesamoidectomy; Lapidus-type procedure.	9.43	9.29	9.29	No.
28298	Correction, hallux valgus (bunion), with or without sesamoidectomy; by phalanx osteotomy.	8.13	7.75	7.75	No.
28299	Correction, hallux valgus (bunion), with or without sesamoidectomy; by double osteotomy.	11.57	9.29	9.29	No.
31500	Intubation, endotracheal, emergency procedure	2.33	2.66	3.00	No.
31551	Laryngoplasty; for laryngeal stenosis, with graft, without indwelling stent placement, younger than 12 years of age.	NEW	21.50	21.50	No.
31552	Laryngoplasty; for laryngeal stenosis, with graft, without indwelling stent placement, age 12 years or older.	NEW	20.50	20.50	No.
31553	Laryngoplasty; for laryngeal stenosis, with graft, with indwelling stent placement, younger than 12 years of age.	NEW	22.00	22.00	No.
31554	Laryngoplasty; for laryngeal stenosis, with graft, with indwelling stent placement, age 12 years or older.	NEW	22.00	22.00	No.
31572	Laryngoscopy, flexible; with ablation or destruction of lesion(s) with laser, unilateral.	NEW	3.01	3.01	No.
31573	Laryngoscopy, flexible; with therapeutic injection(s) (eg, chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral.	NEW	2.43	2.43	No.
31574	Laryngoscopy, flexible; with injection(s) for augmentation (eg, percutaneous, transoral), unilateral.	NEW	2.43	2.43	No.
31575	Laryngoscopy, flexible fiberoptic; diagnostic	1.10	0.94	0.94	No.
31576	Laryngoscopy, flexible fiberoptic; with biopsy	1.97	1.89	1.89	No.
31577	Laryngoscopy, flexible fiberoptic; with removal of foreign body.	2.47	2.19	2.19	No.
31578	Laryngoscopy, flexible fiberoptic; with removal of lesion	2.84	2.43	2.43	No.
31579	Laryngoscopy, flexible or rigid fiberoptic, with stroboscopy	2.26	1.88	1.88	No.
31580	Laryngoplasty; for laryngeal web, 2-stage, with keel insertion and removal.	14.66	14.60	14.60	No.
31584	Laryngoplasty; with open reduction of fracture	20.47	17.58	17.58	No.
31587	Laryngoplasty, cricoid split	15.27	15.27	15.27	No.
31591	Laryngoplasty, medialization; unilateral	NEW	13.56	13.56	No.
31592	Cricotracheal resection	NEW	25.00	25.00	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation.	NEW	13.00	14.00	No.
33390	Valvuloplasty, aortic valve, open, with cardiopulmonary bypass; simple (i.e., valvotomy, debridement, debulking and/or simple commissural resuspension).	NEW	35.00	35.00	No.
33391	Valvuloplasty, aortic valve, open, with cardiopulmonary bypass; complex (eg, leaflet extension, leaflet resection, leaflet reconstruction or annuloplasty).	NEW	41.50	41.50	No.
36440	Push transfusion, blood, 2 years or younger	1.03	1.03	1.03	No.
36450	Exchange transfusion, blood; newborn	2.23	3.50	3.50	No.
36455	Exchange transfusion, blood; other than newborn	2.43	2.43	2.43	No.
36456	Partial exchange transfusion, blood, plasma or crystalloid necessitating the skill of a physician or other qualified health care professional, newborn.	NEW	2.00	2.00	No.
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated.	NEW	3.50	3.50	No.
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites.	NEW	1.75	1.75	No.
36901	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiologic supervision and interpretation and image documentation and report.	NEW	2.82	2.82	No.
36902	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiologic supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty.	NEW	4.24	4.24	No.
36903	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiologic supervision and interpretation and image documentation and report; with transcatheter placement of intravascular stent(s) peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment.	NEW	5.85	5.85	No.
36904	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s).	NEW	6.73	6.73	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
36905	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty.	NEW	8.46	8.46	No.
36906	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transcatheter placement of an intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation to perform the stenting and all angioplasty within the peripheral dialysis circuit.	NEW	9.88	9.88	No.
36907	Transluminal balloon angioplasty, central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the angioplasty.	NEW	2.48	2.48	No.
36908	Transcatheter placement of an intravascular stent(s), central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the stenting, and all angioplasty in the central dialysis segment.	NEW	3.73	3.73	No.
36909	Dialysis circuit permanent vascular embolization or occlusion (including main circuit or any accessory veins), endovascular, including all imaging and radiological supervision and interpretation necessary to complete the intervention.	NEW	3.48	3.48	No.
37246	Transluminal balloon angioplasty (except lower extremity artery(s) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; initial artery.	NEW	7.00	7.00	No.
37247	Transluminal balloon angioplasty (except lower extremity artery(s) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; each additional artery.	NEW	3.50	3.50	No.
37248	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein.	NEW	6.00	6.00	No.
37249	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; each additional vein.	NEW	2.97	2.97	No.
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session.	3.50	3.50	3.50	No.
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed.	7.75	7.75	7.75	No.
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed.	NEW	9.03	10.13	No.
43285	Removal of esophageal sphincter augmentation device	NEW	9.37	10.47	No.
47531	Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; existing access.	1.80	1.30	1.30	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
47532	Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access (eg, percutaneous transhepatic cholangiogram).	4.25	4.25	4.25	No.
47533	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; external.	6.00	5.38	5.38	No.
47534	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; internal-external.	8.03	7.60	7.60	No.
47535	Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy), and all associated radiological supervision and interpretation.	4.50	3.95	3.95	No.
47536	Exchange of biliary drainage catheter (eg, external, internal-external, or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy), and all associated radiological supervision and interpretation.	2.88	2.61	2.61	No.
47537	Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (eg, with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy), and all associated radiological supervision and interpretation.	1.83	1.84	1.84	No.
47538	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange(s) and catheter removal(s) when performed, and all associated radiological supervision and interpretation, each stent; existing access.	6.60	4.75	4.75	No.
47539	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange(s) and catheter removal(s) when performed, and all associated radiological supervision and interpretation, each stent; new access, without placement of separate biliary drainage catheter.	9.00	8.75	8.75	No.
47540	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange(s) and catheter removal(s) when performed, and all associated radiological supervision and interpretation, each stent; new access, with placement of separate biliary drainage catheter (eg, external or internal-external).	10.75	9.03	9.03	No.
47541	Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation, new access.	5.61	5.38	6.75	No.
47542	Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (eg, fluoroscopy), and all associated radiological supervision and interpretation, each duct.	2.50	2.85	2.85	No.
47543	Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps, and/or needle), including imaging guidance (eg, fluoroscopy), and all associated radiological supervision and interpretation, single or multiple.	3.07	3.00	3.00	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
47544	Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy), and all associated radiological supervision and interpretation.	4.29	3.28	3.28	No.
49185	Sclerotherapy of a fluid collection (eg, lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic study, imaging guidance (eg, ultrasound, fluoroscopy) and radiological supervision and interpretation when performed.	2.35	2.35	2.35	No.
50606	Endoluminal biopsy of ureter and/or renal pelvis, non-endoscopic, including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	3.16	3.16	3.16	No.
50705	Ureteral embolization or occlusion, including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	4.03	4.03	4.03	No.
50706	Balloon dilation, ureteral stricture, including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	3.80	3.80	3.80	No.
51700	Bladder irrigation, simple, lavage and/or instillation	0.88	0.60	0.60	No.
51701	Insertion of non-indwelling bladder catheter (eg, straight catheterization for residual urine).	0.50	0.50	0.50	No.
51702	Insertion of temporary indwelling bladder catheter; simple (eg, Foley).	0.50	0.50	0.50	No.
51703	Insertion of temporary indwelling bladder catheter; complicated (eg, altered anatomy, fractured catheter/balloon).	1.47	1.47	1.47	No.
51720	Bladder instillation of anticarcinogenic agent (including retention time).	1.50	0.87	0.87	No.
51784	Electromyography studies (EMG) of anal or urethral sphincter, other than needle, any technique.	1.53	0.75	0.75	No.
52000	Cystourethroscopy (separate procedure)	2.23	1.53	1.53	No.
55700	Biopsy, prostate; needle or punch, single or multiple, any approach.	2.58	2.06	2.50	No.
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed.	21.36	21.36	26.80	No.
58555	Hysteroscopy, diagnostic (separate procedure)	3.33	2.65	2.65	No.
58558	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C.	4.74	4.17	4.17	No.
58559	Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method).	6.16	5.20	5.20	No.
58560	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method).	6.99	5.75	5.75	No.
58561	Hysteroscopy, surgical; with removal of leiomyomata	9.99	6.60	6.60	No.
58562	Hysteroscopy, surgical; with removal of impacted foreign body.	5.20	4.00	4.00	No.
58563	Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation).	6.16	4.47	4.47	No.
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency.	NEW	14.08	14.08	No.
61640	Balloon dilatation of intracranial vasospasm, percutaneous; initial vessel.	N	N	N	No.
61641	Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in same vascular family.	N	N	N	No.
61642	Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in different vascular family.	N	N	N	No.
61645	Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s).	15.00	15.00	15.00	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
61650	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; initial vascular territory.	10.00	10.00	10.00	No.
61651	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; each additional vascular territory.	4.25	4.25	4.25	No.
62320	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance.	NEW	1.80	1.80	No.
62321	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (i.e., fluoroscopy or CT).	NEW	1.95	1.95	No.
62322	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance.	NEW	1.55	1.55	No.
62323	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (i.e., fluoroscopy or CT).	NEW	1.80	1.80	No.
62324	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance.	NEW	1.89	1.89	No.
62325	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (i.e., fluoroscopy or CT).	NEW	2.20	2.20	No.
62326	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance.	NEW	1.78	1.78	No.
62327	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (i.e., fluoroscopy or CT).	NEW	1.90	1.90	No.
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar.	NEW	9.09	C	No.
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	1.75	1.75	1.75	No.
64462	Paravertebral block (PVB) (paraspinous block), thoracic; second and any additional injection site(s) (includes imaging guidance, when performed).	1.10	1.10	1.10	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
64463	Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed).	1.81	1.81	1.90	No.
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve.	2.36	2.36	2.36	No.
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve).	2.32	2.32	2.32	No.
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming.	0.60	0.60	0.60	No.
65778	Placement of amniotic membrane on the ocular surface; without sutures.	1.00	1.00	1.00	No.
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured.	2.50	2.50	2.50	No.
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers.	7.81	7.81	7.81	No.
65855	Trabeculoplasty by laser surgery	2.66	3.00	3.00	No.
66170	Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery.	11.27	13.94	13.94	No.
66172	Fistulization of sclera for glaucoma; trabeculectomy ab externo with scarring from previous ocular surgery or trauma (includes injection of antifibrotic agents).	12.57	14.84	14.84	No.
67101	Repair of retinal detachment, 1 or more sessions; cryotherapy or diathermy, including drainage of subretinal fluid, when performed.	8.80	3.50	3.50	No.
67105	Repair of retinal detachment, 1 or more sessions; photocoagulation, including drainage of subretinal fluid, when performed.	8.53	3.39	3.39	No.
67107	Repair of retinal detachment; scleral buckling (such as lamellar scleral dissection, imbrication or encircling procedure), including, when performed, implant, cryotherapy, photocoagulation, and drainage of subretinal fluid.	14.06	16.00	16.00	No.
67108	Repair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique.	15.19	17.13	17.13	No.
67110	Repair of retinal detachment; by injection of air or other gas (eg, pneumatic retinopexy).	8.31	10.25	10.25	No.
67113	Repair of complex retinal detachment (eg, proliferative vitreoretinopathy, stage C–1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, including, when performed, air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens.	19.00	19.00	19.00	No.
67227	Destruction of extensive or progressive retinopathy (eg, diabetic retinopathy), cryotherapy, diathermy.	3.50	3.50	3.50	No.
67228	Treatment of extensive or progressive retinopathy (eg, diabetic retinopathy), photocoagulation.	4.39	4.39	4.39	No.
70540	Magnetic resonance (eg, proton) imaging, orbit, face, and/or neck; without contrast material(s).	1.35	1.35	1.35	No.
70542	Magnetic resonance (eg, proton) imaging, orbit, face, and/or neck; with contrast material(s).	1.62	1.62	1.62	No.
70543	Magnetic resonance (eg, proton) imaging, orbit, face, and/or neck; without contrast material(s), followed by contrast material(s) and further sequences.	2.15	2.15	2.15	No.
72170	Radiologic examination, pelvis; 1 or 2 views	0.17	0.17	0.17	No.
73501	Radiologic examination, hip, unilateral, with pelvis when performed; 1 view.	0.18	0.18	0.18	No.
73502	Radiologic examination, hip, unilateral, with pelvis when performed; 2–3 views.	0.22	0.22	0.22	No.
73503	Radiologic examination, hip, unilateral, with pelvis when performed; minimum of 4 views.	0.27	0.27	0.27	No.
73521	Radiologic examination, hips, bilateral, with pelvis when performed; 2 views.	0.22	0.22	0.22	No.
73522	Radiologic examination, hips, bilateral, with pelvis when performed; 3–4 views.	0.29	0.29	0.29	No.
73523	Radiologic examination, hips, bilateral, with pelvis when performed; minimum of 5 views.	0.31	0.31	0.31	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
73551	Radiologic examination, femur; 1 view	0.16	0.16	0.16	No.
73552	Radiologic examination, femur; minimum 2 views	0.18	0.18	0.18	No.
74712	Magnetic resonance (eg, proton) imaging, fetal, including placental and maternal pelvic imaging when performed; single or first gestation.	3.00	3.00	3.00	No.
74713	Magnetic resonance (eg, proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional gestation.	1.78	1.85	1.85	No.
76706	Ultrasound, abdominal aorta, real time with image documentation, screening study for abdominal aortic aneurysm.	NEW	0.55	0.55	No.
77001	Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position).	0.38	0.38	0.38	No.
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device).	0.54	0.38	0.54	No.
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid).	0.60	0.38	0.60	No.
77065/G0206	Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral.	NEW	0.81	0.81	No.
77066/G0204	Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral.	NEW	1.00	1.00	No.
77067/G0202	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed.	NEW	0.76	0.76	No.
77332	Treatment devices, design and construction; simple (simple block, simple bolus).	0.54	0.45	0.45	No.
77333	Treatment devices, design and construction; intermediate (multiple blocks, stents, bite blocks, special bolus).	0.84	0.75	0.75	No.
77334	Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts).	1.24	1.15	1.15	No.
77470	Special treatment procedure (eg, total body irradiation, hemibody radiation, per oral or endocavitary irradiation).	2.09	2.03	2.03	No.
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed.	8.00	8.00	8.78	No.
77790	Supervision, handling, loading of radiation source	0.00	0.00	0.00	No.
78264	Gastric emptying imaging study (eg, solid, liquid, or both)	0.74	0.79	0.79	No.
78265	Gastric emptying imaging study (eg, solid, liquid, or both); with small bowel transit.	0.98	0.98	0.98	No.
78266	Gastric emptying imaging study (eg, solid, liquid, or both); with small bowel and colon transit, multiple days.	1.08	1.08	1.08	No.
88104	Cytopathology, fluids, washings or brushings, except cervical or vaginal; smears with interpretation.	0.56	0.56	0.56	No.
88106	Cytopathology, fluids, washings or brushings, except cervical or vaginal; simple filter method with interpretation.	0.37	0.37	0.37	No.
88108	Cytopathology, concentration technique, smears and interpretation (eg, Saccomanno technique).	0.44	0.44	0.44	No.
88112	Cytopathology, selective cellular enhancement technique with interpretation (eg, liquid based slide preparation method), except cervical or vaginal.	0.56	0.56	0.56	No.
88160	Cytopathology, smears, any other source; screening and interpretation.	0.50	0.50	0.50	No.
88161	Cytopathology, smears, any other source; preparation, screening and interpretation.	0.50	0.50	0.50	No.
88162	Cytopathology, smears, any other source; extended study involving over 5 slides and/or multiple stains.	0.76	0.76	0.76	No.
88184	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker.	0.00	0.00	0.00	No.
88185	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker.	0.00	0.00	0.00	No.
88187	Flow cytometry, interpretation; 2 to 8 markers	1.36	0.74	0.74	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
88188	Flow cytometry, interpretation; 9 to 15 markers	1.69	1.20	1.20	No.
88189	Flow cytometry, interpretation; 16 or more markers	2.23	1.70	1.70	No.
88321	Consultation and report on referred slides prepared elsewhere.	1.63	1.63	1.63	No.
88323	Consultation and report on referred material requiring preparation of slides.	1.83	1.83	1.83	No.
88325	Consultation, comprehensive, with review of records and specimens, with report on referred material.	2.50	2.85	2.85	No.
88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure).	0.53	0.56	0.56	No.
88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure.	0.70	0.70	0.70	No.
88344	Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure.	0.77	0.77	0.77	No.
88350	Immunofluorescence, per specimen; each additional single antibody stain procedure.	0.56	0.59	0.59	No.
88364	In situ hybridization (eg, FISH), per specimen; each additional single probe stain procedure.	0.67	0.70	0.70	No.
88369	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each additional single probe stain procedure.	0.67	0.70	0.70	No.
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report.	3.64	2.49	2.49	No.
91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report.	1.00	1.00	1.00	No.
91200	Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report.	0.27	0.27	0.27	No.
92132	Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral.	0.35	0.30	0.30	No.
92133	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve.	0.50	0.40	0.40	No.
92134	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; retina.	0.50	0.45	0.45	No.
92235	Fluorescein angiography (includes multiframe imaging) with interpretation and report.	0.81	0.75	0.75	No.
92240	Indocyanine-green angiography (includes multiframe imaging) with interpretation and report.	1.10	0.80	0.80	No.
92250	Fundus photography with interpretation and report	0.44	0.40	0.40	No.
92242	Fluorescein angiography and indocyanine-green angiography (includes multiframe imaging) performed at the same patient encounter with interpretation and report, unilateral or bilateral.	NEW	0.95	0.95	No.
93050	Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, non-invasive.	0.17	0.17	0.17	No.
93590	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve.	NEW	18.23	21.70	No.
93591	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve.	NEW	14.50	17.97	No.
93592	Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (list separately in addition to code for primary service).	NEW	6.81	8.00	No.
95144	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single dose vial(s) (specify number of vials).	0.06	0.06	0.06	No.
95165	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses).	0.06	0.06	0.06	No.
95812	Electroencephalogram (EEG) extended monitoring; 41–60 minutes.	1.08	1.08	1.08	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
95813	Electroencephalogram (EEG) extended monitoring; greater than 1 hour.	1.73	1.63	1.63	No.
95957	Digital analysis of electroencephalogram (EEG) (eg, for epileptic spike analysis).	1.98	1.98	1.98	No.
95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.	0.78	0.78	0.78	No.
95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.	0.80	0.80	0.80	No.
96160	Administration of patient-focused health risk assessment instrument (eg, health hazard appraisal) with scoring and documentation, per standardized instrument.	NEW	0.00	0.00	No.
96161	Administration of caregiver-focused health risk assessment instrument (eg, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument.	NEW	I	0.00	No.
96931	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, first lesion.	0.00	0.75	0.80	No.
96932	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition only, first lesion.	0.00	0.00	0.00	No.
96933	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, first lesion.	0.00	0.75	0.80	No.
96934	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, each additional lesion.	0.00	0.71	0.76	No.
96935	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition only, each additional lesion.	0.00	0.00	0.00	No.
96936	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion.	0.00	0.71	0.76	No.
97161	Physical therapy evaluation; low complexity	NEW	1.20	1.20	Yes.
97162	Physical therapy evaluation; moderate complexity	NEW	1.20	1.20	No.
97163	Physical therapy evaluation; high complexity	NEW	1.20	1.20	Yes.
97164	Reevaluation of physical therapy established plan of care	NEW	0.60	0.75	No.
97165	Occupational therapy evaluation; low complexity	NEW	1.20	1.20	Yes.
97166	Occupational therapy evaluation; moderate complexity	NEW	1.20	1.20	No.
97167	Occupational therapy evaluation; high complexity	NEW	1.20	1.20	Yes.
97168	Reevaluation of occupational therapy care/established plan of care.	NEW	0.60	0.75	No.
99151	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient younger than 5 years of age.	NEW	0.50	0.50	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
99152	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time, patient age 5 years or older.	NEW	0.25	0.25	No.
99153	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; each additional 15 minutes of intra-service time.	NEW	0.00	0.00	No.
99155	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intra-service time, patient younger than 5 years of age.	NEW	1.90	1.90	No.
99156	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 minutes of intra-service time, patient age 5 years or older.	NEW	1.65	1.65	No.
99157	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; each additional 15 minutes intra-service time.	NEW	1.25	1.25	No.
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.	1.77	2.33	2.33	No.
99358	Prolonged evaluation and management service before and/or after direct patient care; first hour.	2.10	2.10	2.10	No.
99359	Prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes.	1.00	1.00	1.00	No.
99487	Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or substantial revision of a comprehensive care plan, moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month;	0.00	1.00	1.00	No.
99489	Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or substantial revision of a comprehensive care plan, moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.	0.00	0.50	0.50	No.
G0416	Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method.	3.09	3.60	3.60	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
G0500	Moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service that sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time; patient age 5 years or older. (additional time may be reported with 99153, as appropriate).	NEW	0.10	0.10	No.
G0501	Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lift, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient, evaluation and management visit. (List separately in addition to primary service).	NEW	0.48	B	No.
G0502	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	1.59	1.70	No.
G0503	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	1.42	1.53	No.

TABLE 27—FINALIZED CY 2017 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long Descriptor	CY 2016 Work RVU	Proposed CY 2017 Work RVU	Final CY 2017 Work RVU	CMS Work time refinement
G0504	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 (List separately in addition to code for primary procedure). (Use GPPP3 in conjunction with GPPP1, GPPP2).	NEW	0.71	0.82	No.
G0505	Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home.	NEW	3.30	3.44	Yes.
G0506	Comprehensive assessment of and care planning for patients requiring chronic care management services. (List separately in addition to primary monthly care management service).	NEW	0.87	0.87	No.
G0507	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.
G0508	Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth.	NEW	4.00	4.00	No.
G0509	Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth.	NEW	3.86	3.86	No.

TABLE 28—CY 2017 FINAL RULE DIRECT PE REFINEMENT TABLE

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change
11732	Remove nail plate add-on	EF015	mayo stand	NF	.....	0	8	G1: See preamble text	0.01
11732	Remove nail plate add-on	EF031	table, power	NF	.....	7	8	E15: Refined equipment time to conform to changes in clinical labor time.	0.02
11732	Remove nail plate add-on	EQ137	instrument pack, basic ($500–$1499).	NF	.....	0	8	G1: See preamble text	0.02
11732	Remove nail plate add-on	EQ168	light, exam	NF	.....	7	8	E15: Refined equipment time to conform to changes in clinical labor time.	0.00
11732	Remove nail plate add-on	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure.	7	8	G1: See preamble text	0.37
11732	Remove nail plate add-on	SC031	needle, 30g	NF	.....	1	0	S9: Add-on code. Additional supplies not typical; see preamble text.	−0.34
11732	Remove nail plate add-on	SC051	syringe 10–12ml	NF	.....	1	0	S9: Add-on code. Additional supplies not typical; see preamble text.	−0.18
11732	Remove nail plate add-on	SG067	penrose drain (0.25in x 4in)	NF	.....	1	0	S9: Add-on code. Additional supplies not typical; see preamble text.	−0.50
11732	Remove nail plate add-on	SH047	lidocaine 1%–2% inj (Xylocaine)	NF	.....	10	0	S9: Add-on code. Additional supplies not typical; see preamble text.	−0.35
11732	Remove nail plate add-on	SH064	silver sulfadiazene cream (Silvadene).	NF	.....	0.5	0	S9: Add-on code. Additional supplies not typical; see preamble text.	−0.08
11732	Remove nail plate add-on	SJ053	swab-pad, alcohol	NF	.....	2	1	S9: Add-on code. Additional supplies not typical; see preamble text.	−0.01
27197	Clsd tx pelvic ring fx	L037D	RN/LPN/MTA	F	99212 27 minutes	2	0	G1: See preamble text	−19.98
27197	Clsd tx pelvic ring fx	L037D	RN/LPN/MTA	F	99213 36 minutes	1	0	G1: See preamble text	−13.32
27198	Clsd tx pelvic ring fx	L037D	RN/LPN/MTA	F	99212 27 minutes	1	0	G1: See preamble text	−9.99
27198	Clsd tx pelvic ring fx	L037D	RN/LPN/MTA	F	99213 36 minutes	2	0	G1: See preamble text	−26.64
31551	Laryngoplasty laryngeal sten.	EQ137	instrument pack, basic ($500–$1499).	F	.....	138	129	E5: Refined equipment time to conform to established policies for surgical instrument packs.	−0.02
31551	Laryngoplasty laryngeal sten.	EQ167	light source, xenon	F	.....	0	108	E13: Equipment item replaces another item; see preamble text EQ170.	3.00
31551	Laryngoplasty laryngeal sten.	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	F	.....	0	108	E19: Refined equipment time to conform to established policies for scope accessories.	13.97
31551	Laryngoplasty laryngeal sten.	ES060	Video-flexible laryngoscope system.	F	.....	198	0	G1: See preamble text	−62.98
31551	Laryngoplasty laryngeal sten.	ES063	rhinolaryngoscope, flexible, video, non-channeled.	F	.....	0	189	E4: Refined equipment time to conform to established policies for scopes.	8.76
31552	Laryngoplasty laryngeal sten.	EQ137	instrument pack, basic ($500–$1499).	F	.....	138	129	E5: Refined equipment time to conform to established policies for surgical instrument packs.	−0.02
31552	Laryngoplasty laryngeal sten.	EQ167	light source, xenon	F	.....	0	108	E13: Equipment item replaces another item; see preamble text EQ170.	3.00
31552	Laryngoplasty laryngeal sten.	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	F	.....	0	108	E19: Refined equipment time to conform to established policies for scope accessories.	13.97
31552	Laryngoplasty laryngeal sten.	ES060	Video-flexible laryngoscope system.	F	.....	198	0	G1: See preamble text	−62.98
31552	Laryngoplasty laryngeal sten.	ES063	rhinolaryngoscope, flexible, video, non-channeled.	F	.....	0	189	E4: Refined equipment time to conform to established policies for scopes.	8.76
31553	Laryngoplasty laryngeal sten.	EQ137	instrument pack, basic ($500–$1499).	F	.....	138	129	E5: Refined equipment time to conform to established policies for surgical instrument packs.	−0.02

TABLE 28—CY 2017 FINAL RULE DIRECT PE REFINEMENT TABLE—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change
31553	Laryngoplasty laryngeal sten.	EQ167	light source, xenon	F	.....	0	108	E13: Equipment item replaces another item; see preamble text EQ170.	3.00
31553	Laryngoplasty laryngeal sten.	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	F	.....	0	108	E19: Refined equipment time to conform to established policies for scope accessories.	13.97
31553	Laryngoplasty laryngeal sten.	ES060	Video-flexible laryngoscope system.	F	.....	198	0	G1: See preamble text	−62.98
31553	Laryngoplasty laryngeal sten.	ES063	rhinolaryngoscope, flexible, video, non-channeled.	F	.....	0	189	E4: Refined equipment time to conform to established policies for scopes.	8.76
31554	Laryngoplasty laryngeal sten.	EQ137	instrument pack, basic ($500–$1499).	F	.....	138	129	E5: Refined equipment time to conform to established policies for surgical instrument packs.	−0.02
31554	Laryngoplasty laryngeal sten.	EQ167	light source, xenon	F	.....	0	108	E13: Equipment item replaces another item; see preamble text EQ170.	3.00
31554	Laryngoplasty laryngeal sten.	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	F	.....	0	108	E19: Refined equipment time to conform to established policies for scope accessories.	13.97
31554	Laryngoplasty laryngeal sten.	ES060	Video-flexible laryngoscope system.	F	.....	198	0	G1: See preamble text	−62.98
31554	Laryngoplasty laryngeal sten.	ES063	rhinolaryngoscope, flexible, video, non-channeled.	F	.....	0	189	E4: Refined equipment time to conform to established policies for scopes.	8.76
31572	Largsc w/laser dstrj les	EQ167	light source, xenon	NF	.....	0	38	E19: Refined equipment time to conform to established policies for scope accessories.	1.05
31572	Largsc w/laser dstrj les	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	0	38	E19: Refined equipment time to conform to established policies for scope accessories.	4.92
31572	Largsc w/laser dstrj les	ES061	Video-flexible channeled laryngoscope system.	NF	.....	59	0	G1: See preamble text	−14.89
31572	Largsc w/laser dstrj les	ES064	rhinolaryngoscope, flexible, video, channeled.	NF	.....	0	65	E4: Refined equipment time to conform to established policies for scopes.	3.39
31572	Largsc w/laser dstrj les	SF029	laser tip, bare (single use)	NF	.....	0	1	S8: Supply item replaces another item; see preamble SF030.	150.00
31572	Largsc w/laser dstrj les	SF030	laser tip, diffuser fiber	NF	.....	1	0	S7: Supply item replaced by another item; see preamble SF029.	−850.00
31573	Largsc w/ther injection	EQ167	light source, xenon	NF	.....	0	33	E19: Refined equipment time to conform to established policies for scope accessories.	0.92
31573	Largsc w/ther injection	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	0	33	E19: Refined equipment time to conform to established policies for scope accessories.	4.27
31573	Largsc w/ther injection	ES061	Video-flexible channeled laryngoscope system.	NF	.....	54	0	G1: See preamble text	−13.63
31573	Largsc w/ther injection	ES064	rhinolaryngoscope, flexible, video, channeled.	NF	.....	0	60	E4: Refined equipment time to conform to established policies for scopes.	3.13
31574	Largsc w/njx augmentation	EQ167	light source, xenon	NF	.....	0	33	E19: Refined equipment time to conform to established policies for scope accessories.	0.92
31574	Largsc w/njx augmentation	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	0	33	E19: Refined equipment time to conform to established policies for scope accessories.	4.27

31574	Largsc w/njx augmentation	ES060	Video-flexible laryngoscope system.	NF	.....	60	0	G1: See preamble text	−19.09	
31574	Largsc w/njx augmentation	ES063	rhinolaryngoscope, flexible, video, non-channeled.	NF	.....	0	60	E4: Refined equipment time to conform to established policies for scopes.	2.78	
31575	Diagnostic laryngoscopy ...	EF008	chair with headrest, exam, reclining.	NF	.....	23	21	E15: Refined equipment time to conform to changes in clinical labor time.	−0.02	
31575	Diagnostic laryngoscopy ...	EQ167	light source, xenon	NF	.....	0	18	E19: Refined equipment time to conform to established policies for scope accessories.	0.50	
31575	Diagnostic laryngoscopy ...	EQ170	light, fiberoptic headlight w-source.	NF	.....	23	21	E15: Refined equipment time to conform to changes in clinical labor time.	−0.02	
31575	Diagnostic laryngoscopy ...	EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	23	21	E15: Refined equipment time to conform to changes in clinical labor time.	−0.02	
31575	Diagnostic laryngoscopy ...	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	0	18	E19: Refined equipment time to conform to established policies for scope accessories.	2.33	
31575	Diagnostic laryngoscopy ...	ES060	Video-flexible laryngoscope system.	NF	.....	44	0	G1: See preamble text	−14.00	
31575	Diagnostic laryngoscopy ...	ES063	rhinolaryngoscope, flexible, video, non-channeled.	NF	.....	0	47	E4: Refined equipment time to conform to established policies for scopes.	2.18	
31575	Diagnostic laryngoscopy ...	L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff.	3	1	G1: See preamble text	−0.74	
31576	Laryngoscopy with biopsy	EQ167	light source, xenon	NF	.....	0	28	E19: Refined equipment time to conform to established policies for scope accessories.	0.78	
31576	Laryngoscopy with biopsy	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	0	28	E19: Refined equipment time to conform to established policies for scope accessories.	3.62	
31576	Laryngoscopy with biopsy	ES061	Video-flexible channeled laryngoscope system.	NF	.....	55	0	G1: See preamble text	−13.88	
31576	Laryngoscopy with biopsy	ES064	rhinolaryngoscope, flexible, video, channeled.	NF	.....	0	55	E4: Refined equipment time to conform to established policies for scopes.	2.87	
31577	Remove foreign body larynx.	EF008	chair with headrest, exam, reclining.	NF	.....	99	96	E15: Refined equipment time to conform to changes in clinical labor time.	−0.03	
31577	Remove foreign body larynx.	EF015	mayo stand	NF	.....	99	96	E15: Refined equipment time to conform to changes in clinical labor time.	0.00	
31577	Remove foreign body larynx.	EQ137	instrument pack, basic ($500–$1499).	NF	.....	40	39	E15: Refined equipment time to conform to changes in clinical labor time.	0.00	
31577	Remove foreign body larynx.	EQ167	light source, xenon	NF	.....	0	30	E19: Refined equipment time to conform to established policies for scope accessories.	0.83	
31577	Remove foreign body larynx.	EQ170	light, fiberoptic headlight w-source.	NF	.....	99	96	E15: Refined equipment time to conform to changes in clinical labor time.	−0.02	
31577	Remove foreign body larynx.	EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	99	96	E15: Refined equipment time to conform to changes in clinical labor time.	−0.03	
31577	Remove foreign body larynx.	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	0	30	E19: Refined equipment time to conform to established policies for scope accessories.	3.88	
31577	Remove foreign body larynx.	ES061	Video-flexible channeled laryngoscope system.	NF	.....	54	0	G1: See preamble text	−13.63	
31577	Remove foreign body larynx.	ES064	rhinolaryngoscope, flexible, video, channeled.	NF	.....	0	59	E4: Refined equipment time to conform to established policies for scopes.	3.08	

TABLE 28—CY 2017 FINAL RULE DIRECT PE REFINEMENT TABLE—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change
31577	Remove foreign body larynx.	L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff.	3	1	G1: See preamble text	−0.74
31577	Remove foreign body larynx.	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	2	L17: Clinical labor task redundant with clinical labor task "Assist physician in performing the procedure" (L041B).	−0.37
31578	Removal of larynx lesion ..	EQ167	light source, xenon	NF	.....	0	33	E19: Refined equipment time to conform to established policies for scope accessories.	0.92
31578	Removal of larynx lesion ..	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	0	33	E19: Refined equipment time to conform to established policies for scope accessories.	4.27
31578	Removal of larynx lesion ..	ES061	Video-flexible channeled laryngoscope system.	NF	.....	54	0	G1: See preamble text	−13.63
31578	Removal of larynx lesion ..	ES064	rhinolaryngoscope, flexible, video, channeled.	NF	.....	0	60	E4: Refined equipment time to conform to established policies for scopes.	3.13
31579	Diagnostic laryngoscopy ...	EF008	chair with headrest, exam, reclining.	NF	.....	31	28	E15: Refined equipment time to conform to changes in clinical labor time.	−0.03
31579	Diagnostic laryngoscopy ...	EF015	mayo stand	NF	.....	31	28	E15: Refined equipment time to conform to changes in clinical labor time.	0.00
31579	Diagnostic laryngoscopy ...	EQ167	light source, xenon	NF	.....	0	25	E19: Refined equipment time to conform to established policies for scope accessories.	0.69
31579	Diagnostic laryngoscopy ...	EQ170	light, fiberoptic headlight w-source.	NF	.....	31	28	E15: Refined equipment time to conform to changes in clinical labor time.	−0.02
31579	Diagnostic laryngoscopy ...	EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	31	28	E15: Refined equipment time to conform to changes in clinical labor time.	−0.03
31579	Diagnostic laryngoscopy ...	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	0	25	E19: Refined equipment time to conform to established policies for scope accessories.	3.23
31579	Diagnostic laryngoscopy ...	ES063	rhinolaryngoscope, flexible, video, non-channeled.	NF	.....	0	54	E4: Refined equipment time to conform to established policies for scopes.	2.50
31579	Diagnostic laryngoscopy ...	ES065	stroboscopy system	NF	.....	49	44	E19: Refined equipment time to conform to established policies for scope accessories.	−0.33
31579	Diagnostic laryngoscopy ...	L037D	RN/LPN/MTA	NF	Clean room/equipment by physician staff.	3	1	G1: See preamble text	−0.74
31579	Diagnostic laryngoscopy ...	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	2	L17: Clinical labor task redundant with clinical labor task "Assist physician in performing the procedure" (L041B).	−0.37
31580	Revision of larynx	EQ137	instrument pack, basic ($500–$1499).	F	.....	138	129	E5: Refined equipment time to conform to established policies for surgical instrument packs.	−0.02
31580	Revision of larynx	EQ167	light source, xenon	F	.....	0	108	E13: Equipment item replaces another item; see preamble text EQ170.	3.00
31580	Revision of larynx	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	F	.....	0	108	E19: Refined equipment time to conform to established policies for scope accessories.	13.97
31580	Revision of larynx	ES060	Video-flexible laryngoscope system.	F	.....	198	0	G1: See preamble text	−62.98

31580	Revision of larynx	ES063	rhinolaryngoscope, flexible, video, non-channeled.	F	.....	0	189	E4: Refined equipment time to conform to established policies for scopes.	8.76
31584	Treat larynx fracture	EQ137	instrument pack, basic ($500–$1499).	F	.....	138	129	E5: Refined equipment time to conform to established policies for surgical instrument packs.	−0.02
31584	Treat larynx fracture	EQ167	light source, xenon	F	.....	0	108	E13: Equipment item replaces another item; see preamble text EQ170.	3.00
31584	Treat larynx fracture	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	F	.....	0	108	E19: Refined equipment time to conform to established policies for scope accessories.	13.97
31584	Treat larynx fracture	ES060	Video-flexible laryngoscope system.	F	.....	198	0	G1: See preamble text	−62.98
31584	Treat larynx fracture	ES063	rhinolaryngoscope, flexible, video, non-channeled.	F	.....	0	189	E4: Refined equipment time to conform to established policies for scopes.	8.76
31587	Revision of larynx	EQ137	instrument pack, basic ($500–$1499).	F	.....	138	129	E5: Refined equipment time to conform to established policies for surgical instrument packs.	−0.02
31587	Revision of larynx	EQ167	light source, xenon	F	.....	0	108	E13: Equipment item replaces another item; see preamble text EQ170.	3.00
31587	Revision of larynx	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	F	.....	0	108	E19: Refined equipment time to conform to established policies for scope accessories.	13.97
31587	Revision of larynx	ES060	Video-flexible laryngoscope system.	F	.....	198	0	G1: See preamble text	−62.98
31587	Revision of larynx	ES063	rhinolaryngoscope, flexible, video, non-channeled.	F	.....	0	189	E4: Refined equipment time to conform to established policies for scopes.	8.76
31591	Laryngoplasty medialization.	EQ137	instrument pack, basic ($500–$1499).	F	.....	138	129	E5: Refined equipment time to conform to established policies for surgical instrument packs.	−0.02
31591	Laryngoplasty medialization.	EQ167	light source, xenon	F	.....	0	108	E13: Equipment item replaces another item; see preamble text EQ170.	3.00
31591	Laryngoplasty medialization.	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	F	.....	0	108	E19: Refined equipment time to conform to established policies for scope accessories.	13.97
31591	Laryngoplasty medialization.	ES060	Video-flexible laryngoscope system.	F	.....	198	0	G1: See preamble text	−62.98
31591	Laryngoplasty medialization.	ES063	rhinolaryngoscope, flexible, video, non-channeled.	F	.....	0	189	E4: Refined equipment time to conform to established policies for scopes.	8.76
31592	Cricotracheal resection	EQ137	instrument pack, basic ($500–$1499).	F	.....	138	129	E5: Refined equipment time to conform to established policies for surgical instrument packs.	−0.02
31592	Cricotracheal resection	EQ167	light source, xenon	F	.....	0	108	E13: Equipment item replaces another item; see preamble text EQ170.	3.00
31592	Cricotracheal resection	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	F	.....	0	108	E19: Refined equipment time to conform to established policies for scope accessories.	13.97
31592	Cricotracheal resection	ES060	Video-flexible laryngoscope system.	F	.....	198	0	G1: See preamble text	−62.98
31592	Cricotracheal resection	ES063	rhinolaryngoscope, flexible, video, non-channeled.	F	.....	0	189	E4: Refined equipment time to conform to established policies for scopes.	8.76
36473	Endovenous mchnchem 1st vein.	EF014	light, surgical	NF	.....	0	48	E13: Equipment item replaces another item; see preamble text EL015.	0.48
36473	Endovenous mchnchem 1st vein.	EF031	table, power	NF	.....	0	48	E13: Equipment item replaces another item; see preamble text EL015.	0.78

TABLE 28—CY 2017 FINAL RULE DIRECT PE REFINEMENT TABLE—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change
36473	Endovenous mchnchem 1st vein.	EL015	room, ultrasound, general	NF	.....	39	0	E12: Equipment item replaced by another item; see preamble text EQ250.	−54.67
36473	Endovenous mchnchem 1st vein.	EQ250	ultrasound unit, portable	NF	.....	0	48	E13: Equipment item replaces another item; see preamble text EL015.	5.58
36473	Endovenous mchnchem 1st vein.	L037D	RN/LPN/MTA	NF	Prepare room, equipment, supplies.	2	0	G1: See preamble text	−0.74
36473	Endovenous mchnchem 1st vein.	L054A	Vascular Technologist	NF	Availability of prior images confirmed.	2	0	G1: See preamble text	−1.08
36473	Endovenous mchnchem 1st vein.	L054A	Vascular Technologist	NF	Exam documents scanned into U/S machine. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.	1	0	G1: See preamble text	−0.54
36473	Endovenous mchnchem 1st vein.	L054A	Vascular Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist.	2	0	G1: See preamble text	−1.08
36473	Endovenous mchnchem 1st vein.	L054A	Vascular Technologist	NF	Review examination with interpreting MD.	2	0	G1: See preamble text	−1.08
36473	Endovenous mchnchem 1st vein.	L054A	Vascular Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page.	2	0	G1: See preamble text	−1.08
36473	Endovenous mchnchem 1st vein.	SA016	kit, guidewire introducer (Micro-Stick).	NF	.....	1	0	S3: Supply not typically used in this service.	−23.00
36473	Endovenous mchnchem 1st vein.	SH108	Sotradecol Sclerosing Agent	NF	.....	2	1	S6: Refined supply quantity to what is typical for the procedure.	−110.20
36474	Endovenous mchnchem add-on.	EF014	light, surgical	NF	.....	0	30	E13: Equipment item replaces another item; see preamble text EL015.	0.30
36474	Endovenous mchnchem add-on.	EF031	table, power	NF	.....	0	30	E13: Equipment item replaces another item; see preamble text EL015.	0.49
36474	Endovenous mchnchem add-on.	EL015	room, ultrasound, general	NF	.....	30	0	E12: Equipment item replaced by another item; see preamble text EQ250.	−42.05
36474	Endovenous mchnchem add-on.	EQ250	ultrasound unit, portable	NF	.....	0	30	E13: Equipment item replaces another item; see preamble text EL015.	3.49
36474	Endovenous mchnchem add-on.	SH108	Sotradecol Sclerosing Agent	NF	.....	2	1	S6: Refined supply quantity to what is typical for the procedure.	−110.20
36901	Intro cath dialysis circuit ...	ED050	PACS Workstation Proxy	NF	.....	54	52	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
36901	Intro cath dialysis circuit ...	EL011	room, angiography	NF	.....	37	35	E15: Refined equipment time to conform to changes in clinical labor time.	−10.51
36901	Intro cath dialysis circuit ...	L037D	RN/LPN/MTA	NF	Prepare and position pt/monitor pt/set up IV.	5	3	G1: See preamble text	−0.74
36901	Intro cath dialysis circuit ...	SJ041	povidone soln (Betadine)	NF	.....	60	0	S7: Supply item replaced by another item; see preamble SJ088.	−0.48

36901	Intro cath dialysis circuit ...	SJ088	swab, patient prep, 3.0 ml (chloraprep).	NF	.....	0	2	S8: Supply item replaces another item; see preamble SJ041.	3.62
36902	Intro cath dialysis circuit ...	ED050	PACS Workstation Proxy	NF	.....	69	67	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
36902	Intro cath dialysis circuit ...	EL011	room, angiography	NF	.....	52	50	E15: Refined equipment time to conform to changes in clinical labor time.	−10.51
36902	Intro cath dialysis circuit ...	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/set up IV.	5	3	G1: See preamble text	−0.74
36902	Intro cath dialysis circuit ...	SJ041	povidone soln (Betadine)	NF	.....	60	0	S7: Supply item replaced by another item; see preamble.	−0.48
36902	Intro cath dialysis circuit ...	SJ088	swab, patient prep, 3.0 ml (chloraprep).	NF	.....	0	2	S8: Supply item replaces another item; see preamble.	3.62
36903	Intro cath dialysis circuit ...	ED050	PACS Workstation Proxy	NF	.....	79	77	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
36903	Intro cath dialysis circuit ...	EL011	room, angiography	NF	.....	62	60	E15: Refined equipment time to conform to changes in clinical labor time.	−10.51
36903	Intro cath dialysis circuit ...	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/set up IV.	5	3	G1: See preamble text	−0.74
36903	Intro cath dialysis circuit ...	SJ041	povidone soln (Betadine)	NF	.....	60	0	S7: Supply item replaced by another item; see preamble.	−0.48
36903	Intro cath dialysis circuit ...	SJ088	swab, patient prep, 3.0 ml (chloraprep).	NF	.....	0	2	S8: Supply item replaces another item; see preamble.	3.62
36904	Thrmbc/nfs dialysis circuit	ED050	PACS Workstation Proxy	NF	.....	89	87	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
36904	Thrmbc/nfs dialysis circuit	EL011	room, angiography	NF	.....	72	70	E15: Refined equipment time to conform to changes in clinical labor time.	−10.51
36904	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Complete pre-service diagnostic and referral forms.	3	0	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36904	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services.	6	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36904	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Follow-up phone calls and prescriptions.	6	0	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−2.22
36904	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility.	6	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36904	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	6	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36904	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	6	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36904	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/ monitor pt/set up IV.	5	3	G1: See preamble text	−0.74
36904	Thrmbc/nfs dialysis circuit	SD032	catheter, thrombectomy-Fogarty	NF	.....	1	0	S2: Supply removed due to redundancy when used together with supply SA015.	−101.75
36904	Thrmbc/nfs dialysis circuit	SD136	vascular sheath	NF	.....	2	1	S2: Supply removed due to redundancy when used together with supply SA015.	−20.50
36904	Thrmbc/nfs dialysis circuit	SJ041	povidone soln (Betadine)	NF	.....	60	0	S7: Supply item replaced by another item; see preamble.	−0.48
36904	Thrmbc/nfs dialysis circuit	SJ088	swab, patient prep, 3.0 ml (chloraprep).	NF	.....	0	2	S8: Supply item replaces another item; see preamble.	3.62
36905	Thrmbc/nfs dialysis circuit	ED050	PACS Workstation Proxy	NF	.....	104	102	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04

TABLE 28—CY 2017 FINAL RULE DIRECT PE REFINEMENT TABLE—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change
36905	Thrmbc/nfs dialysis circuit	EL011	room, angiography	NF	.....	87	85	E15: Refined equipment time to conform to changes in clinical labor time.	−10.51
36905	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Complete pre-service diagnostic and referral forms.	3	0	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36905	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services.	6	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36905	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Follow-up phone calls and prescriptions.	6	0	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−2.22
36905	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility.	6	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36905	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	6	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36905	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	6	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36905	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/monitor pt/set up IV.	5	3	G1: See preamble text	−0.74
36905	Thrmbc/nfs dialysis circuit	SD032	catheter, thrombectomy-Fogarty	NF	.....	1	0	S2: Supply removed due to redundancy when used together with supply SA015.	−101.75
36905	Thrmbc/nfs dialysis circuit	SD136	vascular sheath	NF	.....	2	1	S2: Supply removed due to redundancy when used together with supply SA015.	−20.50
36905	Thrmbc/nfs dialysis circuit	SJ041	povidone soln (Betadine)	NF	.....	60	0	S7: Supply item replaced by another item; see preamble.	−0.48
36905	Thrmbc/nfs dialysis circuit	SJ088	swab, patient prep, 3.0 ml (chloraprep).	NF	.....	0	2	S8: Supply item replaces another item; see preamble.	3.62
36906	Thrmbc/nfs dialysis circuit	ED050	PACS Workstation Proxy	NF	.....	119	117	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
36906	Thrmbc/nfs dialysis circuit	EL011	room, angiography	NF	.....	102	100	E15: Refined equipment time to conform to changes in clinical labor time.	−10.51
36906	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Complete pre-service diagnostic and referral forms.	3	0	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36906	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services.	6	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36906	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Follow-up phone calls and prescriptions.	6	0	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−2.22
36906	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility.	6	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36906	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	6	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11
36906	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	6	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.11

36906	Thrmbc/nfs dialysis circuit	L037D	RN/LPN/MTA	NF	Prepare and position pt/monitor pt/set up IV.	5	3	G1: See preamble text	−0.74
36906	Thrmbc/nfs dialysis circuit	SD032	catheter, thrombectomy-Fogarty	NF	.....	1	0	S2: Supply removed due to redundancy when used together with supply SA015.	−101.75
36906	Thrmbc/nfs dialysis circuit	SD136	vascular sheath	NF	.....	2	1	S2: Supply removed due to redundancy when used together with supply SA015.	−20.50
36906	Thrmbc/nfs dialysis circuit	SJ041	povidone soln (Betadine)	NF	.....	60	0	S7: Supply item replaced by another item; see preamble.	−0.48
36906	Thrmbc/nfs dialysis circuit	SJ088	swab, patient prep, 3.0 ml (chloraprep).	NF	.....	0	2	S8: Supply item replaces another item; see preamble.	3.62
37246	Trluml balo angiop 1st art	ED050	PACS Workstation Proxy	NF	.....	91	89	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
37246	Trluml balo angiop 1st art	EL011	room, angiography	NF	.....	72	70	E15: Refined equipment time to conform to changes in clinical labor time.	−10.51
37246	Trluml balo angiop 1st art	L037D	RN/LPN/MTA	NF	Prepare and position patient/monitor patient/set up IV.	5	3	G1: See preamble text	−0.74
37248	Trluml balo angiop 1st vein.	ED050	PACS Workstation Proxy	NF	.....	91	89	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
37248	Trluml balo angiop 1st vein.	EL011	room, angiography	NF	.....	72	70	E15: Refined equipment time to conform to changes in clinical labor time.	−10.51
37248	Trluml balo angiop 1st vein.	L037D	RN/LPN/MTA	NF	Prepare and position patient/monitor patient/set up IV.	5	3	G1: See preamble text	−0.74
47531	Injection for cholangiogram.	ED050	PACS Workstation Proxy	NF	.....	51	46	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy.	−0.11
47531	Injection for cholangiogram.	EF018	stretcher	NF	.....	87	82	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	−0.03
47531	Injection for cholangiogram.	EF027	table, instrument, mobile	NF	.....	87	82	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	−0.01
47531	Injection for cholangiogram.	EL011	room, angiography	NF	.....	27	24	E15: Refined equipment time to conform to changes in clinical labor time.	−15.76
47531	Injection for cholangiogram.	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	87	82	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	−0.07
47531	Injection for cholangiogram.	EQ032	IV infusion pump	NF	.....	87	82	E6: Refined equipment time to conform to established policies for equipment with 4x monitoring time.	−0.03
47531	Injection for cholangiogram.	EQ168	light, exam	NF	.....	51	40	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.05
47531	Injection for cholangiogram.	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure.	15	0	L11: Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure.	−5.55
47531	Injection for cholangiogram.	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff.	6	3	L1: Refined time to standard for this clinical labor task.	−1.23
47531	Injection for cholangiogram.	L051A	RN	NF	Sedate/Apply anesthesia ..	2	0	L11: Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure.	−1.02
47532	Injection for cholangiogram.	ED050	PACS Workstation Proxy	NF	.....	34	76	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy MS minutes backed out input.	0.92

TABLE 28—CY 2017 FINAL RULE DIRECT PE REFINEMENT TABLE—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change
47532	Injection for cholangiogram.	EF018	stretcher	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47532	Injection for cholangiogram.	EF027	table, instrument, mobile	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	0.00
47532	Injection for cholangiogram.	EL011	room, angiography	NF	.....	57	54	E15: Refined equipment time to conform to changes in clinical labor time MS minutes backed out input.	−15.76
47532	Injection for cholangiogram.	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.04
47532	Injection for cholangiogram.	EQ032	IV infusion pump	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47532	Injection for cholangiogram.	EQ168	light, exam	NF	.....	34	70	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	0.16
47532	Injection for cholangiogram.	EQ250	ultrasound unit, portable	NF	.....	34	70	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	4.18
47532	Injection for cholangiogram.	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff.	6	3	L1: Refined time to standard for this clinical labor task.	−1.23
47532	Injection for cholangiogram.	L051A	RN	NF	Assist Physician in Performing Procedure (CS).	45	0	G1: See preamble text MS minutes backed out input.	−22.95
47532	Injection for cholangiogram.	L051A	RN	NF	Monitor pt. following moderate sedation.	15	0	G1: See preamble text MS minutes backed out input.	−7.65
47532	Injection for cholangiogram.	L051A	RN	NF	Sedate/Apply anesthesia ..	2	0	G1: See preamble text MS minutes backed out input.	−1.02
47532	Injection for cholangiogram.	SA044	pack, conscious sedation	NF	.....	1	0	G1: See preamble text MS supply backed out input.	−17.31
47533	Plmt biliary drainage cath	ED050	PACS Workstation Proxy	NF	.....	34	91	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy MS minutes backed out input.	1.26
47533	Plmt biliary drainage cath	EF018	stretcher	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47533	Plmt biliary drainage cath	EF027	table, instrument, mobile	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	0.00
47533	Plmt biliary drainage cath	EL011	room, angiography	NF	.....	72	69	E15: Refined equipment time to conform to changes in clinical labor time MS minutes backed out input.	−15.76
47533	Plmt biliary drainage cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.04
47533	Plmt biliary drainage cath	EQ032	IV infusion pump	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47533	Plmt biliary drainage cath	EQ168	light, exam	NF	.....	34	85	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	0.22
47533	Plmt biliary drainage cath	EQ250	ultrasound unit, portable	NF	.....	34	85	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	5.93
47533	Plmt biliary drainage cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff.	6	3	L1: Refined time to standard for this clinical labor task.	−1.23
47533	Plmt biliary drainage cath	L051A	RN	NF	Assist Physician in Performing Procedure (CS).	60	0	G1: See preamble text MS minutes backed out input.	−30.60
47533	Plmt biliary drainage cath	L051A	RN	NF	Monitor pt. following moderate sedation.	15	0	G1: See preamble text MS minutes backed out input.	−7.65

47533	Plmt biliary drainage cath	L051A	RN	NF	Sedate/Apply anesthesia ..	2	0	G1: See preamble text MS minutes backed out input.	−1.02
47533	Plmt biliary drainage cath	SA044	pack, conscious sedation	NF	.....	1	0	G1: See preamble text MS supply backed out input.	−17.31
47534	Plmt biliary drainage cath	ED050	PACS Workstation Proxy	NF	.....	34	99	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy MS minutes backed out input.	1.43
47534	Plmt biliary drainage cath	EF018	stretcher	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47534	Plmt biliary drainage cath	EF027	table, instrument, mobile	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	0.00
47534	Plmt biliary drainage cath	EL011	room, angiography	NF	.....	80	77	E15: Refined equipment time to conform to changes in clinical labor time MS minutes backed out input.	−15.76
47534	Plmt biliary drainage cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.04
47534	Plmt biliary drainage cath	EQ032	IV infusion pump	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47534	Plmt biliary drainage cath	EQ168	light, exam	NF	.....	34	93	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	0.26
47534	Plmt biliary drainage cath	EQ250	ultrasound unit, portable	NF	.....	34	93	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	6.86
47534	Plmt biliary drainage cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff.	6	3	L1: Refined time to standard for this clinical labor task.	−1.23
47534	Plmt biliary drainage cath	L051A	RN	NF	Assist Physician in Performing Procedure (CS).	68	0	G1: See preamble text MS minutes backed out input.	−34.68
47534	Plmt biliary drainage cath	L051A	RN	NF	Monitor pt. following moderate sedation.	15	0	G1: See preamble text MS minutes backed out input.	−7.65
47534	Plmt biliary drainage cath	L051A	RN	NF	Sedate/Apply anesthesia ..	2	0	G1: See preamble text MS minutes backed out input.	−1.02
47534	Plmt biliary drainage cath	SA044	pack, conscious sedation	NF	.....	1	0	G1: See preamble text MS supply backed out input.	−17.31
47535	Conversion ext bil drg cath	ED050	PACS Workstation Proxy	NF	.....	34	76	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy MS minutes backed out input.	0.92
47535	Conversion ext bil drg cath	EF018	stretcher	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47535	Conversion ext bil drg cath	EF027	table, instrument, mobile	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	0.00
47535	Conversion ext bil drg cath	EL011	room, angiography	NF	.....	57	54	E15: Refined equipment time to conform to changes in clinical labor time MS minutes backed out input.	−15.76
47535	Conversion ext bil drg cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.04
47535	Conversion ext bil drg cath	EQ032	IV infusion pump	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47535	Conversion ext bil drg cath	EQ168	light, exam	NF	.....	34	70	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	0.16
47535	Conversion ext bil drg cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff.	6	3	L1: Refined time to standard for this clinical labor task.	−1.23
47535	Conversion ext bil drg cath	L051A	RN	NF	Assist Physician in Performing Procedure (CS).	45	0	G1: See preamble text MS minutes backed out input.	−22.95
47535	Conversion ext bil drg cath	L051A	RN	NF	Monitor pt. following moderate sedation.	15	0	G1: See preamble text MS minutes backed out input.	−7.65
47535	Conversion ext bil drg cath	L051A	RN	NF	Sedate/Apply anesthesia ..	2	0	G1: See preamble text MS minutes backed out input.	−1.02
47535	Conversion ext bil drg cath	SA044	pack, conscious sedation	NF	.....	1	0	G1: See preamble text MS supply backed out input.	−17.31

TABLE 28—CY 2017 FINAL RULE DIRECT PE REFINEMENT TABLE—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change
47536	Exchange biliary drg cath	ED050	PACS Workstation Proxy	NF	.....	34	51	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy MS minutes backed out input.	0.37
47536	Exchange biliary drg cath	EF018	stretcher	NF	.....	70	67	G1: See preamble text MS minutes backed out input.	−0.02
47536	Exchange biliary drg cath	EF027	table, instrument, mobile	NF	.....	70	67	G1: See preamble text MS minutes backed out input.	0.00
47536	Exchange biliary drg cath	EL011	room, angiography	NF	.....	32	29	E15: Refined equipment time to conform to changes in clinical labor time MS minutes backed out input.	−15.76
47536	Exchange biliary drg cath	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	70	67	G1: See preamble text MS minutes backed out input.	−0.04
47536	Exchange biliary drg cath	EQ032	IV infusion pump	NF	.....	70	67	G1: See preamble text MS minutes backed out input.	−0.02
47536	Exchange biliary drg cath	EQ168	light, exam	NF	.....	34	45	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	0.05
47536	Exchange biliary drg cath	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff.	6	3	L1: Refined time to standard for this clinical labor task.	−1.23
47536	Exchange biliary drg cath	L051A	RN	NF	Assist Physician in Performing Procedure (CS).	20	0	G1: See preamble text MS minutes backed out input.	−10.20
47536	Exchange biliary drg cath	L051A	RN	NF	Monitor pt. following moderate sedation.	15	0	G1: See preamble text MS minutes backed out input.	−7.65
47536	Exchange biliary drg cath	L051A	RN	NF	Sedate/Apply anesthesia ..	2	0	G1: See preamble text MS minutes backed out input.	−1.02
47536	Exchange biliary drg cath	SA044	pack, conscious sedation	NF	.....	1	0	G1: See preamble text MS supply backed out input.	−17.31
47537	Removal biliary drg cath ...	ED050	PACS Workstation Proxy	NF	.....	51	46	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy.	−0.11
47537	Removal biliary drg cath ...	EF018	stretcher	NF	.....	87	82	G1: See preamble text	−0.03
47537	Removal biliary drg cath ...	EF027	table, instrument, mobile	NF	.....	87	82	G1: See preamble text	−0.01
47537	Removal biliary drg cath ...	EL011	room, angiography	NF	.....	27	24	E15: Refined equipment time to conform to changes in clinical labor time.	−15.76
47537	Removal biliary drg cath ...	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	87	82	G1: See preamble text	−0.07
47537	Removal biliary drg cath ...	EQ032	IV infusion pump	NF	.....	87	82	G1: See preamble text	−0.03
47537	Removal biliary drg cath ...	EQ168	light, exam	NF	.....	51	40	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.05
47537	Removal biliary drg cath ...	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure.	15	0	L11: Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure.	−5.55
47537	Removal biliary drg cath ...	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff.	6	3	L1: Refined time to standard for this clinical labor task.	−1.23
47537	Removal biliary drg cath ...	L051A	RN	NF	Sedate/Apply anesthesia ..	2	0	L11: Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure.	−1.02
47538	Perq plmt bile duct stent ..	ED050	PACS Workstation Proxy	NF	.....	34	84	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy MS minutes backed out input.	1.10

47538	Perq plmt bile duct stent ..	EF018	stretcher	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47538	Perq plmt bile duct stent ..	EF027	table, instrument, mobile	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	0.00
47538	Perq plmt bile duct stent ..	EL011	room, angiography	NF	.....	65	62	E15: Refined equipment time to conform to changes in clinical labor time MS minutes backed out input.	−15.76
47538	Perq plmt bile duct stent ..	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.04
47538	Perq plmt bile duct stent ..	EQ032	IV infusion pump	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47538	Perq plmt bile duct stent ..	EQ168	light, exam	NF	.....	34	78	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	0.19
47538	Perq plmt bile duct stent ..	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff.	6	3	L1: Refined time to standard for this clinical labor task.	−1.23
47538	Perq plmt bile duct stent ..	L051A	RN	NF	Assist Physician in Performing Procedure (CS).	53	0	G1: See preamble text MS minutes backed out input.	−27.03
47538	Perq plmt bile duct stent ..	L051A	RN	NF	Monitor pt. following moderate sedation.	15	0	G1: See preamble text MS minutes backed out input.	−7.65
47538	Perq plmt bile duct stent ..	L051A	RN	NF	Sedate/Apply anesthesia ..	2	0	G1: See preamble text MS minutes backed out input.	−1.02
47538	Perq plmt bile duct stent ..	SA044	pack, conscious sedation	NF	.....	1	0	G1: See preamble text MS supply backed out input.	−17.31
47538	Perq plmt bile duct stent ..	SD150	catheter, balloon ureteral (Dowd)	NF	.....	0	2	S8: Supply item replaces another item; see preamble.	130.00
47538	Perq plmt bile duct stent ..	SD152	catheter, balloon, PTA	NF	.....	2	0	S7: Supply item replaced by another item; see preamble.	−487.00
47539	Perq plmt bile duct stent ..	ED050	PACS Workstation Proxy	NF	.....	34	106	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy MS minutes backed out input.	1.59
47539	Perq plmt bile duct stent ..	EF018	stretcher	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47539	Perq plmt bile duct stent ..	EF027	table, instrument, mobile	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	0.00
47539	Perq plmt bile duct stent ..	EL011	room, angiography	NF	.....	87	84	E15: Refined equipment time to conform to changes in clinical labor time MS minutes backed out input.	−15.76
47539	Perq plmt bile duct stent ..	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.04
47539	Perq plmt bile duct stent ..	EQ032	IV infusion pump	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47539	Perq plmt bile duct stent ..	EQ168	light, exam	NF	.....	34	100	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	0.29
47539	Perq plmt bile duct stent ..	EQ250	ultrasound unit, portable	NF	.....	34	100	E15: Refined equipment time to conform to changes in clinical labor time MS minutes backed out input.	7.67
47539	Perq plmt bile duct stent ..	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff.	6	3	L1: Refined time to standard for this clinical labor task.	−1.23
47539	Perq plmt bile duct stent ..	L051A	RN	NF	Assist Physician in Performing Procedure (CS).	75	0	G1: See preamble text MS minutes backed out input.	−38.25
47539	Perq plmt bile duct stent ..	L051A	RN	NF	Monitor pt. following moderate sedation.	15	0	G1: See preamble text MS minutes backed out input.	−7.65
47539	Perq plmt bile duct stent ..	L051A	RN	NF	Sedate/Apply anesthesia ..	2	0	G1: See preamble text MS minutes backed out input.	−1.02
47539	Perq plmt bile duct stent ..	SA044	pack, conscious sedation	NF	.....	1	0	G1: See preamble text MS supply backed out input.	−17.31
47539	Perq plmt bile duct stent ..	SD150	catheter, balloon ureteral (Dowd)	NF	.....	0	2	S8: Supply item replaces another item; see preamble.	130.00
47539	Perq plmt bile duct stent ..	SD152	catheter, balloon, PTA	NF	.....	2	0	S7: Supply item replaced by another item; see preamble.	−487.00

TABLE 28—CY 2017 FINAL RULE DIRECT PE REFINEMENT TABLE—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change
47540	Perq plmt bile duct stent ..	ED050	PACS Workstation Proxy	NF	.....	34	116	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy MS minutes backed out input.	1.81
47540	Perq plmt bile duct stent ..	EF018	stretcher	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47540	Perq plmt bile duct stent ..	EF027	table, instrument, mobile	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	0.00
47540	Perq plmt bile duct stent ..	EL011	room, angiography	NF	.....	97	94	E15: Refined equipment time to conform to changes in clinical labor time MS minutes backed out input.	−15.76
47540	Perq plmt bile duct stent ..	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.04
47540	Perq plmt bile duct stent ..	EQ032	IV infusion pump	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47540	Perq plmt bile duct stent ..	EQ168	light, exam	NF	.....	34	110	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	0.33
47540	Perq plmt bile duct stent ..	EQ250	ultrasound unit, portable	NF	.....	34	110	E15: Refined equipment time to conform to changes in clinical labor time MS minutes backed out input.	8.83
47540	Perq plmt bile duct stent ..	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff.	6	3	L1: Refined time to standard for this clinical labor task.	−1.23
47540	Perq plmt bile duct stent ..	L051A	RN	NF	Assist Physician in Performing Procedure (CS).	85	0	G1: See preamble text MS minutes backed out input.	−43.35
47540	Perq plmt bile duct stent ..	L051A	RN	NF	Monitor pt. following moderate sedation.	15	0	G1: See preamble text MS minutes backed out input.	−7.65
47540	Perq plmt bile duct stent ..	L051A	RN	NF	Sedate/Apply anesthesia ..	2	0	G1: See preamble text MS minutes backed out input.	−1.02
47540	Perq plmt bile duct stent ..	SA044	pack, conscious sedation	NF	.....	1	0	G1: See preamble text MS supply backed out input.	−17.31
47540	Perq plmt bile duct stent ..	SD150	catheter, balloon ureteral (Dowd)	NF	.....	0	2	S8: Supply item replaces another item; see preamble SD152.	130.00
47540	Perq plmt bile duct stent ..	SD152	catheter, balloon, PTA	NF	.....	2	0	S7: Supply item replaced by another item; see preamble SD150.	−487.00
47541	Plmt access bil tree sm bwl.	ED050	PACS Workstation Proxy	NF	.....	34	91	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy MS minutes backed out input.	1.26
47541	Plmt access bil tree sm bwl.	EF018	stretcher	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47541	Plmt access bil tree sm bwl.	EF027	table, instrument, mobile	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	0.00
47541	Plmt access bil tree sm bwl.	EL011	room, angiography	NF	.....	72	69	E15: Refined equipment time to conform to changes in clinical labor time MS minutes backed out input.	−15.76
47541	Plmt access bil tree sm bwl.	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.04
47541	Plmt access bil tree sm bwl.	EQ032	IV infusion pump	NF	.....	190	187	G1: See preamble text MS minutes backed out input.	−0.02
47541	Plmt access bil tree sm bwl.	EQ168	light, exam	NF	.....	34	85	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	0.22

47541	Plmt access bil tree sm bwl.	EQ250	ultrasound unit, portable	NF	.....	34	85	E1: Refined equipment time to conform to established policies for non-highly technical equipment MS minutes backed out input.	5.93
47541	Plmt access bil tree sm bwl.	L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff.	6	3	L1: Refined time to standard for this clinical labor task.	−1.23
47541	Plmt access bil tree sm bwl.	L051A	RN	NF	Assist Physician in Performing Procedure (CS).	60	0	G1: See preamble text MS minutes backed out input.	−30.60
47541	Plmt access bil tree sm bwl.	L051A	RN	NF	Monitor pt. following moderate sedation.	15	0	G1: See preamble text MS minutes backed out input.	−7.65
47541	Plmt access bil tree sm bwl.	L051A	RN	NF	Sedate/Apply anesthesia ..	2	0	G1: See preamble text MS minutes backed out input.	−1.02
47541	Plmt access bil tree sm bwl.	SA044	pack, conscious sedation	NF	.....	1	0	G1: See preamble text MS supply backed out input.	−17.31
47542	Dilate biliary duct/ampulla	EF018	stretcher	NF	.....	30	0	G1: See preamble text MS minutes backed out input.	−0.15
47542	Dilate biliary duct/ampulla	EF027	table, instrument, mobile	NF	.....	30	0	G1: See preamble text MS minutes backed out input.	−0.04
47542	Dilate biliary duct/ampulla	EQ011	ECG, 3-channel (with Sp02, NIBP, temp, resp).	NF	.....	30	0	G1: See preamble text MS minutes backed out input.	−0.42
47542	Dilate biliary duct/ampulla	EQ032	IV infusion pump	NF	.....	30	0	G1: See preamble text MS minutes backed out input.	−0.19
47542	Dilate biliary duct/ampulla	L051A	RN	NF	Assist Physician in Performing Procedure (CS).	30	0	G1: See preamble text MS minutes backed out input.	−15.30
47542	Dilate biliary duct/ampulla	SD150	catheter, balloon ureteral (Dowd)	NF	.....	0	1	S8: Supply item replaces another item; see preamble.	65.00
47542	Dilate biliary duct/ampulla	SD152	catheter, balloon, PTA	NF	.....	1	0	S7: Supply item replaced by another item; see preamble.	−243.50
47543	Endoluminal bx biliary tree	EF018	stretcher	NF	.....	30	0	G1: See preamble text MS minutes backed out input.	−0.15
47543	Endoluminal bx biliary tree	EF027	table, instrument, mobile	NF	.....	30	0	G1: See preamble text MS minutes backed out input.	−0.04
47543	Endoluminal bx biliary tree	EQ011	ECG, 3-channel (with Sp02, NIBP, temp, resp).	NF	.....	30	0	G1: See preamble text MS minutes backed out input.	−0.42
47543	Endoluminal bx biliary tree	EQ032	IV infusion pump	NF	.....	30	0	G1: See preamble text MS minutes backed out input.	−0.19
47543	Endoluminal bx biliary tree	L051A	RN	NF	Assist Physician in Performing Procedure (CS).	30	0	G1: See preamble text MS minutes backed out input.	−15.30
47543	Endoluminal bx biliary tree	SD315	Stone basket	NF	.....	1	0	G1: See preamble text	−417.00
47544	Removal duct glbldr calculi	EF018	stretcher	NF	.....	45	0	G1: See preamble text MS minutes backed out input.	−0.23
47544	Removal duct glbldr calculi	EF027	table, instrument, mobile	NF	.....	45	0	G1: See preamble text MS minutes backed out input.	−0.06
47544	Removal duct glbldr calculi	EQ011	ECG, 3-channel (with Sp02, NIBP, temp, resp).	NF	.....	45	0	G1: See preamble text MS minutes backed out input.	−0.63
47544	Removal duct glbldr calculi	EQ032	IV infusion pump	NF	.....	45	0	G1: See preamble text MS minutes backed out input.	−0.28
47544	Removal duct glbldr calculi	L051A	RN	NF	Assist Physician in Performing Procedure (CS).	45	0	G1: See preamble text MS minutes backed out input.	−22.95
47544	Removal duct glbldr calculi	SD150	catheter, balloon ureteral (Dowd)	NF	.....	0	1	S8: Supply item replaces another item; see preamble.	65.00
47544	Removal duct glbldr calculi	SD152	catheter, balloon, PTA	NF	.....	1	0	S7: Supply item replaced by another item; see preamble.	−243.50
47544	Removal duct glbldr calculi	SD315	Stone basket	NF	.....	0	1	G1: See preamble text	417.00
50606	Endoluminal bx urtr rnl plvs.	EL011	room, angiography	NF	.....	46	47	G1: See preamble text	5.25
50705	Ureteral embolization/occl	EL011	room, angiography	NF	.....	61	62	G1: See preamble text	5.25
50706	Balloon dilate urtrl strix	EL011	room, angiography	NF	.....	61	62	G1: See preamble text	5.25
51700	Irrigation of bladder	SD024	catheter, Foley	NF	.....	0	1	S8: Supply item replaces another item; see preamble SD030.	7.82
51700	Irrigation of bladder	SD030	catheter, straight	NF	.....	1	0	S7: Supply item replaced by another item; see preamble SD024.	−1.70
51700	Irrigation of bladder	SJ031	leg or urinary drainage bag	NF	.....	0	1	S8: Supply item replaces another item; see preamble SD030.	3.08
51701	Insert bladder catheter	SD024	catheter, Foley	NF	.....	1	0	S7: Supply item replaced by another item; see preamble SD030.	−7.82

TABLE 28—CY 2017 FINAL RULE DIRECT PE REFINEMENT TABLE—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change
51701	Insert bladder catheter	SD030	catheter, straight	NF	.....	0	1	S8: Supply item replaces another item; see preamble SD024.	1.70
51701	Insert bladder catheter	SJ031	leg or urinary drainage bag	NF	.....	1	0	S7: Supply item replaced by another item; see preamble SD030.	−3.08
52000	Cystoscopy	EF027	table, instrument, mobile	NF	.....	17	22	E4: Refined equipment time to conform to established policies for scopes.	0.01
52000	Cystoscopy	EF031	table, power	NF	.....	17	22	E4: Refined equipment time to conform to established policies for scopes.	0.08
52000	Cystoscopy	EQ167	light source, xenon	NF	.....	17	22	E4: Refined equipment time to conform to established policies for scopes.	0.14
52000	Cystoscopy	ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	17	22	E4: Refined equipment time to conform to established policies for scopes.	0.65
58555	Hysteroscopy dx sep proc	L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions.	0	3	L1: Refined time to standard for this clinical labor task.	1.11
58558	Hysteroscopy biopsy	EQ235	suction machine (Gomco)	NF	.....	51	0	E9: Equipment removed due to redundancy when used together with equipment EQ378.	−0.10
58558	Hysteroscopy biopsy	SA123	Hysteroscopic fluid management tubing kit.	NF	.....	0	1	G1: See preamble text	320.00
58558	Hysteroscopy biopsy	SD009	canister, suction	NF	.....	1	0	S1: Duplicative; supply is included in EQ378.	−3.91
58558	Hysteroscopy biopsy	SD031	catheter, suction	NF	.....	1	0	S1: Duplicative; supply is included in EQ378.	−0.62
58562	Hysteroscopy remove fb ...	L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions.	0	3	L1: Refined time to standard for this clinical labor task.	1.11
62321	Njx interlaminar crv/thrc	EF018	stretcher	NF	.....	73	75	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
62321	Njx interlaminar crv/thrc	EQ211	pulse oximeter w-printer	NF	.....	73	75	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
62323	Njx interlaminar lmbr/sac ..	EF018	stretcher	NF	.....	73	75	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
62323	Njx interlaminar lmbr/sac ..	EQ211	pulse oximeter w-printer	NF	.....	73	75	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
62325	Njx interlaminar crv/thrc	EF018	stretcher	NF	.....	73	75	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
62325	Njx interlaminar crv/thrc	EQ211	pulse oximeter w-printer	NF	.....	73	75	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
62327	Njx interlaminar lmbr/sac ..	EF018	stretcher	NF	.....	73	75	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
62327	Njx interlaminar lmbr/sac ..	EQ211	pulse oximeter w-printer	NF	.....	73	75	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
70540	Mri orbit/face/neck w/o dye	ED053	Professional PACS Workstation ..	NF	.....	24	22	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy.	−0.12

70542	Mri orbit/face/neck w/dye ..	ED053	Professional PACS Workstation ..	NF	.....	25	23	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy.	−0.12
70543	Mri orbt/fac/nck w/o &w/ dye.	ED053	Professional PACS Workstation ..	NF	.....	30	28	E18: Refined equipment time to conform to established policies for PACS Workstation Proxy.	−0.12
77001	Fluoroguide for vein device.	ED050	PACS Workstation Proxy	NF	.....	27	25	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
77001	Fluoroguide for vein device.	EL014	room, radiographic-fluoroscopic ..	NF	.....	24	22	E15: Refined equipment time to conform to changes in clinical labor time.	−2.79
77001	Fluoroguide for vein device.	L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies.	2	0	L6: Add-on code. Additional time for clinical labor task not typical; see preamble text.	−0.82
77002	Needle localization by xray	ED050	PACS Workstation Proxy	NF	.....	27	25	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
77002	Needle localization by xray	EL014	room, radiographic-fluoroscopic ..	NF	.....	24	22	E15: Refined equipment time to conform to changes in clinical labor time.	−2.79
77002	Needle localization by xray	L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies.	2	0	L6: Add-on code. Additional time for clinical labor task not typical; see preamble text.	−0.82
77003	Fluoroguide for spine inject.	ED050	PACS Workstation Proxy	NF	.....	27	25	E15: Refined equipment time to conform to changes in clinical labor time.	−0.04
77003	Fluoroguide for spine inject.	EL014	room, radiographic-fluoroscopic ..	NF	.....	24	22	E15: Refined equipment time to conform to changes in clinical labor time.	−2.79
77003	Fluoroguide for spine inject.	L041B	Radiologic Technologist	NF	Prepare room, equipment, supplies.	2	0	L6: Add-on code. Additional time for clinical labor task not typical; see preamble text.	−0.82
88184	Flowcytometry/tc 1 marker	L033A	Lab Technician	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure).	2	1	L1: Refined time to standard for this clinical labor task.	−0.33
88184	Flowcytometry/tc 1 marker	L033A	Lab Technician	NF	Enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation.	4	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service.	−1.32
88184	Flowcytometry/tc 1 marker	L045A	Cytotechnologist	NF	Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling.	15	13	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−0.90
88184	Flowcytometry/tc 1 marker	L045A	Cytotechnologist	NF	Load specimen into flow cytometer, run specimen, monitor data acquisition, and data modeling, and unload flow cytometer.	10	7	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.35
88184	Flowcytometry/tc 1 marker	L045A	Cytotechnologist	NF	Print out histograms, assemble materials with paperwork to pathologists.	5	2	L1: Refined time to standard for this clinical labor task.	−1.35
88184	Flowcytometry/tc 1 marker	SL186	antibody, flow cytometry (each test).	NF	.....	1.6	1	G1: See preamble text	−5.10

TABLE 28—CY 2017 FINAL RULE DIRECT PE REFINEMENT TABLE—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change
88185	Flowcytometry/tc add-on ..	L033A	Lab Technician	NF	Enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation.	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service.	−0.33
88185	Flowcytometry/tc add-on ..	SL089	lysing reagent (FACS)	NF	.....	3	2	G1: See preamble text	−4.49
88185	Flowcytometry/tc add-on ..	SL186	antibody, flow cytometry (each test).	NF	.....	1.6	1	G1: See preamble text	−5.10
88321	Microslide consultation	L037B	Histotechnologist	NF	Assemble and deliver slides with paperwork to pathologists.	1	0	L2: Clinical labor task redundant with clinical labor task.	−0.37
88321	Microslide consultation	L037B	Histotechnologist	NF	Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist.	0	1	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	0.37
88323	Microslide consultation	L037B	Histotechnologist	NF	Assemble and deliver slides with paperwork to pathologists.	1	0	L2: Clinical labor task redundant with clinical labor task.	−0.37
88323	Microslide consultation	L037B	Histotechnologist	NF	Clean equipment while performing service.	1	0	L2: Clinical labor task redundant with clinical labor task.	−0.37
88323	Microslide consultation	L037B	Histotechnologist	NF	Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist.	0	1	G1: See preamble text	0.37
88323	Microslide consultation	SL135	stain, hematoxylin	NF	.....	32	16	G1: See preamble text	−0.70
88325	Comprehensive review of data.	L037B	Histotechnologist	NF	Assemble and deliver slides with paperwork to pathologists.	1	0	L2: Clinical labor task redundant with clinical labor task.	−0.37
88325	Comprehensive review of data.	L037B	Histotechnologist	NF	Clean Equipment while performing service.	1	0	L2: Clinical labor task redundant with clinical labor task.	−0.37
88325	Comprehensive review of data.	L037B	Histotechnologist	NF	Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist.	0	1	G1: See preamble text	0.37
88325	Comprehensive review of data.	SL135	stain, hematoxylin	NF	.....	32	16	G1: See preamble text	−0.70
95812	EEG 41–60 minutes	EF003	bedroom furniture (hospital bed, table, reclining chair).	NF	.....	108	99	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.05
95812	EEG 41–60 minutes	EQ017	EEG, digital, prolonged testing system (computer w-remote camera).	NF	.....	108	99	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−1.32
95812	EEG 41–60 minutes	L047B	REEGT	NF	Perform procedure	62	50	G1: See preamble text	−5.64
95813	EEG over 1 hour	EF003	bedroom furniture (hospital bed, table, reclining chair).	NF	.....	142	129	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.08
95813	EEG over 1 hour	EQ017	EEG, digital, prolonged testing system (computer w-remote camera).	NF	.....	142	129	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−1.91
95813	EEG over 1 hour	L047B	REEGT	NF	Perform procedure	96	80	G1: See preamble text	−7.52
96933	Rcm celulr subcelulr img skn.	L042A	RN/LPN	NF	Review imaging with interpreting physician.	2	0	G1: See preamble text	−0.84
96934	Rcm celulr subcelulr img skn.	EF031	table, power	NF	.....	32	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02

96934	Rcm celulr subcelulr img skn.	EQ168	light, exam	NF	.....	32	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.00
96934	Rcm celulr subcelulr img skn.	ES056	reflectance confocal imaging system.	NF	.....	32	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.37
96934	Rcm celulr subcelulr img skn.	L042A	RN/LPN	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist.	2	0	L6: Add-on code. Additional time for clinical labor task not typical; see preamble text.	−0.84
96934	Rcm celulr subcelulr img skn.	L042A	RN/LPN	NF	Prepare and position pt/monitor pt/set up IV.	2	1	L6: Add-on code. Additional time for clinical labor task not typical; see preamble text.	−0.42
96934	Rcm celulr subcelulr img skn.	L042A	RN/LPN	NF	Review imaging with interpreting physician.	2	1	G1: See preamble text	−0.42
96935	Rcm celulr subcelulr img skn.	EF031	table, power	NF	.....	32	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.02
96935	Rcm celulr subcelulr img skn.	EQ168	light, exam	NF	.....	32	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	0.00
96935	Rcm celulr subcelulr img skn.	ES056	reflectance confocal imaging system.	NF	.....	32	31	E1: Refined equipment time to conform to established policies for non-highly technical equipment.	−0.37
96935	Rcm celulr subcelulr img skn.	L042A	RN/LPN	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist.	2	0	L6: Add-on code. Additional time for clinical labor task not typical; see preamble text.	−0.84
96935	Rcm celulr subcelulr img skn.	L042A	RN/LPN	NF	Prepare and position pt/monitor pt/set up IV.	2	1	L6: Add-on code. Additional time for clinical labor task not typical; see preamble text.	−0.42
96935	Rcm celulr subcelulr img skn.	L042A	RN/LPN	NF	Review imaging with interpreting physician.	2	0	G1: See preamble text	−0.84
97161	Pt eval low complex 20 min.	EF028	table, mat, hi-lo, 6 x 8 platform ...	NF	.....	13	20	E11: Refined equipment time to conform with other codes in the family.	0.07
97161	Pt eval low complex 20 min.	EQ219	rehab and testing system (BTE primus).	NF	.....	5	10	E11: Refined equipment time to conform with other codes in the family.	0.89
97161	Pt eval low complex 20 min.	EQ243	treadmill	NF	.....	5	3	E11: Refined equipment time to conform with other codes in the family.	−0.03
97161	Pt eval low complex 20 min.	L023A	Physical Therapy Aide	NF	Prepare and position pt/monitor pt/set up IV.	0	2	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	0.46
97161	Pt eval low complex 20 min.	L039B	Physical Therapy Assistant	NF	Assist physical therapist with exam/evaluation, obtain records/measures.	5	10	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	1.95
97161	Pt eval low complex 20 min.	L039B	Physical Therapy Assistant	NF	Conduct phone calls/call in prescriptions.	0	3	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	1.17
97161	Pt eval low complex 20 min.	L039B	Physical Therapy Assistant	NF	Obtain/record medical and medication history, self assessment tools, and fall screening for PT review.	5	8	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	1.17
97161	Pt eval low complex 20 min.	L039B	Physical Therapy Assistant	NF	Obtain vital signs	3	5	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	0.78
97162	Pt eval mod complex 30 min.	L039B	Physical Therapy Assistant	NF	Obtain/record medical and medication history, self assessment tools, and fall screening for PT review.	10	8	G1: See preamble text	−0.78

TABLE 28—CY 2017 FINAL RULE DIRECT PE REFINEMENT TABLE—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change
97163	Pt eval high complex 45 min.	EF028	table, mat, hi-lo, 6 x 8 platform ...	NF	.....	30	20	E11: Refined equipment time to conform with other codes in the family.	−0.10
97163	Pt eval high complex 45 min.	EQ148	kit, hand dexterity, sensory, strength.	NF	.....	5	2	E11: Refined equipment time to conform with other codes in the family.	−0.01
97163	Pt eval high complex 45 min.	EQ201	parallel bars, platform mounted ..	NF	.....	5	0	E11: Refined equipment time to conform with other codes in the family.	−0.02
97163	Pt eval high complex 45 min.	EQ243	treadmill	NF	.....	0	3	E11: Refined equipment time to conform with other codes in the family.	0.04
97163	Pt eval high complex 45 min.	L039B	Physical Therapy Assistant	NF	Assist physical therapist with exam/evaluation, obtain records/measures.	15	10	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.95
97163	Pt eval high complex 45 min.	L039B	Physical Therapy Assistant	NF	Obtain/record medical and medication history, self assessment tools, and fall screening for PT review.	12	8	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−1.56
97163	Pt eval high complex 45 min.	SM022	sanitizing cloth-wipe (surface, instruments, equipment).	NF	.....	6	5	S5: Refined supply quantity to conform with other codes in the family.	−0.05
97164	Pt re-eval est plan care	L039B	Physical Therapy Assistant	NF	Obtain/record medical and medication history, self assessment tools, and fall screening for PT review.	5	4	G1: See preamble text	−0.39
97165	Ot eval low complex 20 min.	EF033	table, treatment, hi-lo	NF	.....	0	10	E11: Refined equipment time to conform with other codes in the family.	0.05
97165	Ot eval low complex 20 min.	EL002	environmental module—kitchen ..	NF	.....	10	11	E11: Refined equipment time to conform with other codes in the family.	0.11
97165	Ot eval low complex 20 min.	EQ068	balance assessment-retraining system (Balance Master).	NF	.....	0	8	E11: Refined equipment time to conform with other codes in the family.	0.43
97165	Ot eval low complex 20 min.	EQ143	kit, ADL	NF	.....	8	11	E11: Refined equipment time to conform with other codes in the family.	0.00
97165	Ot eval low complex 20 min.	EQ151	kit, motor coordination	NF	.....	2	3	E11: Refined equipment time to conform with other codes in the family.	0.00
97165	Ot eval low complex 20 min.	EQ152	kit, sensory	NF	.....	2	3	E11: Refined equipment time to conform with other codes in the family.	0.00
97165	Ot eval low complex 20 min.	ES057	environmental module—bathroom.	NF	.....	0	10	E11: Refined equipment time to conform with other codes in the family.	0.64
97165	Ot eval low complex 20 min.	ES058	kit, vision	NF	.....	0	3	E11: Refined equipment time to conform with other codes in the family.	0.00
97165	Ot eval low complex 20 min.	L039B	Physical Therapy Assistant	NF	Assist physician in performing procedure (15%).	5	7	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	0.78
97165	Ot eval low complex 20 min.	L039B	Physical Therapy Assistant	NF	Obtain measurements	4	6	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	0.78
97165	Ot eval low complex 20 min.	L039B	Physical Therapy Assistant	NF	Obtain vital signs	3	5	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	0.78
97166	Ot eval mod complex 30 min.	L039B	Physical Therapy Assistant	NF	Obtain measurements	8	6	G1: See preamble text	−0.78
97167	Ot eval high complex 45 min.	EF033	table, treatment, hi-lo	NF	.....	15	10	E11: Refined equipment time to conform with other codes in the family.	−0.03
97167	Ot eval high complex 45 min.	EL002	environmental module—kitchen ..	NF	.....	14	11	E11: Refined equipment time to conform with other codes in the family.	−0.34
97167	Ot eval high complex 45 min.	EQ068	balance assessment-retraining system (Balance Master).	NF	.....	0	8	E11: Refined equipment time to conform with other codes in the family.	0.43
97167	Ot eval high complex 45 min.	EQ117	evaluation system for upper extremity-hand (Greenleaf).	NF	.....	5	4	E11: Refined equipment time to conform with other codes in the family.	−0.07

97167	Ot eval high complex 45 min.	EQ143	kit, ADL	NF	.....	15	11	E11: Refined equipment time to conform with other codes in the family.	−0.01
97167	Ot eval high complex 45 min.	EQ185	neurobehavioral status instrument.	NF	.....	11	0	E11: Refined equipment time to conform with other codes in the family.	−0.59
97167	Ot eval high complex 45 min.	EQ219	rehab and testing system (BTE primus).	NF	.....	5	3	E11: Refined equipment time to conform with other codes in the family.	−0.36
97167	Ot eval high complex 45 min.	ES057	environmental module — bathroom.	NF	.....	14	10	E11: Refined equipment time to conform with other codes in the family.	−0.26
97167	Ot eval high complex 45 min.	L039B	Physical Therapy Assistant	NF	Assist physician in performing procedure (15%).	9	7	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−0.78
97167	Ot eval high complex 45 min.	L039B	Physical Therapy Assistant	NF	Obtain measurements	12	6	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family.	−2.34
97168	Ot re-eval est plan care	L039B	Physical Therapy Assistant	NF	Obtain measurements	3	2	G1: See preamble text	−0.39
G0416	Prostate biopsy, any mthd	SL063	eosin y	NF	.....	48	0	S7: Supply item replaced by another item; see preamble SL201.	−38.45
G0416	Prostate biopsy, any mthd	SL201	stain, eosin	NF	.....	0	48	S8: Supply item replaces another item; see preamble SL063.	3.24

TABLE 29—CY 2017 FINAL RULE NO PE REFINEMENT TABLE

HCPCS Code	Short Descriptor
00740	Anesth upper gi visualize.
00810	Anesth low intestine scope.
11730	Removal of nail plate.
19298	Place breast rad tube/caths.
20245	Bone biopsy excisional.
20550	Inj tendon sheath/ligament.
20552	Inj trigger point 1/2 muscl.
20553	Inject trigger points 3/>.
20982	Ablate bone tumor(s) perq.
20983	Ablate bone tumor(s) perq.
22512	Vertebroplasty addl inject.
22515	Perq vertebral augmentation.
22526	Idet single level.
22527	Idet 1 or more levels.
22853	Insj biomechanical device.
22854	Insj biomechanical device.
22859	Insj biomechanical device.
22867	Insj stablj dev w/dcmprn.
22868	Insj stablj dev w/dcmprn.
22869	Insj stablj dev w/o dcmprn.
22870	Insj stablj dev w/o dcmprn.
28289	Repair hallux rigidus.
28291	Corrj halux rigdus w/implt.
28292	Correction of bunion.
28295	Correction hallux valgus.
28296	Correction of bunion.
28297	Correction of bunion.
28298	Correction of bunion.
28299	Correction of bunion.
31615	Visualization of windpipe.
31622	Dx bronchoscope/wash.
31623	Dx bronchoscope/brush.
31624	Dx bronchoscope/lavage.
31625	Bronchoscopy w/biopsy(s).
31626	Bronchoscopy w/markers.
31627	Navigational bronchoscopy.
31628	Bronchoscopy/lung bx each.
31629	Bronchoscopy/needle bx each.
31632	Bronchoscopy/lung bx addl.
31633	Bronchoscopy/needle bx addl.
31634	Bronch w/balloon occlusion.
31635	Bronchoscopy w/fb removal.
31645	Bronchoscopy clear airways.
31646	Bronchoscopy reclear airway.
31652	Bronch ebus samplng 1/2 node.
31653	Bronch ebus samplng 3/node.
31654	Bronch ebus ivntj perph les.
32405	Percut bx lung/mediastinum.
32550	Insert pleural cath.
32553	Ins mark thor for rt perq.
33340	Perq clsr tcat l atr apndge.
33390	Valvuloplasty aortic valve.
33391	Valvuloplasty aortic valve.
35471	Repair arterial blockage.
35472	Repair arterial blockage.
35475	Repair arterial blockage.
35476	Repair venous blockage.
36010	Place catheter in vein.
36140	Establish access to artery.
36147	Access av dial grft for eval.
36148	Access av dial grft for proc.
36200	Place catheter in aorta.
36227	Place cath xtrnl carotid.
36228	Place cath intracranial art.
36245	Ins cath abd/l-ext art 1st.
36246	Ins cath abd/l-ext art 2nd.
36247	Ins cath abd/l-ext art 3rd.
36248	Ins cath abd/l-ext art addl.
36481	Insertion of catheter vein.
36555	Insert non-tunnel cv cath.
36557	Insert tunneled cv cath.
36558	Insert tunneled cv cath.
36560	Insert tunneled cv cath.
36561	Insert tunneled cv cath.
36563	Insert tunneled cv cath.
36565	Insert tunneled cv cath.
36566	Insert tunneled cv cath.
36568	Insert picc cath.
36570	Insert picvad cath.
36571	Insert picvad cath.
36576	Repair tunneled cv cath.
36578	Replace tunneled cv cath.
36581	Replace tunneled cv cath.
36582	Replace tunneled cv cath.
36583	Replace tunneled cv cath.
36585	Replace picvad cath.
36590	Removal tunneled cv cath.
36870	Percut thrombect av fistula.
36907	Balo angiop ctr dialysis seg.
36908	Stent plmt ctr dialysis seg.
36909	Dialysis circuit embolj.
37183	Remove hepatic shunt (tips).
37185	Prim art m-thrmbc sbsq vsl.
37186	Sec art thrombectomy add-on.
37193	Rem endovas vena cava filter.
37222	Iliac revasc add-on.
37223	Iliac revasc w/stent add-on.
37232	Tib/per revasc add-on.
37233	Tibper revasc w/ather add-on.
37234	Revsc opn/prq tib/pero stent.
37235	Tib/per revasc stnt & ather.
37237	Open/perq place stent ea add.
37239	Open/perq place stent ea add.
37247	Trluml balo angiop addl art.
37249	Trluml balo angiop addl vein.
37252	Intrvasc us noncoronary 1st.
37253	Intrvasc us noncoronary addl.
43200	Esophagoscopy flexible brush.
43201	Esoph scope w/submucous inj.
43202	Esophagoscopy flex biopsy.
43206	Esoph optical endomicroscopy.
43213	Esophagoscopy retro balloon.
43215	Esophagoscopy flex remove fb.
43216	Esophagoscopy lesion removal.
43217	Esophagoscopy snare les remv.
43220	Esophagoscopy balloon <30mm.
43226	Esoph endoscopy dilation.
43227	Esophagoscopy control bleed.
43229	Esophagoscopy lesion ablate.
43231	Esophagoscop ultrasound exam.
43232	Esophagoscopy w/us needle bx.
43235	Egd diagnostic brush wash.
43236	Uppr gi scope w/submuc inj.
43239	Egd biopsy single/multiple.
43245	Egd dilate stricture.
43247	Egd remove foreign body.
43248	Egd guide wire insertion.
43249	Esoph egd dilation <30 mm.
43250	Egd cautery tumor polyp.
43251	Egd remove lesion snare.
43252	Egd optical endomicroscopy.
43255	Egd control bleeding any.
43270	Egd lesion ablation.
43284	Laps esophgl sphnctr agmntj.
43285	Rmvl esophgl sphnctr dev.
43450	Dilate esophagus 1/mult pass.
43453	Dilate esophagus.
44380	Small bowel endoscopy br/wa.
44381	Small bowel endoscopy br/wa.
44382	Small bowel endoscopy.
44385	Endoscopy of bowel pouch.
44386	Endoscopy bowel pouch/biop.
44388	Colonoscopy thru stoma spx.
44389	Colonoscopy with biopsy.
44390	Colonoscopy for foreign body.
44391	Colonoscopy for bleeding.
44392	Colonoscopy & polypectomy.
44394	Colonoscopy w/snare.
44401	Colonoscopy with ablation.
44404	Colonoscopy w/injection.
44405	Colonoscopy w/dilation.
45303	Proctosigmoidoscopy dilate.
45305	Proctosigmoidoscopy w/bx.
45307	Proctosigmoidoscopy fb.
45308	Proctosigmoidoscopy removal.
45309	Proctosigmoidoscopy removal.
45315	Proctosigmoidoscopy removal.
45317	Proctosigmoidoscopy bleed.

TABLE 29—CY 2017 FINAL RULE NO PE REFINEMENT TABLE—Continued

HCPCS Code	Short Descriptor
45320	Proctosigmoidoscopy ablate.
45332	Sigmoidoscopy w/fb removal.
45333	Sigmoidoscopy & polypectomy.
45334	Sigmoidoscopy for bleeding.
45335	Sigmoidoscopy w/submuc inj.
45338	Sigmoidoscopy w/tumr remove.
45340	Sig w/tndsc balloon dilation.
45346	Sigmoidoscopy w/ablation.
45350	Sgmdsc w/band ligation.
45378	Diagnostic colonoscopy.
45379	Colonoscopy w/fb removal.
45380	Colonoscopy and biopsy.
45381	Colonoscopy submucous njx.
45382	Colonoscopy w/control bleed.
45384	Colonoscopy w/lesion removal.
45385	Colonoscopy w/lesion removal.
45386	Colonoscopy w/balloon dilat.
45388	Colonoscopy w/ablation.
45398	Colonoscopy w/band ligation.
47000	Needle biopsy of liver.
47382	Percut ablate liver rf.
47383	Perq abltj lvr cryoablation.
49411	Ins mark abd/pel for rt perq.
49446	Change g-tube to g-j perc.
50200	Renal biopsy perq.
50592	Perc rf ablate renal tumor.
50593	Perc cryo ablate renal tum.
51702	Insert temp bladder cath.
51703	Insert bladder cath complex.
51720	Treatment of bladder lesion.
51784	Anal/urinary muscle study.
55700	Biopsy of prostate.
57155	Insert uteri tandem/ovoids.
58559	Hysteroscopy lysis.
58560	Hysteroscopy resect septum.
58561	Hysteroscopy remove myoma.
58563	Hysteroscopy ablation.
58674	Laps abltj uterine fibroids.
61640	Dilate ic vasospasm init.
61641	Dilate ic vasospasm add-on.
61642	Dilate ic vasospasm add-on.
62320	Njx interlaminar crv/thrc.
62322	Njx interlaminar lmbr/sac.
62324	Njx interlaminar crv/thrc.
62326	Njx interlaminar lmbr/sac.
62380	Ndsc dcmprn 1 ntrspc lumbar.
66720	Destruction ciliary body.
67101	Repair detached retina.
67105	Repair detached retina.
69300	Revise external ear.
76706	Us abdl aorta screen aaa.
77332	Radiation treatment aid(s).
77333	Radiation treatment aid(s).
77334	Radiation treatment aid(s).
77470	Special radiation treatment.
77600	Hyperthermia treatment.
77605	Hyperthermia treatment.
77610	Hyperthermia treatment.
77615	Hyperthermia treatment.
91110	Gi tract capsule endoscopy.
91111	Esophageal capsule endoscopy.
92132	Cmptr ophth dx img ant segmt.
92133	Cmptr ophth img optic nerve.
92134	Cptr ophth dx img post segmt.
92235	Eye exam with photos.
92240	Icg angiography.
92242	Fluorescein icg angiography.
92250	Eye exam with photos.
92960	Cardioversion electric ext.
93312	Echo transesophageal.
93314	Echo transesophageal.
93451	Right heart cath.
93452	Left hrt cath w/ ventrclgrphy.
93453	R&l hrt cath w/ ventriclgrphy.
93454	Coronary artery angio s&i.
93455	Coronary art/grft angio s&i.
93456	R hrt coronary artery angio.
93457	R hrt art/grft angio.
93458	L hrt artery/ventricle angio.
93459	L hrt art/grft angio.
93460	R&l hrt art/ventricle angio.
93461	R&l hrt art/ventricle angio.
93464	Exercise w/hemodynamic meas.
93505	Biopsy of heart lining.
93566	Inject r ventr/atrial angio.
93567	Inject suprvlv aortography.
93568	Inject pulm art hrt cath.
93590	Perq transcath cls mitral.
93591	Perq transcath cls aortic.
93592	Perq transcath closure each.
93642	Electrophysiology evaluation.
93644	Electrophysiology evaluation.
95144	Antigen therapy services.
95165	Antigen therapy services.
95957	EEG digital analysis.
96160	Pt-focused hlth risk assmt.
96161	Caregiver health risk assmt.
96440	Chemotherapy intracavitary.
96931	Rcm celulr subcelulr img skn.
96932	Rcm celulr subcelulr img skn.
96936	Rcm celulr subcelulr img skn.
99151	Mod sed same phys/qhp <5 yrs.
99152	Mod sed same phys/qhp 5/ yrs.
99153	Mod sed same phys/qhp ea.
99155	Mod sed oth phys/qhp <5 yrs.
99156	Mod sed oth phys/qhp 5/ yrs.
99157	Mod sed other phys/qhp ea.
G0341	Percutaneous islet celltrans.

TABLE 30—CY 2017 FINAL RULE NEW INVOICES TABLE

Invoices received for New Direct PE inputs					
CPT/HCPCS codes	Item name	CMS code	Average price	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
31551, 31552, 31553, 31554, 31574, 31575, 31579, 31580, 31584, 31587, 31591, 31592.	rhinolaryngoscope, flexible, video, non-channeled.	ES063	8,000.00	1	541,537
31572, 31573, 31576, 31577, 31578.	rhinolaryngoscope, flexible, video, channeled ..	ES064	9,000.00	1	756
31576, 31577, 31578	Disposable biopsy forceps	SD318	26.84	1	574

TABLE 30—CY 2017 FINAL RULE NEW INVOICES TABLE—Continued

Invoices received for New Direct PE inputs					
CPT/HCPCS codes	Item name	CMS code	Average price	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
31579	stroboscopy system	ES065	16,843.87	1	54,466
31574	Voice Augmentation Gel	SJ090	575.00	1	99
36473	Claravein Kit	SA122	890.00	1	264
36473, 36474	Sotradecol Sclerosing Agent	SH108	110.20	1	528
55700	Biopsy Guide	EQ375	7,000.00	0	85,731
58558	Hysteroscopic tissue removal device	SF059	629.00	2	2,677
58558	Hysteroscopic fluid management system	EQ378	14,698.38	1	2,677
58558	Hysteroscopic resection system (control unit, footpiece, handpiece, sheath, and calibration device).	EQ379	19,772.25	1	2,677
58558	Hysteroscopic fluid management tubing kit	SA123	320.00	1	2,677
70540, 70542, 70543; over 400 additional codes.	Professional PACS Workstation	ED053	14,616.93	9	32,571,650
77332	knee wedge/foot block system	EQ376	3,290.00	1	48,831
77333	Thermoplastic tissue bolus 30X30X0.3cm	SD321	23.90	1	3,493
77333	water bath, digital control	EP120	2,350.00	1	3,493
77333, 77334	Supine Breast/Lung Board	EQ377	5,773.15	1	290,969
77334	Urethane Foaming Agent	SL519	53.50	1	287,476
88184, 88185	flow cytometry analytics software	EQ380	14,000.00	1	1,680,252
95144, 95165	antigen vial transport envelope	SK127	1.50	2	6,464,311
96161	Beck Depression Inventory, Second Edition (BDI–II).	SK128	2.26	1	1
96416	IV infusion pump, ambulatory	EQ381	2,384.45	0	116,894
96931, 96932	Imaging Tray	SA121	34.75	1	5
96931, 96932	adhesive ruler	SK125	9.95	1	5
96931, 96932, 96934, 96935	reflectance confocal imaging system	ES056	98,500.00	1	9
97166, 97167, 97168	environmental module—bathroom	ES057	25,000.00	1	115,107
97166, 97167	kit, vision	ES058	410.00	1	86,912
G0202, G0204, G0206	PACS Mammography Workstation	ED054	103,616.47	8	2,274,249
G0501	patient lift system	EF045	2,824.33	3	15,115,789
G0501	wheelchair accessible scale	EF046	875.92	3	15,115,789
G0501	leg positioning system	EF047	1,076.50	3	15,115,789
No Codes	Chloraprep applicator (26 ml)	SJ091	8.48	3	0
No Codes	LED Light Source (50W LED)	EQ382	1,915.00	1	0

TABLE 31—CY 2017 FINAL RULE EXISTING INVOICES TABLE

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
19030, 19081, 19082, 19281, 19282, 19283, 19284, 77053, 77054, G0202, G0204, G0206.	room, digital mammography.	EL013	168,214.00	362,935.00	116	10	2,294,862
31551, 31552, 31553, 31554, 31572, 31573, 31574, 31575, 31576, 31577, 31578, 31579, 31580, 31584, 31587, 31591, 31592, 190+ other codes.	video system, endoscopy (processor, digital capture, monitor, printer, cart).	ES031	33,232.50	33,391.00	0	3	1,497,130
58555, 58562, 58563, 58565.	endoscope, rigid, hysteroscopy.	ES009	4,990.50	6,207.50	24	1	672

TABLE 31—CY 2017 FINAL RULE EXISTING INVOICES TABLE—Continued

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
88323, 88355, 88380, 88381.	stain, eosin	SL201	0.04	0.07	55	5	45,393
88360, 88361	Antibody Estrogen Receptor monoclonal.	SL493	3.19	14.00	339	4	216,208
91110	kit, capsule endoscopy w-application supplies (M2A).	SA005	450.00	520.00	16	1	30,464
91110, 91111	video system, capsule endoscopy (software, computer, monitor, printer).	ES029	17,000.00	12,450.00	−27	1	30,586
91111	kit, capsule, ESO, endoscopy w-application supplies (ESO).	SA094	450.00	472.80	5	1	122
91200	Fibroscan with printer.	ER101	124,950.00	183,390.00	47	1	6,226
95145, 95146, 95148, 95149.	antigen, venom	SH009	16.67	20.14	21	4	50,772
95147, 95148, 95149.	antigen, venom, trivespid.	SH010	30.22	44.05	46	3	37,955
122 codes	light source, xenon	EQ167	6,723.33	7,000.00	4	1	2,149,616
59 codes	fiberscope, flexible, rhinolaryngoscopy.	ES020	6,301.93	4,250.00	−33	1	581,924

M. Therapy Caps

1. Outpatient Therapy Caps for CY 2017

Section 1833(g) of the Act requires application of annual per beneficiary limitations on the amount of expenses that can be considered as incurred expenses for outpatient therapy services under Medicare Part B, commonly referred to as ''therapy caps.'' There is one therapy cap for outpatient occupational therapy (OT) services and another separate therapy cap for physical therapy (PT) and speech-language pathology (SLP) services combined.

The therapy caps apply to outpatient therapy services furnished in all settings, including the previously exempted hospital setting (effective October 1, 2012), critical access hospitals (CAHs) (effective January 1, 2014), and Maryland hospitals paid under the Maryland All-Payer Model (effective January 1, 2016).

The therapy cap amounts under section 1833(g) of the Act are updated each year based on the Medicare Economic Index (MEI). Specifically, the annual caps are calculated by updating the previous year's cap by the MEI for the upcoming calendar year and rounding to the nearest $10.00. Increasing the CY 2016 therapy cap of $1,960 by the CY 2017 MEI of 1.2 percent and rounding to the nearest $10.00 results in a CY 2017 therapy cap amount of $1,980.

An exceptions process for the therapy caps has been in effect since January 1, 2006. Originally required by section 5107 of the Deficit Reduction Act of 2005 (DRA), which amended section 1833(g)(5) of the Act, the exceptions process for the therapy caps has been extended multiple times through subsequent legislation as described in the CY 2015 PFS final rule with comment period (79 FR 67730) and most recently extended by the MACRA. Our current authority to provide an exceptions process for therapy caps expires on December 31, 2017.

CMS tracks each beneficiary's incurred expenses annually and counts them towards the therapy caps by applying the PFS rate for each service less any applicable multiple procedure payment reduction (MPPR) amount. As required by section 1833(g)(6)(B) of the Act, added by section 603(b) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) and extended by subsequent legislation, the PFS-rate accrual process is applied to outpatient therapy services furnished by CAHs even though they are paid on a cost basis. As we explained in the CY 2016 PFS final rule, we use cost-based rates to track each beneficiary's incurred expenses amounts for the outpatient therapy services furnished by the Maryland hospitals paid under the Maryland All-Payer Model, currently being tested under the authority of section 1115A of the Act. After expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the therapy caps, therapy suppliers and providers use the KX modifier on claims for subsequent services to request an exception to the therapy caps. By using the KX modifier, the therapist is attesting that the services above the therapy caps are reasonable and necessary and that there is documentation of medical necessity for the services in the beneficiary's medical record. Claims for outpatient therapy services over the caps without the KX modifier are denied.

Since October 1, 2012, under section 1833(g)(5)(C) of the Act as amended by the Middle Class Tax Relief and Jobs Creation Act of 2012 (MCTRJCA) (Pub. L. 112–96), we have been required to apply a manual medical review process to therapy claims when a beneficiary's incurred expenses for outpatient therapy services exceed a threshold amount of $3,700. Just as there are two separate therapy caps, there are two separate thresholds of $3,700, one for OT services and one for PT and SLP services combined; and incurred expenses are counted towards these thresholds in the same manner as the caps. Under section 1833(g)(5) of the Act, as amended by section 202(b) of the MACRA, not all claims exceeding the therapy thresholds are subject to a manual medical review process as they were before. Instead, since MACRA, we are permitted to do a more targeted medical review on these claims using factors specified in section 1833(g)(5)(E)(ii) of the Act as amended by section 202(b) of the MACRA, including targeting those therapy providers with a high claims denial rate for therapy services or with aberrant billing practices compared to their peers. The manual medical review process required under section 1833(g)(5)(C) of the Act expires at the same time as the exceptions process for therapy caps, on December 31, 2017. For information on the manual medical review process, go to *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/TherapyCap.html*

III. Other Provisions of the Final Rule for PFS

A. Chronic Care Management (CCM) and Transitional Care Management (TCM) Supervision Requirements in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In the CY 2016 PFS final rule with comment period (80 FR 71080 through 71088), 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. Payment is made when CPT code 99490 is billed alone or with other payable services on a RHC or FQHC claim, and the rate is based on the PFS national average non-facility payment rate. The requirement that RHC or FQHC services be furnished face-to-face was waived for CCM services furnished to a RHC or FQHC patient because CCM services are not required to be furnished face-to-face.

Medicare payment for TCM services furnished by a RHC or FQHC practitioner was effective January 1, 2013, consistent with the effective date of payment for TCM services under the PFS (77 FR 68978 through 68994; also, see CMS-Pub. 100–02, Medicare Benefit Policy Manual, chapter 13, section 110.4).

TCM services are billable only when furnished within 30 days of the date of the patient's discharge from a hospital (including outpatient observation or partial hospitalization), skilled nursing facility, or community mental health center. Communication (direct contact, telephone, or electronic) with the patient or caregiver must commence within 2 business days of discharge, and a face-to-face visit must occur within 14 days of discharge for moderate complexity decision making (CPT code 99495), or within 7 days of discharge for high complexity decision making (CPT code 99496). The TCM visit is billed on the day that the TCM visit takes place, and only one TCM visit may be paid per beneficiary for services furnished during that 30 day post-discharge period. If the TCM visit occurs on the same day as another billable visit, only one visit may be billed. TCM and CCM cannot be billed during the same time period for the same patient.

In the CY 2016 PFS final rule with comment period (80 FR 71087), we responded to comments requesting that we make an exception to the supervision requirements for auxiliary personnel furnishing CCM and TCM services incident to physician services in RHCs and FQHCs (80 FR 71087). Auxiliary personnel in RHCs and FQHCs furnish services incident to a RHC or FQHC visit and include nurses, medical assistants, and other clinical personnel who work under the direct supervision of a RHC or FQHC practitioner. The commenters suggested that the regulatory language be amended to be consistent with the provision in § 410.26(b)(5) for CCM and TCM services under the PFS, which states that services and supplies furnished incident to CCM and TCM services can be furnished under general supervision of the physician (or other practitioner) when they are provided by clinical staff. It further specifies that the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based, but only the supervising physician (or other practitioner) may bill Medicare for incident to services. We responded that due to the differences between physician offices and RHCs and FQHCs in their models of care and payment structures, we believe that the direct supervision requirement for services furnished by auxiliary personnel is appropriate for RHCs and FQHCs, but that we would consider changing this in future rulemaking if RHCs and FQHCs found that requiring direct supervision presents a barrier to furnishing CCM services.

Since payment for CCM in RHCs and FQHCs began on January 1, 2016, some RHCs and FQHCs have informed us that, in their view, the direct supervision requirement for auxiliary personnel has limited their ability to furnish CCM services. Specifically, these RHCs and FQHCs have stated that the direct supervision requirement prevented them from entering into contracts with third party companies to provide CCM services, especially during hours that they were not open, and that they were unable to meet the CCM requirements within their current staffing and budget constraints.

To bill for CCM services, RHCs and FQHCs must ensure that there is access to care management services on a 24 hour a day, 7 day a week basis. This includes providing the patient with a means to make timely contact with RHC or FQHC practitioners who have access to the patient's electronic care plan to address his or her urgent chronic care needs. The RHC or FQHC must ensure the care plan is available electronically at all times to anyone within the RHC or FQHC who is providing CCM services.

Once the RHC or FQHC practitioner has initiated CCM services and the patient has consented to receiving this service, CCM services can be furnished by a RHC or FQHC practitioner, or by auxiliary personnel, as defined in § 410.26(a)(1), which includes nurses, medical assistants, and other personnel working under physician supervision who meet the requirements to provide incident to services. Auxiliary personnel in RHCs and FQHCs must furnish services under direct supervision, which requires that a RHC or FQHC practitioner be present in the RHC or FQHC and immediately available to furnish assistance and direction. The RHC or FQHC practitioner does not need to be present

in the room when the service is furnished.

Although many RHCs and FQHCs prefer to furnish CCM and TCM services utilizing existing personnel, some RHCs and FQHCs would like to contract with a third party to furnish aspects of their CCM and TCM services, but cannot do so because of the direct supervision requirement. Without the ability to contract with a third party, these RHCs and FQHCs have stated that they find it difficult to meet the CCM requirements for 24 hours a day, 7 days a week access to services.

To enable RHCs and FQHCs to effectively contract with third parties to furnish aspects of CCM and TCM services, we proposed to revise § 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 a RHC or FQHC practitioner. The proposed exception to the direct supervision requirement would apply only to auxiliary personnel furnishing CCM or TCM incident to services, and would not apply to any other RHC or FQHC services. The proposed revisions for CCM and TCM services and supplies furnished by RHCs and FQHCs are 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.

The following is a summary of the comments we received on revising the supervision requirements for RHCs and FQHCs to allow general supervision for auxiliary personnel furnishing CCM or TCM services.

Comment: We received 23 comments on our proposal to allow services and supplies furnished incident to CCM and TCM services to be furnished under general supervision of a RHC or FQHC practitioner. All commenters supported this change.

Response: We appreciate the support for this proposal.

Comment: One commenter urged CMS to use the Advisory Panel on Hospital Outpatient Payment to determine RHC and FQHC supervision levels.

Response: Auxiliary personnel in RHCs and FQHCs work under direct supervision of a RHC or FQHC practitioner (consistent with statutory and regulatory authority), and we proposed to make an exception for CCM and TCM services because they are the only RHC and FQHC services that have a non-face-to-face component. We do not foresee any additional exceptions to this policy.

After considering the comments, we are finalizing this policy to revise § 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 a RHC or FQHC practitioner.

B. FQHC-Specific Market Basket

1. Background

Section 10501(i)(3)(A) of the Affordable Care Act (Pub. L. 111–148 and Pub. L. 111–152) added section 1834(o) of the Act to establish a payment system for the costs of FQHC services under Medicare Part B based on prospectively set rates. In the Prospective Payment System (PPS) for FQHC Final Rule published in the May 2, 2014 **Federal Register** (79 FR 25436), CMS implemented a methodology and payment rates for the FQHC PPS. The FQHC PPS base payment rate was determined using FQHC cost report and claims data and was effective for FQHC payments from October 1, 2014, through December 31, 2015 (implementation year). The adjusted base payment rate for the implementation year was $158.85 (79 FR 25455). When calculating the FQHC PPS payment, the base payment rate is multiplied by the FQHC geographic adjustment factor (GAF) based on the location of the FQHC, and adjusted for new patients or when an initial preventive physical examination or annual wellness visit are furnished. Beginning on October 1, 2014, FQHCs began to transition to the FQHC PPS based on their cost reporting periods. As of January 1, 2016, all FQHCs are paid under the FQHC PPS.

Section 1834(o)(2)(B)(ii) of the Act requires that the payment for the first year after the implementation year be increased by the percentage increase in the MEI. Therefore, in CY 2016, the FQHC PPS base payment rate was increased by the MEI. The MEI was based on 2006 data from the American Medical Association (AMA) for self-employed physicians and was used in the PFS Sustainable Growth Rate (SGR) formula to determine the conversion factor for physician service payments. (See the CY 2014 PFS final rule (78 FR 74264) for a complete discussion of the 2006-based MEI). Section 1834(o)(2)(B)(ii) of the Act also requires that beginning in CY 2017, the FQHC PPS base payment rate is to be increased by the percentage increase in a market basket of FQHC goods and services, or if such an index is not available, by the percentage increase in the MEI.

For CY 2017, we proposed to create a 2013-based FQHC market basket. The market basket uses Medicare cost report (MCR) data submitted by freestanding FQHCs. In the discussion in the CY 2017 PFS proposed rule (81 FR 46378–46386) we provided an overview of the market basket and described the methodologies used to determine the cost categories, cost weights, and price proxies. In addition, we compared the growth rates of the proposed FQHC market basket to the growth rates of the MEI.

2. Overview of the FQHC Market Basket

The 2013-based FQHC market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this final rule, the base period is CY 2013), total base period costs are estimated for a set of mutually exclusive and exhaustive cost categories, and the proportion of total costs that each cost category represents is calculated. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage variable, referred to as a price proxy. These price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the cost weight for each cost category is multiplied by the established price proxy index level. The sum of these products (that is, the cost weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket for the given time period. Repeating this step for other periods produces a series of market basket levels over time. Dividing the composite index level of one period by the composite index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish FQHC services. The effects on total costs resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a FQHC hiring more nurses to accommodate the needs of patients would increase the volume

of goods and services purchased by the FQHC, but would not be factored into the price change measured by a fixed-weight FQHC market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market baskets periodically so that the cost weights reflect a current mix of goods and services purchased (FQHC inputs) to furnish FQHC services.

3. Creating a FQHC Market Basket

In 2015, we began researching the possibility of creating a FQHC market basket that would be used in place of the MEI to update the FQHC PPS base payment rate annually. A FQHC market basket should reflect the cost structures of FQHCs while the MEI reflects the cost structures of self-employed physician offices. At the time of implementation of the FQHC PPS, a FQHC market basket had not been developed, and therefore, the law stipulated that the FQHC PPS base payment rate be updated by the MEI for the first year after implementation (CY 2016). In subsequent years, the FQHC PPS base payment rate should be annually updated by a FQHC market basket, if available.

The MEI cost weights were derived from data collected by the AMA on the Physician Practice Expense Information Survey (PPIS), since physicians, unlike other Medicare providers, are not required to complete and submit a Medicare Cost Report. FQHCs submit expense data annually on the Medicare Cost Report form CMS–222–92 (OMB NO: 0938–0107), ''Independent Rural Health Clinic and Freestanding Federally Qualified Health Center Cost Report''; therefore, we were able to estimate relative cost weights specific to FQHCs. We define a ''major cost weight'' as one calculated using the Medicare cost reports (for example, FQHC practitioner compensation). However, the Medicare cost report data allows multiple methods for reporting detailed expenses, either in detailed cost center lines or more broadly reported in general categories of expenses. An alternative data source is used to disaggregate further residual costs that could not be classified into a major cost category directly using only the Medicare Cost Report data. We estimated the cost weights for each year 2009 through 2013 and found the cost weights from each year to be similar, which provided confidence in the derived cost weights.

We believe that the proposed methodologies for the FQHC market basket better reflect the cost structure of FQHC since it captures the scope of services that FQHCs furnish compared to the 2006-based MEI.

4. Development of Cost Categories and Cost Weights for the 2013-Based FQHC Market Basket

a. Use of Medicare Cost Report Data

The 2013-based FQHC market basket consists of eight major cost categories, which were derived from the CY 2013 Medicare cost reports for freestanding FQHCs. These categories are FQHC-Practitioner Compensation, Other Clinical Compensation, Non-Health Compensation, Fringe Benefits, Pharmaceuticals, Fixed Capital, Moveable Capital, and an All Other (Residual) cost category. The All Other (Residual) cost category reflects the costs not captured in the other seven cost categories. The CY 2013 Medicare cost reports include all FQHCs whose cost reporting period began on or after January 1, 2013, and prior to or on December 31, 2013. We selected CY 2013 as the base year because the Medicare cost reports for that year were the most recent, complete set of Medicare cost report data available for FQHCs at the time of development of the cost share weights and proposed 2013-based FQHC market basket. As stated above, we compared the cost share weights from the MCR for CY 2009 through CY 2013 and the CY 2013 weights were consistent with the weights from prior years.

The resulting 2013-based FQHC market basket cost weights reflect Medicare allowable costs. We define Medicare allowable costs for freestanding FQHC facilities as: Worksheet A, Columns 1 and 2, cost centers lines 1 through 51 but excluding line 20, which is professional liability insurance (PLI). We excluded PLI costs from the total Medicare allowable costs because FQHCs that receive section 330 grant funds also are eligible to apply for medical malpractice coverage under Federally Supported Health Centers Assistance Act (FSHCAA) of 1992 (Pub. L. 102–501) and FSHCAA of 1995 (Pub. L. 104–73 amending section 224 of the Public Health Service Act).

Below we summarize how we derive the eight major cost category weights.

(1) *FQHC Practitioner Compensation:* A FQHC practitioner is defined as one of the following occupations: Physicians, NPs, PAs, CNMs, Clinical Psychologist (CPs), and Clinical Social Worker (CSWs). Under certain conditions, a FQHC visit also may be provided by qualified practitioners of outpatient DSMT and MNT when the FQHC meets the relevant program requirements for provision of these services. FQHC Practitioner Compensation costs are derived as the sum of compensation and other costs as reported on Worksheet A; columns 1 and 2; lines 1, 2, 3, 6, 7, 13, 14. The Medicare cost reports also captures ''Other'' compensation costs (the sum of costs reported on Worksheet A; columns 1 and 2; lines 9, 10, 11, and 15). We allocated a portion of these compensation costs to FQHC Practitioner compensation by multiplying this amount by the ratio of FQHC Practitioner compensation costs to the sum of FQHC Practitioner compensation costs and Other Clinical compensation costs. We believe that the assumption of distributing the costs proportionally is reasonable since there is no additional detail on the specific occupations these compensation costs represent. We also included a proportion of Fringe Benefit costs as described in section III.B.1.a.iv of this final rule.

(2) *Other Clinical Compensation:* Other Clinical Compensation includes any health-related clinical staff who does not fall under the definition of a FQHC practitioner from paragraph (1) (FQHC Practitioner Compensation). Other Clinical Compensation costs are derived as the sum of compensation and other costs as reported on Worksheet A; columns 1 and 2; lines 4, 5, and 8. Similar to the FQHC Practitioner compensation, we also allocate a proportion of the ''Other'' Clinical compensation costs by multiplying this amount by the ratio of Other Clinical Compensation costs to the sum of FQHC Practitioner Compensation costs and Other Clinical compensation costs. Given the ambiguity in the costs reported on these lines, we believe that the assumption of distributing the costs proportionally is reasonable since there is no additional detail on the specific occupations these compensation costs represent. We also include a proportion of Fringe Benefit costs as described in section III.B.1.a.iv of this final rule.

(3) *Non-Health Compensation:* Non-Health Compensation includes compensation costs for Office Staff, Housekeeping & Maintenance, and Pharmacy. Non-Health Compensation costs are derived as the sum of compensation costs as reported on Worksheet A; column 1 only for lines 32 and 51; and Worksheet A; both columns 1 and 2 for line 38. We only use the costs from column 1 for housekeeping and maintenance and pharmacy since we believe that there are considerable costs other than compensation that could be reported for these categories. We use the costs from both column 1

and column 2 for office salaries (line 38) since only salaries or compensation should be reported on this line. We also include a proportion of Fringe Benefit costs as described in section III.B.1.a.iv of this final rule.

(4) *Fringe Benefits:* Worksheet A; columns 1 and 2; line 45 of the Medicare cost report captures fringe benefits and payroll tax expenses. The fringe benefit cost weight are estimated as the fringe benefits costs divided by total Medicare allowable costs. We allocate the Fringe Benefits cost weight to the three compensation cost categories (FQHC practitioner compensation, other clinical compensation, and non-health compensation) based on their relative proportions. The fringe benefits ratio is equal to the compensation cost weight as a percent of the sum of the compensation cost weights for all three types of workers. These allocation ratios are 46 percent, 14 percent, and 40 percent, respectively. Therefore, we proposed to allocate 46 percent of the fringe benefits cost weight to the FQHC practitioner cost weight, 14 percent of the fringe benefits cost weight to the clinical compensation cost weight, and 40 percent of the fringe benefits cost weight to the non-health compensation cost weight. Table 32 shows the three compensation category cost weights after the fringe benefit cost weight is allocated for the 2013-based FQHC market basket.

TABLE 32—COMPENSATION CATEGORY COST WEIGHTS AFTER FRINGE BENEFITS ALLOCATION

Cost category	Before fringe benefits allocation %	After fringe benefits allocation %
FQHC Practitioner Compensation	26.8	31.8
Other Clinical Compensation	8.1	9.5
Non-Health Compensation	23.1	27.4
Fringe Benefits (distribute to comp)	10.7	0.0

(5) *Pharmaceuticals:* Drugs and biologicals that are not usually self-administered, and certain Medicare-covered preventive injectable drugs are paid incident to a FQHC visit. Therefore, pharmaceutical costs include the non-compensation costs reported on Worksheet A, column 2, for the pharmacy cost center (line 51). We note that pharmaceutical costs are not included in the MEI since pharmaceutical costs are paid outside of the PFS.

(6) *Fixed Capital:* Fixed capital costs are equal to the sum of costs for rent, interest on mortgage loans, depreciation on buildings and fixtures, and property tax as reported on Worksheet A; columns 1 and 2; lines 26, 28, 30, and 33.

(7) *Moveable Capital:* Moveable capital costs are equal to the sum of costs for depreciation of medical equipment, office equipment, and other equipment as reported on Worksheet A; column 1 and 2; lines 19, 31, and 39.

(8) *All Other (Residual):* After estimating the expenses for the seven cost categories listed above, we summed all remaining costs together for each FQHC to come up with All Other (Residual) costs. The costs included in the All Other (Residual) category include all costs reported for medical supplies, transportation, allowable GME pass through costs, facility insurance, utilities, office supplies, legal, accounting, administrative insurance, telephone, housekeeping & maintenance, nondescript healthcare costs, nondescript facility costs, and nondescript administrative costs.

Although a cost weight for these categories could be obtained directly from the costs reported in that cost center's respective line on the cost report form, some FQHCs reported significant costs in other (specify), or ''free form,'' lines which made it difficult to determine the accuracy of these costs. For example, some FQHCs reported costs only in the free form lines and not in the cost center specific lines, while other FQHCs reported costs in both the cost center specific lines and the free form lines. Since a majority of FQHCs used the free form lines, relying solely on the costs reported in the cost center specific lines for costs could lead to an inaccurate cost weights in the market basket. For example, if a FQHC reported all other healthcare costs in line 21 rather than breaking the healthcare costs into the detailed cost centers (lines 17 through 20.50), then the cost weight for medical supplies could be lower than it should be if we did not allocate the costs reported in the free form lines to medical supplies.

Section III.B.1.b explains the method used to allocate the residual costs to more detailed cost categories.

After we derived costs for the eight major cost categories for each FQHC using the Medicare cost report data as previously described, we addressed data outliers using the following steps. First, we divided the costs for each of the eight categories by total Medicare allowable costs for each FQHC. We then removed those FQHCs whose derived cost weights fell in the top and bottom 5 percent of provider specific derived cost weights. Five percent is the standard trim applied for all CMS market basket cost weights. After these outliers were removed, we summed the costs for each category across all remaining FQHCs. We then divided this by the sum of total Medicare allowable costs across all remaining FQHCs to obtain a cost weight for the 2013-based FQHC market basket for the given category. See Table 33 for the resulting cost weights for these major cost categories that we obtained from the Medicare cost reports.

TABLE 33—MAJOR COST CATEGORIES AS DERIVED FROM MEDICARE COST REPORTS

Cost category	2013 FQHC weight (%)
FQHC Practitioner Compensation	26.8
Other Clinical Compensation	8.1
Non-Health Compensation	23.1
Fringe Benefits (distribute to compensation)	10.7
Fixed Capital	4.5
Moveable Capital	1.7
Non Salary Pharmaceuticals	5.1
All Other (Residual)	20.1

Totals may not sum to 100.0% due to rounding.

b. Derivation of Detailed Cost Categories From the All Other (Residual) Cost Weight

The All Other Residual cost weight was derived from summing all expenses reported on the Medicare cost report Worksheet A, columns 1 and 2 for medical supplies (line 17), transportation (line 18), allowable GME pass through costs (line 20.50), facility

insurance (line 27), utilities (line 29), office supplies (line 40), legal (line 41), accounting (line 42), administrative insurance (line 43), telephone (line 44), non-compensation housekeeping & maintenance (line 32, column 2 only), nondescript healthcare costs (lines 21–23), nondescript facility costs (lines 34–36), and nondescript administrative costs (lines 46–48).

To further divide the ''All Other'' residual cost weight (20.1 percent) estimated from the CY 2013 Medicare cost report data into more detailed cost categories, we used the relative cost shares from the 2006-based MEI for nine detailed cost categories: Utilities; Miscellaneous Office Expenses; Telephone; Postage; Medical Equipment; Medical Supplies; Professional, Scientific, & Technical Services; Administrative & Facility Services; and Other Services. For example, the Utilities cost represents 7 percent of the sum of the 2006-based MEI ''All Other'' cost category weights; therefore, the Utilities cost weight would represent 7 percent of the 2013-based FQHC market basket's ''All Other'' cost category (20.066 percent), yielding a ''final'' Utilities cost weight of 1.4 percent in the 2013-based FQHC market basket (7 percent * 20.1 percent = 1.4 percent).

Table 34 shows the cost weight for each matching category from the 2006-based MEI, the percent each cost category represents of the 2006-baesd MEI ''All Other'' cost weight, and the resulting proposed 2013-based FQHC market basket cost weights for detailed cost categories.

TABLE 34—DETAILED FQHC COST CATEGORY WEIGHTS

FQHC Detailed cost categories	2006-based MEI cost weights (%)	Percent of the 2006-based MEI ''All other'' cost weight (%)	2013-based FQHC detailed cost weights (%)
Total All Other (Residual)	17.976	100.000	20.1
Utilities	1.266	7.0	1.4
Miscellaneous Office Expenses	2.478	13.8	2.8
Telephone	1.501	8.4	1.7
Postage	0.898	5.0	1.0
Medical Equipment	1.978	11.0	2.2
Medical supplies	1.760	9.8	2.0
Professional, Scientific, & Tech. Services	2.592	14.4	2.9
Administrative & Facility Services	3.052	17.0	3.4
Other Services	2.451	13.6	2.7

FQHCs have liberty in how and where certain costs are reported on the Medicare cost report form CMS–222–92. We believe that, given the ambiguity in how the data are reported for these overhead cost centers on the FQHC cost report form, relying on the relative shares determined from the MEI is reasonable. We believe that the revised FQHC cost report form will allow us to better estimate the detailed cost weights for these categories directly. We expect all FQHCs to report PPS costs on the new form for cost report periods beginning after October 1, 2014. The following is a description of the types of expenses included in the FQHC detailed cost categories derived from the All Other (Residual) cost category:

- *Utilities:* Includes expenses classified in the fuel, oil and gas, water and sewage, and electricity industries. These types of industries are classified in NAICS and include NAICS 2211 (Electric power generation, transmission, and distribution), 2212 (Natural gas distribution), and 2213 (Water, sewage, and other systems).
- *Miscellaneous Office Expense:* Includes expenses for office expenses not reported in other categories, miscellaneous expenses, included but not limited to, paper (such as paper towels), printing (such as toner for printers), miscellaneous chemicals (such as soap and hand sanitizer).
- *Telephone:* Includes expenses classified in NAICS 517 (Telecommunications) and NAICS 518 (Internet service providers), and NAICS 515 (Cable and other subscription programming). Telephone service, which is one component of the Telecommunications expenses, accounts for the majority of the expenditures in this cost category.
- *Postage:* Includes expenses classified in NAICS 491 (Postal services) and NAICS 492 (Courier services).
- *Medical Equipment Expenses:* Includes the expenses related to maintenance contracts, and the leases or rental of medical equipment used in diagnosis or treatment of patients. It would also include the expenses for any medical equipment that was purchased in a single year and not financed.
- *Medical Supplies Expenses:* Includes the expenses related to medical supplies such as sterile gloves, needles, bandages, specimen containers, and catheters. We note that the Medical Supply cost category does not include expenses related to pharmaceuticals (drugs and biologicals).
- *Professional, Scientific, & Technical Services:* Includes the expenses for any professional services purchased from an outside agency or party and could include fees including but not limited to, legal, marketing, professional association memberships, licensure fees, journal fees, continuing education.
- *Administrative & Facility Services:* Includes the expenses for any administrative and facility services purchased from an outside agency or party and could include fees including but not limited to, accounting, billing, office management services, security services, transportation services, landscaping, or professional car upkeep.
- *Other Services:* Includes other service expenses including, but not limited to, nonresidential maintenance and repair, machinery repair, janitorial, and security services.

Table 35 shows the cost categories and weights for the 2013-based FQHC market basket. The resulting cost weights include combining the cost weights derived from the Medicare Cost Report Data (shown in Table 33), distributing the fringe benefits weight across the three compensation cost categories (shown in Table 32), and disaggregating the residual cost weight into detailed cost categories (shown in Table 34). Additionally, we compare the cost weights of the 2013-based FQHC market basket to the cost weights in the 2006-based MEI, where we have grouped the cost weights from the MEI to align with the FQHC cost categories.

TABLE 35—PROPOSED FQHC MARKET BASKET AND MEI, COST CATEGORIES, COST WEIGHTS

FQHC cost category	2013 FQHC weight (%)	2006 MEI weight (%)	MEI cost category
FQHC Market Basket	100.0	100.000	MEI.
Total Compensation	68.7	67.419	Total Compensation.
FQHC Practitioner Compensation	31.7	50.866	Physician Compensation.
Other Clinical Compensation	9.5	6.503	Other Clinical Compensation.
Non-health Compensation	27.4	10.050	Non-health Compensation.
All Other Products	16.1	14.176	All Other Products.
Utilities	1.4	1.266	Utilities.
Miscellaneous Office Expenses	2.8	2.478	Miscellaneous Office Expenses.
Telephone	1.7	1.501	Telephone.
Postage	1.0	0.898	Postage.
Medical Equipment	2.2	1.978	Medical Equipment.
Medical Supplies	2.0	1.760	Medical Supplies.
Professional Liability Insurance	—	4.295	Professional Liability Insurance.
Pharmaceuticals	5.1	—	Pharmaceuticals.
All Other Services	9.0	8.095	All Other Services.
Professional, Scientific & Technical Services	2.9	2.592	Professional, Scientific & Technical Services.
Administrative & Facility Services	3.4	3.052	Administrative & Facility Services.
Other Services	2.7	2.451	Other Services.
Capital	6.1	10.310	Capital.
Fixed Capital	4.5	8.957	Fixed Capital.
Moveable Capital	1.7	1.353	Moveable Capital.

Although the overall cost structure of the MEI, the index currently used to update the FQHC PPS base payment, is similar to the FQHC cost structure, there are a few key differences. First, though total compensation costs in the FQHC market basket and the MEI are each approximately 67–68 percent of total costs, non-health compensation accounts for a larger share of compensation costs in the FQHC setting than in the self-employed physician office. Likewise, physician compensation accounts for a larger percentage of costs in the MEI than FQHC practitioner compensation accounts for in the FQHC market basket. Second, the FQHC market basket includes a cost category for pharmaceuticals, while drug costs are excluded from the MEI. Drug costs are an expense in the FQHC PPS base payment rate since drugs and biologicals that are not usually self-administered, and certain Medicare-covered preventive injectable drugs are paid incident to a visit while drug costs are reimbursed separately under the PFS. Third, as mentioned previously, PLI expenditures are excluded from the FQHC market basket since most FQHC's PLI costs are covered under the FSHCAA, while in the MEI the PLI costs are a significant expense for self-employed physicians. Finally, fixed capital expenses, which include costs such as office rent and depreciation, are about half of the share in the FQHC market basket as they are in the MEI.

c. Selection of Price Proxies for the 2013-Based FQHC Market Basket

After establishing the 2013 cost weights for the FQHC market basket, an appropriate price proxy was selected for each cost category. The price proxies are chosen from a set of publicly available price indexes that best reflect the rate of price change for each cost category in the FQHC market basket. All of the proxies for the 2013-based FQHC market basket are based on indexes published by the Bureau of Labor Statistics (BLS) and are grouped into one of the following BLS categories:

- *Producer Price Indexes:* Producer Price Indexes (PPIs) measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that businesses purchase as inputs. For example, we proposed to use a PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because healthcare providers generally purchase drugs directly from a wholesaler. The PPIs measure price changes at the final stage of production.
- *Consumer Price Indexes:* CPIs measure change in the prices of final goods and services bought by the typical consumer. Because they may not represent the price encountered by a producer, we use CPIs only if an appropriate PPI is not available, or if the expenditures are more like those faced by retail consumers than by purchasers of goods at the wholesale level.
- *Employment Cost Indexes:* Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. We believe the PPIs, CPIs, and ECIs selected meet these criteria.

Table 36 lists all price proxies for the 2013-based FQHC market basket. Below is a detailed explanation of the price proxies for each cost category; we note that many of the proxies for the 2013-based FQHC market basket are the same as those used for the 2006-based MEI.

(1) *FQHC Practitioner Compensation:* We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related) (BLS series code CIU2010000120000I) to measure price growth of this category. There is no specific ECI for physicians and, therefore, similar to the MEI, we proposed to use an index that is based on professionals that receive advanced training. We note that the 2006-based MEI has a separate cost category for

Physician Wages and Salaries and Physician Benefits. For these cost categories, the MEI uses the ECI for Wages and Salaries and ECI for Benefits for Professional and Related Occupations.

(2) *Other Clinical Compensation:* We proposed to use the ECI for Total Compensation for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU1016200000000I) to measure the price growth of this cost category. This cost category consists of compensation costs for Nurses, Laboratory Technicians, and all other health staff not included in the FQHC practitioner compensation category. Based on the clinical composition of these workers, we believe that the ECI for health-related workers is an appropriate proxy to measure compensation price pressures for these workers. The MEI uses the ECI for Wages and Salaries and benefits for Hospitals.

(3) *Non-health Compensation:* We proposed to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. The Non-health compensation cost weight is predominately attributable to administrative and facility type occupations, as reported in the data from the Medicare cost reports. We note the MEI has a composite index of four price proxies, with the majority of the composite index accounted for by administrative occupations, proxied by the ECI for Wages & Salaries of Office and Administrative Support (Private).

(4) *Utilities:* We proposed to use the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

(5) *Miscellaneous Office Expenses:* We proposed to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices already captured elsewhere in the market basket. We note the MEI does not have a separate cost category for miscellaneous office expenses.

(6) *Telephone Services:* We proposed to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same price proxy used in the 2006-based MEI.

(7) *Postage:* We proposed to use the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

(8) *Medical Equipment:* We proposed to use the PPI Commodities for Surgical and Medical Instruments (BLS series code WPU1562) as the price proxy for this category. This is the same proxy used in the current 2006-based MEI.

(9) *Medical Supplies:* We proposed to use a 50/50 blended index comprised of the PPI Commodities for Medical and Surgical Appliances and Supplies (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG). The 50/50 blend is used in all market baskets where we do not have an accurate split available. We believe FQHCs purchase the types of supplies contained within these proxies, including such items as bandages, dressings, catheters, intravenous equipment, syringes, and other general disposable medical supplies, via wholesale purchase, as well as at the retail level. Consequently, we proposed to combine the two aforementioned indexes to reflect those modes of purchase. This is the same proxy used in the 2006-based MEI.

(10) *Pharmaceuticals:* We proposed to use the PPI Commodities for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. We note the MEI does not have a separate cost category for Pharmaceuticals. This price proxy is used to measure prices of Pharmaceuticals in other CMS market baskets, such as 2010-based Inpatient Prospective Payment System and 2010-based Skilled Nursing Facility market baskets.

(11) *Professional, Scientific, & Technical Services:* We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional, Scientific, and Technical Services (BLS series code CIU2015400000000I) to measure the price growth of this cost category. This is the same proxy used in the 2006-based MEI.

(12) *Administrative & Facility Services:* We proposed to use the ECI Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. This is the same price proxy used in the 2006-based MEI.

(13) *Other Services:* We proposed to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same price proxy used in the 2006-based MEI.

(14) *Fixed Capital:* We proposed to use the PPI Industry for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category. This is the same price proxy used in the 2006-based MEI. We believe this is an appropriate proxy since fixed capital expenses in FQHCs should reflect inflation for the rental and purchase of business office space.

(15) *Moveable Capital:* We proposed to use the PPI Commodities for Machinery and Equipment (series code WPU11) to measure the price growth of this cost category as this cost category represents nonmedical moveable equipment. This is the same proxy used in the 2006-based MEI.

Table 36 lists the proposed price proxies for each cost category in the proposed FQHC market basket.

TABLE 36—COST CATEGORIES AND PRICE PROXIES FOR THE FQHC MARKET BASKET

Cost category	FQHC price proxies
FQHC Practitioner Compensation	ECI—for Total Compensation for Private Industry Workers in Professional and Related.
Other Clinical Compensation	ECI—for Total Compensation for all Civilian Workers in Health Care and Social Assistance.
Non-health Compensation	ECI—for Total Compensation for Private Industry Workers in Office and Administrative Support.
Utilities	CPI–U for Fuels and Utilities.
Miscellaneous Office Expense	CPI–U for All Items Less Food And Energy.
Telephone	CPI–U for Telephone.
Postage	CP–U for Postage.

TABLE 36—COST CATEGORIES AND PRICE PROXIES FOR THE FQHC MARKET BASKET—Continued

Cost category	FQHC price proxies
Medical Equipment	PPI Commodities for Surgical and Medical Instruments.
Medical supplies	Blend: PPI Commodities for Medical and Surgical Appliances and Supplies and CPI for Medical Equipment and Supplies.
Pharmaceuticals	PPI Commodities for Pharmaceuticals for Human Use, Prescription.
Professional, Scientific, and Technical Services	ECI—for Total Compensation for Private Industry Workers in Professional, Scientific, and Technical Services.
Administrative & Facility Services	ECI—for Total Compensation for Private Industry Workers in Office and Administrative Support.
Other Services	ECI—for Total compensation for Private industry workers in Service Occupations.
Fixed Capital	PPI Industry—for Lessors of nonresidential buildings.
Moveable Capital	PPI Commodities—for Machinery and Equipment.

d. Inclusion of Multi-factor Productivity in the FQHC Market Basket

Section 1834(o)(2)(B)(ii) of the Act describes the methods for determining updates to FQHC PPS payment. After the first year of implementation, the FQHC PPS base payment rate must be increased by the percentage increase in the MEI. In subsequent years, the FQHC PPS base payment rate shall be increased by the percentage increase in a market basket of FQHC goods and services as established through regulations or, if not available, the MEI published in the PFS final rule.

The MEI published in the PFS final rule has a productivity adjustment. The MEI has been adjusted for changes in productivity since its inception. In the CY 2003 PFS final rule with comment period (67 FR 80019), we implemented a change in the way the MEI was adjusted to account for changes in productivity. In 2012, we convened the MEI Technical Panel to review all aspects of the MEI including and the productivity adjustment. For more information regarding the MEI Technical Panel, see the CY 2014 PFS final rule with comment period (78 FR 74264). The MEI Technical Panel concluded in Finding 5.1 that ''such an adjustment continues to be appropriate. This adjustment prevents 'double counting' of the effects of productivity improvements, which would otherwise be reflected in both (i) the increase in compensation and other input price proxies underlying the MEI, and (ii) the growth in the number of physician services performed per unit of input resources, which results from advances in productivity by individual physician practices.''

We proposed to include a productivity adjustment similar to the MEI in the FQHC market basket. We believe that applying a productivity adjustment is appropriate because this would be consistent with the MEI, which has an embedded productivity adjustment. We note that the MEI Technical Panel concluded that a productivity adjustment is appropriate for the MEI given the type of services performed in physician's offices. Specifically, the MEI Technical Panel report states that ''The input price increases within the MEI are reflected in the price proxies, such as changes in wages and benefits. Wages increase, in part, due to the ability of workers to increase the amount of output per unit of input. Absent a productivity adjustment in the MEI, physicians would be receiving increased payments resulting both from their ability to increase their individual outputs and from the productivity gains already reflected in the wage proxies used in the index. The productivity adjustment used in the MEI ensures the productivity gains reflected in increased outputs are not double counted, or paid for twice. Currently, the productivity adjustment in the MEI is based on changes in economy-wide productivity based on the rationale that the price proxy for physician income reflects changes in economy-wide wages. Implicitly, this assumes physicians can achieve the same level of productivity as the average general wage earner.'' We believe that the services performed in FQHC facilities are similar to those covered by physician visits, and therefore, a productivity adjustment is appropriate to avoid double counting of the effects of productivity improvements in the FQHC market basket.

We proposed to use the most recent estimate of the 10-year moving average of changes in annual private nonfarm business (economy-wide) multifactor productivity (MFP), which is the same measure of MFP used in the MEI. The BLS publishes the official measure of private nonfarm business MFP. (See *http://www.bls.gov/mfp* for the published BLS historical MFP data). For the final FQHC market basket update, we proposed to use the most recent historical estimate of annual MFP as published by the BLS. Generally, the most recent historical MFP estimate is lagged two years from the payment year. Therefore, we proposed to use the 2015 MFP as published by BLS in the CY2017 FQHC market basket update.

We note that MFP is derived by subtracting the contribution of labor and capital input growth from output growth. Since at the time of the proposed rule the 2015 MFP has not been published by BLS, we rely on a projection of MFP. The projection of MFP is currently produced by IHS Global Insight (IGI), a national economic forecasting firm with which CMS contracts to forecast the components of the market basket and MFP. A complete description of the MFP projection methodology is available at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.*

Using IGI's first quarter 2016 forecast, the productivity adjustment for CY 2017 (the 10-year moving average of MFP for the period ending CY 2015) was projected to be 0.4 percent. If more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data to determine the CY 2017 increase in the FQHC market basket in the final rule.

5. CY 2017 Market Basket Update: CY 2017 FQHC Market Basket Update Compared to the MEI Update for CY 2017

For CY 2017, we proposed to use the 2013-based FQHC market basket increase factor to update the FQHC PPS base payment rate. Consistent with CMS practice, we estimated the market basket update for the FQHC PPS based on the most recent forecast from IGI. Identical to the MEI, we proposed to use the update based on the most recent historical data available at the time of

publication of the final rule. For example, the final CY 2017 FQHC update would be based on the four-quarter moving-average percent change of the FQHC market basket through the second quarter of 2016 (based on the final rule's statutory publication schedule).

Based on IGI's first quarter 2016 forecast with historical data through the fourth quarter of 2015, the projected proposed FQHC market basket increase factor for CY 2017 was 1.7 percent. This reflected a 2.1-percent increase of FQHC input prices and a 0.4-percent adjustment for productivity. We also proposed that if more recent data are subsequently available (for example, a more recent estimate of the market basket or MFP) we would use such data, to determine the CY 2017 update in the final rule.

For comparison, the 2006-based MEI was projected to be 1.3 percent in CY 2017; this estimate was based on IGI's first quarter 2016 forecast (with historical data through the fourth quarter of 2015). Table 37 compares the proposed 2013-based FQHC market basket updates and the proposed 2006-based MEI market basket updates for CY 2017.

TABLE 37—PROPOSED FQHC MARKET BASKET AND MEI, COST CATEGORIES, COST WEIGHTS, MFP, AND CY 2017 UPDATE [1]

FQHC cost category	CY 2017 update (percent)		MEI Cost category
FQHC Market Basket	1.7	1.3	MEI.
Productivity adjustment	0.4	0.4	Productivity adjustment.
FQHC Market Basket (unadjusted)	2.1	1.7	MEI (unadjusted).
Total Compensation	2.1	2.0	Total Compensation.
FQHC Practitioner Comp.	1.9	2.0	Physician Compensation.
Other Clinical Compensation	1.9	2.0	Other Clinical Compensation.
Non-health Compensation	2.4	2.4	Non-health Compensation.
All Other Products	2.6	−0.6	All Other Products.
Utilities	−3.9	−3.9	Utilities.
Miscellaneous Office Expenses	2.0	−1.7	Miscellaneous Office Expenses.
Telephone	0.4	0.4	Telephone.
Postage	0.3	0.3	Postage.
Medical Equipment	1.2	1.2	Medical Equipment.
Medical Supplies	−0.4	−0.4	Medical Supplies.
Professional Liability Insurance		−0.4	Professional Liability Insurance.
Pharmaceuticals	7.8		Pharmaceuticals.
All Other Services	2.0	2.0	All Other Services.
Professional, Scientific & Technical Services	1.5	1.5	Professional, Scientific & Technical Services.
Administrative & Facility Services	2.4	2.4	Administrative & Facility Services.
Other Services	1.9	1.9	Other Services.
Capital	1.6	1.9	Capital.
Fixed Capital	2.1	2.1	Fixed Capital.
Moveable Capital	0.1	0.1	Moveable Capital.

[1] Based on IGI's first quarter 2016 forecast.

For CY 2017, the proposed 2013-based FQHC market basket update (1.7 percent) is 0.4 percent higher than the 2006-based MEI (1.3 percent). The 0.4 percentage point difference stems mostly from the inclusion of pharmaceuticals in the FQHC market basket. This cost category and associated price pressures are not included in the MEI.

We proposed to update the FQHC PPS base payment rate by 1.7 percent for CY 2017 based on the 2013-based FQHC market basket. The FQHC market basket would more accurately reflect the actual costs and scope of services that FQHCs furnish compared to the 2006-based MEI. We invited public comment on all aspects of the FQHC market basket proposals.

6. Summary of Comments and the Associated Responses on the Proposed FQHC Market Basket

We received 12 comments on the proposed FQHC market-basket. The following is a summary of the comments we received:

Comment: Commenters expressed their support for the creation of a FQHC-specific market basket to update the FQHC PPS base payment rate annually. We would note that of the comments received none indicated an objection to the use of an FQHC market basket compared to the MEI. Commenters stated that the MEI is outdated and does not appropriately capture the cost of services that FQHCs furnish.

Response: We appreciate the commenters support for the creation of the FQHC-specific market basket. As stated in the proposed rule, we believe that the 2013-based FQHC market basket would more accurately reflect the actual costs and scope of services that FQHCs furnish compared to the 2006-based MEI.

Comment: Many commenters requested that we rebase the FQHC market basket at the earliest possible opportunity to capture new Medicare cost report data from the revised FQHC cost report. Commenters stated that CMS finalized and issued a revised Medicare FQHC cost report (Form CMS–224–14) required to be submitted by FQHCs for cost reporting periods under Medicare's PPS methodology. The commenters stated that the revised Medicare FQHC cost report would provide higher quality data than the previous cost report (Form CMS–222–92).

Response: We appreciate the commenters request to use the most appropriate and up-to-date data for the development of the FQHC market basket. We agree with the commenters that the FQHC market basket should be rebased using the costs as reported under the PPS, coinciding with data reported on the revised FQHC cost report (Form CMS–224–14). The revised cost report form must be used for all cost reports that begin on or after October 1, 2014, which coincides with the implementation of the FQHC PPS. We plan to update the FQHC market basket to reflect FQHC costs paid under

the PPS when we have complete data from the revised cost report form and can verify that the costs reported are accurate and reliable.

Comment: Many commenters that supported the creation of the FQHC-specific market basket recommended some clarifications and modifications to the proposed market basket cost-weight methodology. Several commenters recommended that the healthcare staff costs for ''Visiting Nurse'' services be included in the ''FQHC Practitioner Compensation'' cost category rather than in the ''Other Clinical Compensation'' cost category, as proposed. The commenters note that Chapter 13 of the Medicare Benefit Policy Manual includes ''visiting nurse (RN or LPN)'' as a type of practitioner that can render a medically necessary FQHC visit under certain conditions.

Response: As the commenters stated, the compensation costs associated with ''Visiting Nurse'' services were allocated to the market basket cost category for ''Other Clinical Compensation'' rather than the market basket cost category for ''FQHC Practitioner Compensation.'' Commenters are correct that under certain circumstances, FQHCs can bill for a visit when an RN or LPN furnishes visiting nurse services to a homebound patient in an area with a shortage of home health agencies. In this situation only, the RN or LPN would be considered a FQHC practitioner. All other services furnished by a RN or LPN would be considered incident to a visit and not separately billable. Since most services furnished by nurses in FQHCs are considered incident to a FQHC visit and are not separately billable visits, we believe that it is prudent to keep these costs allocated to the cost category ''Other Clinical Compensation'' at this time.

Additionally, only 17 FQHCs reported costs in line 4 (Visiting Nurse) of Worksheet A of the cost report, which is approximately 1.4 percent of all FQHCs that submitted cost reports. Had these costs been allocated to ''FQHC Practitioner Compensation,'' the proposed ''FQHC Practitioner Compensation'' cost share weight would essentially be unchanged (31.9 percent if we were to include the Visiting Nurse Compensation costs in that category compared to the proposed 31.7 percent). This small difference, based on a very small proportion of FQHC's who report this data, would not impact the growth rate of the FQHC market basket. Thus, we believe that changing our proposed classification of these expenses is not necessary at this time. We will consider this issue when we rebase and revise the FQHC market basket in the future using the revised cost report form.

Comment: Commenters requested confirmation that compensation costs related to FQHC services furnished by certified nurse midwives and qualified practitioners of outpatient diabetes self-management training (DSMT) and medical nutrition therapy (MNT) are included within the ''FQHC Practitioner Compensation'' cost category.

Response: There are no specific identified line items on Worksheet A of the FQHC cost report form (CMS–222–92) for reporting these costs. We believe that costs associated with these services would have been reported in lines 9 through 11 or line 15 on Worksheet A. As explained in 81 FR 46379, we allocate a portion of these compensation costs to ''FQHC Practitioner Compensation'' and ''Other Clinical Compensation'' by multiplying the sum of costs reported on Worksheet A lines 9 through 11 and 15, by the ratio of ''FQHC Practitioner Compensation'' costs to the sum of ''FQHC Practitioner Compensation'' costs and ''Other Clinical Compensation'' costs. We believe that the assumption of distributing the costs proportionally is reasonable since there is no additional detail on the specific occupations these compensation costs represent. On the revised FQHC Medicare cost report (Form CMS–224–14), these costs are separately reported on lines 29 and 33 of Worksheet A. Therefore, when we rebase the FQHC market basket reflecting the revised FQHC Medicare cost report form, we will be able to more directly allocate these costs.

Comment: Commenters requested clarification whether there was an error in the explanation of the ''nondescript administrative costs.'' Commenters stated that the proposed rule had listed the expenses reported on lines 54–56 of Worksheet A of the cost report; however, those particular lines capture ''costs other than FQHC'' rather than ''administrative costs.'' The commenters stated the appropriate lines are 46–48 of Worksheet A for ''nondescript administrative costs,'' and if so, requested that we verify this to be true and revise the line number references in the final rule language.

Response: We thank the commenters for noting that there was an error in the explanation of the ''nondescript administrative costs'' in the proposed rule. We would like to clarify that the ''nondescript administrative costs'' include expenses from lines 46–48 not lines 54–56. The proposed rule used the correct data from the cost report, and therefore, no changes are necessary to the computation of the cost category weight. Rather, we are clarifying and correcting that the nondescript administrative costs include expenses reported on Worksheet A, lines 46–48. The expenses reported on Worksheet A, lines 54–56 were excluded from the total costs for FQHC expenses. We apologize for the confusion this may have caused and appreciate the opportunity to correct this language in the final rule.

Comment: Many commenters stated that the proposed productivity adjustment to the FQHC market basket is not justified and that absent further study by CMS of FQHC services, it is premature to apply a productivity adjustment to the FQHC market basket. The commenters stated that FQHC operations are not mirror images of self-employed physician practice operations and the argument that the adjustment is similar to that used in the MEI to avoid double counting of effects of productivity improvements is not warranted at this time.

Response: We respectfully disagree that a productivity adjustment to the FQHC market basket is not warranted at this time. As discussed in the proposed rule, the productivity adjustment included in the FQHC market basket is based on the 10-year moving average of changes in annual private nonfarm business (economy-wide) multifactor productivity. We believe that FQHC services are similar to those that would otherwise be provided by a primary care physician, mental health professional, or other clinical care provider, which have demonstrated the ability to achieve productivity gains consistent with the overall economy as stated in the development of the MEI. Therefore, in order to avoid the double counting of FQHC provider productivity, it is necessary to include a productivity adjustment to the FQHC market basket, consistent with inclusion of a productivity adjustment in the MEI that is used for physician services. We believe this rationale justifies the inclusion of a productivity adjustment in the FQHC market basket. We will continue to evaluate whether the productivity adjustment in the FQHC market basket (which is based on economy-wide productivity) is the most appropriate measure.

7. Final FQHC Market Basket and Final CY 2017 Market Basket Update

After considering the public comments, we are finalizing the FQHC market basket, as proposed. We believe that the FQHC market basket, as proposed, more accurately reflects the actual costs and scope of services that FQHCs furnish relative to the MEI. We

did not find any technical reason to refine the cost weight methodology based on the comments received, but will consider some of these comments in the future when we rebase the market basket based on FQHC cost report data from the revised form CMS–224–14. We are also finalizing our proposal to include a productivity adjustment to the FQHC market basket update, as we did not find any compelling technical reason that we should not implement this adjustment to the FQHC market basket.

Table 38 shows the final 2013-based FQHC Market Basket cost categories, cost weights, and price proxies.

TABLE 38—FINAL CY 2013-BASED FQHC MARKET BASKET COST CATEGORIES, COST WEIGHTS, AND PRICE PROXIES

FQHC cost category	Price proxy	2013 Cost weight (%)
FQHC Market Basket		100.0
Total Compensation		68.7
FQHC Practitioner Comp.	ECI—for Total Compensation for Private Industry Workers in Professional and Related.	31.7
Other Clinical Compensation	ECI—for Total Compensation for all Civilian Workers in Health Care and Social Assistance.	9.5
Non-health Compensation	ECI—for Total Compensation for Private Industry Workers in Office and Administrative Support.	27.4
All Other Products		16.1
Utilities	CPI–U for Fuels and Utilities	1.4
Miscellaneous Office Expenses	CPI–U for All Items Less Food and Energy	2.8
Telephone	CPI–U for Telephone	1.7
Postage	CP–U for Postage	1.0
Medical Equipment	PPI Commodities for Surgical and Medical Instruments	2.2
Medical Supplies	Blend: PPI Commodities for Medical and Surgical Appliances and Supplies and CPI for Medical Equipment and Supplies.	2.0
Pharmaceuticals	PPI Commodities for Pharmaceuticals for Human Use, Prescription	5.1
All Other Services		9.0
Professional, Scientific & Technical Services.	ECI—for Total Compensation for Private Industry Workers in Professional, Scientific, and Technical Services.	2.9
Administrative & Facility Services.	ECI—for Total Compensation for Private Industry Workers in Office and Administrative Support.	3.4
Other Services	ECI—for Total compensation for Private Industry Workers in Service Occupations	2.7
Capital		6.1
Fixed Capital	PPI Industry—for Lessors of Nonresidential Buildings	4.5
Moveable Capital	PPI Commodities—for Machinery and Equipment	1.7

We also proposed that we would use the most recent data available to determine the final FQHC market basket and MFP update for CY 2017. Based on IGI's third quarter 2016 forecast with historical data through the second quarter of 2016, the final FQHC market basket increase factor for CY 2017 is 1.8 percent. This reflects a 2.2 percent increase of FQHC input prices and a 0.4-percent adjustment for productivity. For comparison, the MEI increase factor for CY 2017 is 1.2 percent (a 1.6 percent MEI update and a 0.4 percent MFP adjustment); these updates reflect the most historical data available, with historical data through the second quarter of 2016.

Table 39 shows the final 2013-based FQHC market basket updates compared to the proposed 2013-based FQHC market basket updates for CY 2017.

TABLE 39—FQHC MARKET BASKET FINAL CY 2017 UPDATE OF ALL COST CATEGORIES

FQHC Cost category	CY 2017 Final update* (%)	CY 2017 Proposed update (%)
FQHC Market Basket	1.8	1.7
Productivity adjustment	0.4	0.4
FQHC Market Basket (unadjusted)	2.2	2.1
Total Compensation	2.0	2.1
FQHC Practitioner Compensation	1.6	1.9
Other Clinical Compensation	1.8	1.9
Non-health Compensation	2.5	2.4
All Other Products	3.1	2.6
Utilities	−2.5	−3.9
Miscellaneous Office Expenses	2.1	2.0
Telephone	−0.1	0.4
Postage	0.5	0.3
Medical Equipment	1.6	1.2
Medical Supplies	−0.6	−0.4
Professional Liability Insurance		
Pharmaceuticals	8.4	7.8
All Other Services	2.1	2.0
Professional, Scientific & Technical Services	1.5	1.5
Administrative & Facility Services	2.5	2.4

TABLE 39—FQHC MARKET BASKET FINAL CY 2017 UPDATE OF ALL COST CATEGORIES—Continued

FQHC Cost category	CY 2017 Final update* (%)	CY 2017 Proposed update (%)
Other Services	2.1	1.9
Capital	1.5	1.6
Fixed Capital	2.0	2.1
Moveable Capital	0.1	0.1

*Based on historical data through the 2nd quarter 2016.

For the productivity adjustment, the 10-year moving average percent change adjustment for CY 2017 is 0.4 percent, which is based on the most historical data available from BLS at the time of the final rule, and reflects annual MFP estimates through 2015.

C. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the PAMA amended Title XVIII of the Act to add section 1834(q) 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 we established 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 were posted on the CMS Web site at the end of June 2016 at which time their AUC libraries became specified AUC for purposes of section 1834(q)(2)(A) of the Act.

This rule proposed requirements and processes for specification of qualified clinical decision support mechanisms (CDSMs) under the Medicare AUC program; the initial list of priority clinical areas; and exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services.

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 are 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 and/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 would 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 definitions of CDSM 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. Previous CDSM Experience

In the CY 2016 PFS final rule with comment period, we included a discussion of the Medicare Imaging Demonstration (MID), which was required by section 135(b) of the MIPPA, in addition to independent experiences of implementing AUC by several healthcare systems and academic medical centers. Two key aspects of that discussion remain relevant to the CDSM component of this program. First, AUC, and the CDSMs through which clinicians access AUC, must be integrated into the clinical workflow and facilitate, not obstruct, evidence-based care delivery. For instance, a CDSM may be fully integrated with or part of a provider's Certified EHR system, partially integrated, or entirely outside of it. A CDSM that is external to a provider's primary user interface could utilize an application program interface (API), a set of protocols and tools specifying how software components should interact, to pull relevant information into the decision support application and provide support back to the primary interface. It could also provide decision support, based on the pulled EHR data, via a separate interface. By adhering to common interoperability standards, such as the national standards advanced through certified health IT (see 2015 edition of certification criteria available in the **Federal Register** (80 FR 62601) and described in the Interoperability Standards Advisory at *https://www.healthit.gov/standards-advisory*), CDSMs could both ensure integration of patient-specific data from EHRs, and allow clinicians to optimize the time spent using the tool.

Second, the ideal AUC is an evidence-based guide that starts with a patient's specific clinical condition or presentation (symptoms) and assists the clinician in the overall patient workup, treatment, and follow-up. Imaging would appear as key nodes within the clinical management decision tree.

Other options outside of certified EHR technology exist to access AUC through CDSMs. Stand-alone, internet-based CDSMs are available and, although they will not interact with EHR data, can nonetheless search for and present AUC relevant to a patient's presenting symptoms or condition.

In communicating an appropriateness rating to the ordering practitioner, some CDSMs provide a scale with numeric ratings, some output a red, yellow, or green light while others provide a dichotomous yes or no. At this time, we do not believe there is one correct approach to communicating the level of appropriateness to the ordering professional. However, section 1834(q)(4)(B) of the Act requires that information be reported on the claim form as to whether the service would or would not adhere to the specified AUC consulted through a particular CDSM, or whether the AUC was not applicable to

the service. We requested feedback from commenters regarding how appropriateness ratings provided by CDSMs could be interpreted and recorded for the purposes of this program. There are different views about the comprehensiveness of AUC that should be accessible within CDSMs. Some stakeholders believe that the CDSM should contain as comprehensive a collection of AUC as possible, incorporating individual criteria from across all specified AUC libraries. The intent would be for ordering professionals to avoid the frustration, experienced and voiced by many clinicians participating in the MID, of spending time navigating the CDSM only to find that no criterion for their patient's specific clinical condition exists.

Other stakeholders believe, based on decades of experience rolling out AUC in the context of robust quality improvement programs that it is best to start with a CDSM that contains AUC for a few clinical areas where impact is large and evidence is strong. This would ensure that quality AUC are developed, and that clinicians and entire care teams could fully understand the AUC they are using, including when they do not apply to a particular patient.

As we stated in the CY 2016 PFS final rule with comment period, we believe there is merit to both approaches, and it has been suggested to us that the best approach may depend on the particular care setting. The second, ''focused'' approach may work better for a large health system that produces and uses its own AUC. The first, ''comprehensive'' approach may in turn work better for a smaller practice with broad image ordering patterns and fewer resources that wants to simply adopt and start using a complete AUC system developed elsewhere. We believe a successful program would allow flexibility, and under section 1834(q) of the Act, we foresee a number of sets of AUC developed by different PLEs, and an array of CDSMs from which clinicians may choose.

3. Priority Clinical Areas

We established in the CY 2016 PFS final rule with comment period that we would identify priority clinical areas through rulemaking, and that these may be used in the determination of outlier ordering professionals (a future phase of the Medicare AUC program). The concept of priority clinical areas allows us to implement an AUC program that combines the focused and comprehensive approaches to implementation discussed above. Although potentially large volumes of AUC (as some PLEs have large libraries of AUC) would become specified across clinical conditions and advanced imaging technologies, we believe this rapid and comprehensive roll out of specified AUC should be balanced with a more focused approach when identifying outlier ordering professionals. We believe this will provide an opportunity for physicians and practitioners to become familiar with AUC in identified priority clinical areas prior to Medicare claims for those services being part of the input for calculating outlier ordering professionals.

As we describe earlier, CDSMs are the access point for ordering professionals to consult AUC. We believe the combination of the comprehensive and focused approaches should be applied to CDSM requirements as we consider a minimum floor of AUC that must be made available to ordering professionals through qualified CDSMs. AUC that reasonably address the entire clinical scope of priority clinical areas could establish a minimum floor of AUC to be included in qualified CDSMs, and the number of priority clinical areas could be expanded through annual rulemaking and in consultation with physicians and other stakeholders. This allows priority clinical areas to roll out judiciously, and build over time.

4. 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)(3)(A) of the Act requires the Secretary to specify qualified CDSMs that could be used by ordering professionals to consult with specified applicable AUC for applicable imaging services.

5. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date: (1) Establishment of AUC by November 15, 2015 (section 1834(q)(2)); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3)); (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4)); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5)). As we will discuss later in this preamble, we did not identify mechanisms for consultation by April 1, 2016 and will not have specified or published the list of qualified CDSMs by January 1, 2017; therefore, ordering professionals will not be required to consult CDSMs, and furnishing professionals will not be able to report information on the consultation, by this date.

a. Establishment of AUC

In the CY 2016 PFS final rule with comment period, we addressed the first component 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.

A timeline and process was established for PLEs to apply to become qualified and the first list of qualified PLEs was published at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html*.

b. Mechanism for AUC Consultation

The second major component of the Medicare AUC program is the specification of qualified CDSMs that could be used by ordering professionals for consultation with specified applicable AUC under section 1834(q)(3) of the Act. We envision a CDSM as an interactive tool that communicates AUC information to the user. Information regarding the clinical

presentation of the patient would be incorporated into the CDSM from another health IT system or through data entry by the ordering professional. At a minimum, the tool would provide immediate feedback to the ordering professional on the appropriateness of one or more imaging services. Ideally, CDSMs would be integrated within or seamlessly interoperable with existing health IT systems and would automatically receive patient data from the EHR or through an API or other connection. Such integration would minimize burden on practitioners and avoid duplicate documentation. Also useful to clinicians would be the ability to switch between CDSMs that can interoperate based on common standards.

Section 1834(q)(3)(A) of the Act states that the Secretary must specify qualified CDSMs in consultation with physicians, practitioners, health care technology experts, and other stakeholders. This paragraph authorizes the Secretary to specify mechanisms that could include: CDS modules within certified EHR technology; private sector CDSMs that are independent of certified EHR technology; and a CDSM established by the Secretary. The Secretary did not propose to establish a CDSM at this time.

All CDSMs must meet the requirements under section 1834(q)(3)(B) of the Act, which specifies that a mechanism must: Make available to the ordering professional applicable AUC and the documentation supporting the appropriateness of the applicable imaging service that is ordered; where there is more than one applicable appropriate use criterion specified for an applicable imaging service, indicate the criteria it uses for the service; determine the extent to which an applicable imaging service that is ordered is consistent with the applicable AUC; generate and provide to the ordering professional documentation to demonstrate that the qualified CDSM was consulted by the ordering professional; be updated on a timely basis to reflect revisions to the specification of applicable AUC; meet applicable privacy and security standards; and perform such other functions as specified by the Secretary (which may include a requirement to provide aggregate feedback to the ordering professional). Section 1834(q)(3)(C) of the Act specifies that the Secretary must publish an initial list of specified mechanisms no later than April 1, 2016, and that the Secretary must identify on an annual basis the list of specified qualified CDSMs.

As we explained in the CY 2016 PFS proposed rule and final rule with comment period, implementation of many aspects of the amendments made by section 218(b) of the PAMA requires consultation with physicians, practitioners, and other stakeholders, and notice and comment rulemaking. We continue to believe the PFS calendar year rulemaking process is the most appropriate and administratively feasible implementation vehicle. Given the timing of the PFS rulemaking process, we were not able to include proposals in the PFS proposed rule to begin implementation in the same year the PAMA was enacted, as we would have had to interpret and analyze the new statutory language, and develop proposed plans for implementation in under one month. As we did prior to the CY 2016 PFS proposed rule when we met extensively with stakeholders to gain insight and hear their comments and concerns about the AUC program, we used the time prior to the CY 2017 PFS proposed rule to meet with many of the same stakeholders but also a new group of stakeholders specifically related to CDSMs. In addition, we are continuing our stepwise approach to implementing this AUC program. The first phase of the AUC program (specifying AUC including defining what AUC are and specifying the process for developing them) was accomplished through last year's CY 2016 PFS final rule with comment period. For this second phase, we use the CY 2017 PFS rulemaking process as the vehicle to establish requirements for CDSMs, and the process to specify qualified CDSMs, in a transparent manner that allows for stakeholder and public involvement. Therefore, the final CDSM requirements and process for CDSMs to become qualified are included in this CY 2017 PFS final rule.

c. AUC Consultation and Reporting

The third major component of the AUC program is in section 1834(q)(4) of the Act, Consultation with Applicable Appropriate Use Criteria. This section establishes, beginning January 1, 2017, the requirement for an ordering professional to consult with a 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. 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. Section 1834(q)(4)(D) of the Act specifies that the applicable payment systems for the AUC consultation and reporting requirements are the PFS, hospital outpatient prospective payment system, and the ambulatory surgical center payment systems.

Since a list of qualified CDSMs is not yet available and will not be available by January 1, 2017, we will not require ordering professionals to meet this requirement by that date.

d. Identification of Outliers

The fourth component of the AUC program is in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. The identification of outlier ordering professionals under this paragraph facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. Although we did not propose to implement these sections in the CY 2017 PFS proposed rule, we proposed below a list of priority clinical areas which may serve as part of the basis for identifying outlier ordering professionals.

6. Proposals for Implementation

We proposed to amend our regulations at § 414.94, ''Appropriate Use Criteria for Certain Imaging Services.''

a. Definitions

In § 414.94(b), we proposed to codify and add language to clarify some of the definitions provided in section 1834(q) of the Act, as well as define terms that were not defined in statute but for which a definition would be helpful for program implementation. In this section, we provide a description of the terms we proposed to codify to facilitate understanding and encouraged public comment on the AUC program.

We proposed to define CDSM under § 414.94(b) 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. A CDSM would incorporate specified

applicable AUC sets from which an ordering professional could select. A CDSM may be a module 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. If within or available through certified EHR technology, a qualified CDSM would incorporate relevant patient-specific information into the assessment of the appropriateness of an applicable imaging service.

As prescribed in section 1834(q) of the Act and § 414.94(b) of our regulations, the Medicare AUC program imposes requirements only for applicable imaging services furnished in applicable settings. Further, as specified in section 1834(q)(4)(D) of the Act, we proposed to amend our regulation at § 414.94(b) to state that the applicable payment systems for the Medicare AUC program are the PFS under section 1848(b) of the Act, the prospective payment system for hospital outpatient department services under section 1833(t) of the Act, and the ambulatory surgical center payment systems under section 1833(i) of the Act. Applicable payment systems are relevant to implementation of section 1834(q)(4)(B) of the Act, entitled ''Reporting by Furnishing Professionals.''

We remind readers that in PFS rulemaking for CY 2016 we defined applicable imaging service in § 414.94(b) as an advanced diagnostic imaging service as defined in 1834(e)(1)(B) of the Act for which the Secretary determines (i) One or more applicable appropriate use criteria apply; (ii) There are one or more qualified clinical decision support mechanisms listed; and (iii) One or more of such mechanisms is available free of charge.

The following is a summary of the comments we received on the definitions for CDSM and applicable payment system.

Comment: Most comments that addressed the definitions supported our proposals. One commenter requested that in the definition of CDSM, CMS specify that it is a tool for ''ordering clinicians.''

Response: We disagree that the regulatory definition of CDSM should specify exactly who can use a CDSM and believe it should continue to focus on the function and purpose of the tool. We would not want the definition to restrict use to one type of user; however, we expect that the ordering professional would consult the tool. We appreciate commenters' general support of the proposed definitions.

After considering the comments, we have made no changes to the definitions and are finalizing the language at § 414.94(b) as proposed.

b. Priority Clinical Areas

We proposed to establish a new § 414.94(e)(5) to set forth the initial list of priority clinical areas.

To compile this proposed list, we performed an analysis of Medicare claims data using the CMS Chronic Conditions Data Warehouse (CCW) as the primary data source. The CCW contains 100 percent of Medicare claims for beneficiaries who are enrolled in the fee-for-service (FFS) program. Data were derived from the CCW's 2014 Part B non-institutional claim line file, which includes Part B services furnished during CY 2014. This is the main file containing final action claims data for non-institutional health care providers, including physicians, physician assistants, clinical social workers, nurse practitioners, independent clinical laboratories, and freestanding ambulatory surgical centers. The Part B non-institutional claim line file contains the individual line level information from the claim and includes Healthcare Common Procedure Coding System (HCPCS) code(s), diagnosis code(s) using the International Classification of Diseases, Ninth Revision (ICD–9), service dates, and Medicare payment amount. A publicly available version of this dataset can be downloaded from the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html*. We encouraged stakeholders to review this dataset as a source that might help inform public comments related to the proposed priority clinical areas.

In the CY 2016 PFS final rule with comment period, we stated that when identifying priority clinical areas we may consider factors such as incidence and prevalence of disease, the volume and variability of utilization of imaging services, the strength of evidence for their use, and applicability of the clinical area to the Medicare population and to a variety of care settings.

Using the 2014 Medicare claims data referenced above, we ranked ICD–9 codes by the frequency with which they were used as the primary indication for specific imaging procedures, which in turn were identified by the volume of individual Current Procedural Terminology (CPT) codes for which payments were made in 2014. We extracted the top 135 ICD–9 codes from this list and formed clinically-related categories. Next, we searched manually through an electronic list of all ICD–9 codes to find others that would plausibly fit into each clinical grouping. This process required subjective clinical judgment on whether a particular ICD–9 code should be included in a given clinical group. The top eight clinical groupings (by volume of procedures) are what we proposed as the initial list of priority clinical areas. The eight clinical areas account for roughly 40 percent of part B advanced diagnostic imaging services paid for by Medicare in 2014. We are aware that some stakeholders have suggested beginning the AUC program with no more than five priority clinical areas while others have suggested a far greater number. We believed the proposed eight priority clinical areas strike a reasonable balance that allows us to focus on a significant range and volume of advanced diagnostic imaging services.

We also considered extracting pulmonary embolism as a separate priority clinical area from the chest pain grouping based on stakeholder consultation and feedback. However, we decided not to identify pulmonary embolism separately, but asked for public comment on whether pulmonary embolism should be included as a stand-alone priority clinical area. Based on our consultations with physicians, practitioners and other stakeholders, as required by section 1834(q)(3)(A) of the Act, we attempted to be inclusive when grouping ICD–9 codes into cohesive clinical areas. As an example of how we derived the priority clinical area for low back pain, we grouped together 10 ICD–9 codes, incorporating six from the top 135 and four from the manual search of all ICD–9 codes. Included in this grouping are the ICD–9 codes for displacement of lumbar intervertebral disc without myelopathy (722.10), degeneration of lumbar of lumbosacral intervertebral disc (722.52), intervertebral disc disorder with myelopathy lumbar region (722.73), post-laminectomy syndrome of lumbar region (722.83), lumbago (724.2), sciatica (724.3), thoracic or lumbosacral neuritis or radiculitis unspecified (724.4), spinal stenosis, lumbar region, without neurogenic claudication (724.02), lumbosacral spondylosis without myelopathy (721.3), and spondylosis with myelopathy lumbar region (721.42) which resulted in 1,883,617 services. To see all of the priority clinical area groupings of diagnosis codes, a table is available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html*.

Using the above methodology, we developed and proposed eight priority clinical areas. These reflect both the significance and the high prevalence of some of the most disruptive diseases in the Medicare population.

TABLE 40—PROPOSED PRIORITY CLINICAL AREAS WITH CORRESPONDING CLAIMS DATA

Proposed priority clinical area	Total services	% Total services [1]	Total payments	% Total payments [1]
Chest Pain (includes angina, suspected myocardial infarction, and suspected pulmonary embolism)	4,435,240.00	12	$470,395,545	14
Abdominal Pain (any locations and flank pain)	2,973,331.00	8	235,424,592	7
Headache, traumatic and non-traumatic	2,107,868.00	6	89,382,087	3
Low back pain	1,883,617.00	5	180,063,352	5
Suspected stroke	1,810,514.00	5	119,574,141	4
Altered mental status	1,782,794.00	5	83,296,007	3
Cancer of the lung (primary or metastatic, suspected or diagnosed)	1,114,303.00	3	154,872,814	5
Cervical or neck pain	1,045,381.00	3	83,899,299	3

[1] Percentage of 2014 Part B non-institutional claim line file for advanced imaging services from Medicare claims for beneficiaries who are enrolled in the fee-for-service (FFS) program (source: CMS Chronic Conditions Data Warehouse).

We also engaged the CMS Alliance to Modernize Healthcare (CAMH) Federally Funded Research and Development Center (FFRDC), the MITRE Corporation (MITRE), to begin developing efficient and effective processes for managing current and future health technology assessments. MITRE generated an independent report that presents a summary of findings from claims data from the Medicare population and their utilization of advanced imaging procedures. Coupled with our internal analysis, this report has assisted in identification of proposed priority clinical areas for the Medicare AUC program for advanced diagnostic imaging services. Analysis and methods for this report are available at *https://www.mitre.org/publications/technical-papers/claims-data-analysis-to-define-priority-clinical-areas-for-advanced*.

While this year we proposed priority clinical areas based on an analysis of claims data alone, we may use a different approach in future rulemaking cycles. As we specified in § 414.94(e) of our regulations, we may consider factors other than volume when proposing priority clinical areas including incidence and prevalence of disease, variability of use of particular imaging services, strength of evidence supporting particular imaging services and the applicability of a clinical area to a variety of care settings and to the Medicare population.

We encouraged public comments on this proposed initial list of priority clinical areas, including recommendations for other clinical areas that we should include among our list of priority clinical areas. In particular, we were interested in comments on the above methodology or alternate options; whether the proposed priority clinical areas are appropriate including information on the extent to which these proposed priority clinical areas may be represented by clinical guidelines or AUC in the future. Furthermore, we were interested in public comments, supported by published information, for varying levels of evidence that exist across, as well as within priority clinical areas.

The following is a summary of the comments we received on the list of priority clinical areas which may serve as part of the basis for identifying outlier ordering professionals.

Comment: Many commenters addressed the proposed list of priority clinical areas. Some commenters suggested that many of the proposed priority clinical areas were too large and each area was too broadly defined. Commenters expressed concerns that the proposed list does not permit a meaningful, focused approach. As an alternative, one commenter encouraged CMS to limit the number of priority clinical areas from eight to four. Other commenters noted that broadly defined priority clinical areas might result in little opportunity for a change in behavior of ordering professionals. Commenters supported inclusion of low back pain and headache in the list of priority clinical areas. One commenter specifically recommended that CMS refine the proposed clinical areas of ''low back pain'' and ''headache'' to reflect differences between the elderly and non-elderly populations. Other commenters noted the possibility of overlap between priority clinical areas of headache, suspected stroke, and altered mental status, and some commenters recommended combining such areas.

Other commenters recommended eliminating suspected stroke, altered mental status, chest pain and abdominal pain, and creating a stand-alone priority clinical area for suspected pulmonary embolism. For abdominal pain, commenters were concerned that there were not high quality AUC available to cover such a vast clinical area. For suspected stroke, commenters were concerned that using this area for future outlier calculations would not be beneficial as advanced imaging for these patients may be exempt from this program under the emergency medical conditions exception. Commenters disagreed with both suspected stroke and altered mental status because both could fall under other priority clinical areas and they noted there was a lack of high quality AUC available to address them.

Some commenters encouraged and others discouraged CMS from considering alternative priority clinical areas. Some commenters generally asked CMS to refrain from considering other clinical areas beyond what is listed in the CY 2017 PFS proposed rule. Other commenters offered alternatives in both number and scope of priority clinical areas. Other commenters suggested including musculoskeletal (hip pain, knee pain, joint pain, shoulder pain, rotator cuff injury), other cancers (breast, prostate), right upper quadrant pain, solitary pulmonary nodule, pancreatitis, appendicitis, renal colic, suspected abdominal aortic dissection, CT for minor blunt head trauma, suspected cardiac ischemia, and hematuria. One commenter noted that the top ten conditions for which advanced imaging is requested included low back pain, headache, and cervical pain. Another commenter recommended that these priority clinical areas should be phased in at a rate of two per year, with examples of pulmonary embolism and low back pain (as areas where strength of evidence was particularly high), which echoed other general comments to more gradually expand the list of

priority clinical areas after testing and as deemed necessary.

Response: We agree that if priority clinical areas are too broadly defined, it would not be consistent with our purpose to offer both comprehensive and focused approaches to AUC rollout into qualified CDSMs. We further agree that a central goal of the AUC program is to promote appropriate ordering of advanced diagnostic imaging services. Additionally we appreciate the points made by the commenters and see merit in some of their recommended alternatives for priority clinical areas as they take into account factors such as incidence and prevalence of disease, the variability of utilization of specific imaging services, the strength of evidence and AUC available for consultation for a particular clinical scenario, and applicability of each suggested alternative clinical area to the Medicare population and to a variety of care settings, including the emergency department.

We agree with commenters that chest pain is a general symptom and too broad for a focused priority clinical area. We further agree with commenters that supported creating a stand-alone priority clinical area for suspected pulmonary embolism, as discussed in detail below, and one for coronary artery disease. Chest pain may be a clinical symptom of underlying suspected pulmonary embolism and coronary artery disease. There is a solid evidence base from well designed, randomized controlled trials supporting specific protocols and guidelines that consider different signs, symptoms and history associated with working up a patient with suspected pulmonary embolism. There is also strong evidence from multiple large, randomized controlled trials to guide imaging for coronary artery disease. We note that, according to the American Heart Association Statistical Update, coronary artery disease is the leading cause of death among men and women in the United States. The evidence is less robust for many other causes of chest pain. Therefore, based on the above, we are removing chest pain as a priority clinical area and finalizing suspected pulmonary embolism and coronary artery disease as two distinct areas.

We recognize, along with commenters, that the proposed list of priority clinical areas did not include scenarios specific to musculoskeletal indications. As stated in the proposed rule, CMS also engaged MITRE to generate an independent report, which indicates that almost half a million advanced diagnostic imaging services were rendered to Medicare beneficiaries in 2014 for clinical presentations related to joint pain. Furthermore, we agree with commenters who suggested CMS consider additional clinical areas with a reasonably robust volume of literature on appropriate use and agree that the strength of evidence for imaging use and relevance to the Medicare population supports inclusion of hip pain and shoulder pain (to include suspected rotator cuff injury) in the final list of priority clinical areas.

In addition to commenters' support of inclusion of low back pain and headache in the list of priority clinical areas, we also note that the MID cites clinical research demonstrating that use of clinical decision support was associated with a decrease in the utilization of lumbar MRIs for low back pain and head MRIs for headache.

We are finalizing the proposed areas of low back pain and headache, as well as cancer of the lung (primary or metastatic, suspected or diagnosed).

We have removed altered mental status and abdominal pain based on the concerns expressed by commenters summarized above, including the lack of strong evidence to cover the breadth of each of these areas. Based on the commenters' concerns we may review these areas in the future, possibly narrowing their scope.

Regarding stroke, we acknowledge that evidence-based stroke protocols do exist, however, we believe that it is possible that an exception for emergency medical services may disproportionally apply to suspected stroke so there may be a concern for using this priority clinical area for future outlier calculations. Furthermore, there may be some overlap of the clinical areas of suspected stroke and headache. A strong level of evidence specific to headache is available and we believe headache is less likely to be impacted by the emergency medical services exception. Therefore, we are removing suspected stroke and retaining headache in the final list of priority clinical areas. We may consider adding suspected stroke through future rulemaking.

In response to public comments and as supported by the additional information above and further discussion below, we have modified the list of priority clinical areas by: (1) removing chest pain, abdominal pain (any locations and flank pain), suspected stroke and altered mental status; and (2) adding coronary artery disease (suspected or diagnosed), suspected pulmonary embolism, hip pain and shoulder pain (to include suspected rotator cuff injury). We are finalizing as proposed the priority clinical areas of headache (traumatic and non-traumatic), low back pain, cancer of the lung (primary or metastatic, suspected or diagnosed), and cervical or neck pain. The final list of priority clinical areas is 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.

Consistent with section 1834(q) of the Act, we are not AUC developers, and therefore, would not produce AUC tailored to the elderly population. However, § 414.94(c)(1) of our regulations requires qualified PLEs to utilize an evidentiary review process when developing or modifying AUC. This regulation further requires qualified PLEs to identify AUC that are relevant to priority clinical areas, and specifies that to be considered relevant, the AUC must reasonably address the entire clinical scope of the corresponding priority clinical areas. These requirements and the resulting fundamental process ensures that AUC are evidence-based to the extent feasible as required by section 1834(q)(1)(B) of the Act. Therefore, we expect that qualified PLEs will undertake evidence reviews of sufficient depth and quality to ensure that all relevant evidence-based publications in the peer-reviewed medical literature on trials, observational studies, and consensus statements are identified, considered and evaluated; and that such reviews are reproducible.

We do not agree with the suggestion to reduce the total number of priority clinical areas we proposed in CY 2017 rulemaking, and reiterate that ordering professionals must consult AUC for all applicable imaging services, not only those falling within a priority clinical area. Furthermore, we anticipate that additional priority clinical areas will be proposed in future rulemaking, and we believe that Medicare beneficiaries will benefit as ordering professionals become familiar with specified applicable AUC relevant to all advanced diagnostic imaging services.

Comment: One commenter suggested diagnosimetrics—the application of quantitative analysis to the art of disease diagnosis—as an alternative approach to clinical assessment and reassessment, which the commenter believed is an

approach that obviates the need to develop priority clinical areas.

Response: We appreciate alternative considerations for implementation of the AUC program, but we disagree that utilization of diagnosimetrics can eliminate completely the need to establish priority clinical areas. We remind all commenters that we set forth the list of priority clinical areas not only to strike a balance between the focused and comprehensive approach to implementing the AUC program, but also to be transparent about the areas that we anticipate will serve as the basis for identifying outlier professionals in the future. We again note that consultation of AUC will be required for all advanced diagnostic imaging services regardless of whether they fall into a priority clinical area or not.

Comment: Many commenters recommended that pulmonary embolism be included as a stand-alone priority clinical area, based in part on high strength of evidence from multiple, large multicenter, randomized controlled trials (RCTs), and several commenters disagreed. The majority of commenters in support of pulmonary embolism believed that it should be a priority clinical area distinct from chest pain, and further recommended that CMS remove or more narrowly determine any priority clinical area for chest pain. In particular, one commenter did not support inclusion of pulmonary embolism as a separate category stating that eight areas is an appropriate number for the first year of the program. Another commenter supplied published evidence that the decision rules for assessing risk of pulmonary embolism have not been shown to improve appropriate use of diagnostic imaging when compared to clinical judgment alone. One commenter suggested having the pulmonary embolism priority clinical area apply to CT angiograms only. We received one comment that ''shortness of breath'' rather than ''pulmonary embolism'' be included as a stand-alone priority clinical area.

Response: We appreciate the extensive input on this topic and we agree with the majority of commenters, and thus, are finalizing suspected pulmonary embolism as a priority clinical area. We not that qualified PLEs already have AUC for suspected pulmonary embolism that are based on large, multi-center, randomized controlled trials. These evidence-based AUC in turn are further supported by the American Board of Internal Medicine (ABIM) Foundation's Choosing Wisely® list of society recommendations.

Comment: Some commenters advocated for the addition of lung cancer screening to the list of priority clinical areas. The commenters suggested that the inclusion of lung cancer screening would be beneficial as there are well-defined and evidence-based criteria outlining the population that benefits from screening examinations. One commenter remarked on the opportunity it offers for qualified PLEs and CDSMs to gain experience with decision support for a population screening test which may differ from a diagnostic test.

Response: We agree with the commenter that it is important for qualified PLEs and qualified CDSMs to interface to gain experience with implementing specified applicable AUC into an appropriateness rating, specifically for advanced diagnostic imaging services. We also appreciate feedback on areas for which AUC have been developed. However, section 1834(q)(1) of the Act limits this program to promoting the use of AUC for advanced diagnostic imaging services, not to include screening tests.

Comment: Several commenters explicitly raised concerns regarding the scope, number, and frequency with which the list of priority clinical areas would continue to grow. Many commenters noted that a program with too many priority clinical areas would potentially obstruct any meaningful focused approach. Other commenters either supported or offered no objections to the proposed number of priority clinical areas. Some commenters provided additional considerations to impact the selection of additional priority clinical areas including but not limited to the strength of evidence supporting the use or non-use of a particular imaging service, the variability of use of a particular imaging service, and the representation of a given clinical grouping to the existing list of priority clinical areas.

Response: We recognize these concerns and reiterate that we do not believe there is just one correct criterion to form the basis for expanding the list of priority clinical areas over time. We agree with commenters who encouraged us to consider the breadth and depth of clinical scenarios within the proposed priority clinical areas, and acknowledge the impact of priority clinical areas for calculation of outlier ordering professionals. We expect the list of priority clinical areas to expand over time in a judicious and stepwise manner through consultation with physicians and other stakeholders and through the annual notice and comment rulemaking process. We have demonstrated this in the CY 2017 PFS proposed rule, where we solicited comments on recommendations for additional or alternative areas to be included on our list of priority clinical areas. We believe that the final list of priority clinical areas is responsive and reflects the expressed needs and concerns of most commenters.

Comment: Although several commenters generally agreed with the approach used to identify priority clinical areas, some expressed concern about the underlying methodology. Many commenters believed that when we provided claims data analysis and ICD–9 diagnosis codes to describe priority clinical areas, we only considered volume and cost of advanced diagnostic imaging services. Some commenters requested CMS include and/or remove ICD–9 diagnosis codes in one or more of the supplemental tables accompanying the list of priority clinical areas. Many commenters believed that the supplemental table encompassed what CMS believed to be the entire clinical scope of the proposed priority clinical area, while others believed that CMS did not explain what constitutes a priority clinical area such as low back pain. As a consequence, some commenters requested that CMS define priority clinical areas to include all applicable diagnosis codes, and map those diagnosis codes to the most recent ICD–10 diagnosis codes available. One commenter requested that CMS confirm that the data used to ascertain the priority clinical areas did not include services provided in the inpatient and emergency department settings. Another commenter questioned whether the inclusion of too many minor or common symptoms in the data gathering process would consequently weaken the implementation of the AUC program generally.

Response: We equally acknowledge the commenters that agreed with our approach and those that raised concerns with our methodology. Section 414.94(e)(2) of our regulations, as finalized in the CY 2016 PFS final rule with comment period, states that, when identifying priority clinical areas, we will consider incidence and prevalence of disease, the volume and variability of use of particular imaging services, and strength of evidence supporting particular imaging services, as well as applicability of the clinical area to a variety of care settings and to the Medicare population. In the CY 2017 PFS proposed rule, we proposed priority clinical areas based on an analysis of claims data, using subjective clinical judgment on whether a

particular ICD–9 diagnosis code should be included in a given clinical grouping. We remind all commenters that the supplemental table was provided to lend insight into the extent to which a given diagnosis code contributes to orders for advanced diagnostic imaging services, which we used to assist us in identifying proposed priority clinical areas. We continue to believe that the list of priority clinical areas should reflect both the significance and high prevalence of some of the most disruptive diseases in the Medicare population. In particular, the claims data analysis we undertook did not include services furnished in the inpatient setting, but did include services provided in an emergency department as section 1834(q)(4)(C) of the Act excludes applicable imaging services ordered for individuals with emergency conditions as defined in section 1867(e)(1) of the Act, but does not exclude all applicable imaging services provided in the emergency department from the consultation requirement under this program. We further agree with the commenters' observations that a high volume advanced diagnostic imaging service does not by itself indicate high rates of inappropriate testing. Therefore, we are modifying the proposed list of priority clinical areas to more closely align with feedback from commenters on the strength of evidence and AUC available for clinical scenarios within a given clinical area.

Given the transition to ICD–10 in 2015 and changes in the list of priority clinical areas, as well as factors discussed above, we clarify that the supplemental table does not define the final list of priority clinical areas. We expect to address the role of ICD–10 diagnosis codes in claims based reporting, auditing and outlier identification for priority clinical areas with rulemaking next year. We note, however, that we believe that the list of priority clinical areas provides sufficient guidance to CDSMs as they decide whether to apply to be a qualified CDSM in the upcoming application cycle.

Comment: Several commenters provided alternative considerations to methodically determine priority clinical areas, including ICD–10 diagnosis codes, CPT codes, hierarchical condition categories, anatomical regions, variation in treatment, and quality of the evidence. A few commenters suggested that CMS also consider the extent to which the majority of clinical scenarios within a priority clinical area would likely fall under the emergency medical conditions exception, noting that there may be little impact in proposing to address clinical areas exempt from AUC consultation. Furthermore, some commenters requested that CMS exclude from priority clinical area consideration those clinical scenarios for which advanced imaging tests are rarely inappropriate, which commenters stated would reduce alert fatigue by ordering professionals and increase focus on clinical scenarios for which ordering professional behavior may be altered.

Response: Although this year we proposed priority clinical areas based partly on an analysis of claims data, we also considered stakeholder feedback and commenters' alternative considerations. We acknowledge the merit of several acceptable alternative proposals and believe the current definition of priority clinical areas encompasses these considerations. We will continue to maintain close dialogue with physicians and other stakeholders, and may use a different approach to addressing priority clinical areas in future rulemaking cycles, as needed.

Comment: Some commenters expressed additional concerns about the use of diagnosis codes to help form priority clinical areas. One commenter noted that using a diagnosis for suspected stroke should also include other diagnoses in the priority clinical area, such as facial numbness, slurred speech, or limb weakness. Other commenters expressed concerns that publishing a rigid, exact mapping of ICD diagnosis codes for each priority clinical area could give rise to ''gaming.'' Other commenters noted that addressing priority clinical areas with diagnosis codes is problematic because the final diagnosis code is often not known until the advanced imaging study is completed.

Response: We recognize that these comments exemplify the confusion and concerns expressed by many commenters about the definition of each priority clinical area. We did not propose to set forth a diagnosis-code based definition for each priority clinical area; rather, we will continue to use the definition of priority clinical areas in § 414.94(b) which includes clinical conditions, diseases or symptom complexes and associated advanced diagnostic imaging services identified by CMS through annual rulemaking and in consultation with stakeholders which may be used in the determination of outlier ordering professionals. In addition, we clarify that our submission of supplemental data presenting ICD–9 diagnosis codes within each proposed priority clinical area was intended only to explain the portion of Medicare claims data derived from the CCW 2014 Part B non-institutional claim line file for services furnished during CY 2014. We remind all commenters that these data were used to calculate the total services furnished and total payments made to those enrolled in Medicare Part B. We included this supplemental table to be open and transparent to stakeholders regarding the process by which we developed the proposed list of priority clinical areas. We reiterate that our use of the ICD–9 diagnosis codes from CY 2014 claims data was solely a means for estimating volumes of procedures, as a stepping stone in the development of an initial list of priority clinical areas. In the event we use claims data from 2015 or later for analyses, we will use ICD–10 codes, but will continue to assess all options for identifying and establishing priority clinical areas and not necessarily limit ourselves only to ICD diagnosis code analyses.

We acknowledge the alternative opinions of commenters seeking to modify the extent of diagnosis codes in one or more priority clinical areas. We hope to discuss further with physicians and other stakeholders the relevance of mapping ICD diagnosis codes to priority clinical areas as we move forward in formulating the claims reporting implementation strategy (discussed in more detail below) and strategies to avoid areas of concern for commenters. We clarify that ICD–9 diagnosis codes will not be used for claims reporting purposes in this program given the 2015 transition to ICD–10. We expect that the role of ICD–10 diagnosis codes for the purposes of claims based reporting, auditing and outlier identification will be addressed through rulemaking next year.

Comment: Some commenters stated that AUC consultation within priority clinical areas include only high-quality evidence and recommended further consideration and discussion of the level of evidence available for AUC in each priority clinical area. One commenter requested that CMS specify a standard for the strength of any evidence. Many commenters offered to share their guidelines, guidance and other expertise around AUC with CMS, and recommended that CMS engage with them directly. Other commenters suggested that the proposed priority clinical areas more closely align with the ABIM's Choosing Wisely® initiative and/or the ACR's Appropriateness Criteria®. One commenter recommended a number of evidence-based guidelines for imaging of patients with traumatic cervical pain. In

conjunction with the evidence submitted to support one or more priority clinical areas, another commenter suggested only including those priority clinical areas for clinical scenarios for which AUC from multiple PLEs are available.

Some commenters also shared with CMS publications that suggested a lack of evidence-based AUC for clinical scenarios that could reasonably fall within one or more proposed priority clinical areas. In particular, one commenter believed that available appropriateness criteria do not address altered mental status. Commenters generally believed that clinical scenarios providing no appropriateness rating or contradictory recommendations from CDSMs based on AUC using lower grades of evidence or expert opinion would not result in significant modifications in ordering professional behavior. A commenter suggested CMS consider the safety margin inherent in the clinical area where imaging for acute stroke, for example, has a narrow safety margin while imaging for suspected rotator cuff injury has a wider safety margin. Many commenters identified situations when the available high-quality evidence does not cover the entire clinical scope of a priority clinical area. In these situations, a CDSM would either cover less than the entire clinical scope of a priority clinical area and only incorporate AUC based on high-quality evidence or cover the entire clinical scope and in doing so incorporate AUC based on low quality evidence and expert opinion. These commenters cautioned against requiring qualified CDSMs to incorporate specified applicable AUC that encompass the entire clinical scope given the potential for forcing consultation with AUC based on lower quality evidence. As an alternative, a few commenters encouraged CMS to separate priority clinical areas into those that have high quality AUC and those that do not.

Response: We agree that priority clinical areas for which there is little evidence would likely have little impact in changing physician ordering behavior, and may indeed negatively impact patient care. We expect qualified PLEs to identify and focus on that portion of the entire clinical scope within a given priority clinical area where there is sufficient evidence to create high quality AUC. We encourage qualified PLEs to consider the ''safety margins'' discussed above along with strength of evidence and other factors when developing or modifying AUC. Furthermore, we believe that qualified CDSMs, working with qualified PLEs, should incorporate such high quality AUC as part of a clinical decision tree, which includes areas where imaging is triggered by other tests.

We continue to believe that evidence grading is an essential component of the AUC development process for all clinical areas, including priority clinical areas. However, we acknowledge that different grading systems may be more appropriate for different clinical areas. As such, we will not require the use of specific grading mechanisms and leave that decision to qualified PLEs. We recognize that some AUC development processes could invite public comment and include a wide range of experts and stakeholders on the multidisciplinary AUC development team. However, we will not establish these as requirements, and instead require under § 414.94(c)(1) that qualified PLEs post AUC along with the process they use for developing and modifying AUC on their Web site in the public domain to allow for review by all stakeholders.

Comment: Some commenters expressed confusion over which entity determines whether an exam falls within a priority clinical area for the ordering professional. Several commenters noted that determining whether an exam falls under a priority clinical area often will not be an easy yes-or-no decision. One commenter further expressed that this confusion would result in physicians being expected to know if an advanced imaging study falls within a priority clinical area, which would further confuse clinicians about which orders require consultation with CDSMs and which do not. Several commenters explained that ordering professionals may not know whether they are required to consult with AUC through a qualified CDSM at the time of order because the diagnosis is not yet known. Another commenter raised concerns that not all available specified applicable AUC within priority clinical areas, especially those developed by general hospitals or by professional societies, will be well suited for local adaptation, a particular practice, or the patients it serves. To address these concerns, commenters made a few recommendations to CMS. Specifically, commenters suggested qualified PLEs should be responsible for certifying whether an AUC set encompasses the entire scope of a priority clinical area. Additionally, commenters recommended that CMS develop and launch an educational campaign, including a Town Hall meeting.

Response: We understand the commenters' concerns about the difficulty ordering professionals may have in identifying prospectively which clinical scenarios pertain to a priority clinical area. We remind commenters that ordering professionals will be required to consult specified applicable AUC through a qualified CDSM for all applicable imaging services and will not be required to determine which applicable imaging services fall within priority clinical areas. For the purposes of the AUC program, priority clinical areas will be used as part of the input to calculate outlier ordering professionals. We will address the identification of outlier ordering professionals for this program, as specified in section 1834(q)(5) of the Act, in future rulemaking.

Regarding local adaptation, we believe it is important to fit AUC to local circumstances, while also ensuring a rigorous process for doing so. However, only AUC modified by qualified PLEs can become specified applicable AUC. Furthermore, qualified PLEs are required under our regulation at § 414.94(c)(v) to identify each appropriate use criterion or AUC subset that is relevant to a priority clinical area. Stakeholders should expect to see such delineations on the Web site of the qualified PLE.

We are not launching an educational campaign at this time because this program is only partially implemented. However, we believe that physicians and other practitioners, through continued dialogue with us, will continue to become more informed as implementation of this program proceeds, and we will continue to evaluate the programmatic and educational needs of ordering and furnishing professionals impacted by the AUC program over time.

Comment: Many commenters expressed confusion regarding when consultation with specified applicable AUC will be required. Some commenters believed that consultation for all advanced diagnostic imaging services will be required, while others believed that CMS proposed to limit the consultation requirement to only advanced diagnostic imaging services within priority clinical areas. Some commenters recommended that physicians and other practitioners be required to consult AUC only within the priority clinical areas. Commenters believed the impact of limiting AUC consultation to only imaging studies falling within priority clinical areas would be a decrease in the consultation and reporting for ordering professionals. Other commenters recommended a narrower requirement for only ordering professionals who meet an ordering threshold or who order from a list of

specified conditions within their specialty to consult AUC for only priority clinical areas. While still other commenters recommended that ordering professionals be required to consult AUC for advanced diagnostic imaging services including and beyond the priority clinical areas. Another recommendation from commenters included requiring only some ordering professionals consult AUC for limited applicable imaging services by imaging modality. Several commenters agreed with our proposed definition of the applicable payment systems under which consultation with AUC for an advanced diagnostic imaging service would be paid.

Response: We understand commenters' confusion and expect that, in general, the additional regulations we are finalizing in this final rule will provide greater clarity. Section 1834(q)(4) of the Act sets forth the requirement that ordering professionals must consult with specified applicable AUC through a qualified CDSM for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system. The applicable imaging services are not limited under the statute to any particular clinical area. Therefore, we do not have statutory authority to limit the consultation requirement to priority clinical areas. We reiterate that priority clinical areas may be used in the identification of outlier ordering professionals under a future component of this program. By starting to identify these areas now, we believe physicians and practitioners 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 further believe that AUC consultation will help to improve appropriate utilization among all professionals and will continue to engage stakeholders to further this shared goal.

Comment: Many commenters suggested that they agreed with the approach of CMS to use the priority clinical areas for the purposes of identifying outlier ordering professionals. In contrast, one commenter expressed that denial of medical services based on criteria designed solely to decrease the utilization of medical imaging runs counter to the underlying goal of the AUC program under section 218(b) of the PAMA. Commenters also generally agreed that the impact of the AUC program could not be fully realized until after implementation; therefore, many commenters urged CMS to collect at least one year of data from the start of the program and use it to identify priority clinical areas where the AUC program can help reduce variation.

Response: Although commenters appreciated the utility in defining priority clinical areas for the purposes of identifying outlier ordering professionals, we reiterate that we have yet to propose the policies for the annual identification of outlier ordering professionals, and therefore, will revisit comments on this subject in the course of rulemaking for the CY 2018 PFS. We remind all commenters that section 1834(q)(5) of the Act explicitly requires that the Secretary shall use 2 years of data to identify outlier ordering professionals for the purposes of the AUC program.

In response to comments, we are finalizing a modified list of priority clinical areas under § 414.94(e)(5) of our regulations, making the following changes from the proposed list: (1) removed chest pain, abdominal pain (any locations and flank pain), suspected stroke and altered mental status; and (2) added coronary artery disease, (suspected or diagnosed), suspected pulmonary embolism, hip pain and shoulder pain (to include suspected rotator cuff injury). We are finalizing the proposed priority clinical areas of headache (traumatic and non-traumatic), low back pain, cancer of the lung (primary or metastatic, suspected or diagnosed), and cervical or neck pain without change.

c. CDSM Qualifications and Requirements

We proposed to add a new § 414.94(g)(1) to our regulations to establish requirements for qualified CDSMs. Section 1834(q)(3)(A)(iii) of the Act provides relative flexibility for qualified CDSMs, and states that they may include mechanisms that are within certified EHR technology, private sector mechanisms that are independent from certified EHR technology or mechanisms that are established by the Secretary.

We believe that, at least initially, it is in the best interest of the program to establish CDSM requirements that are not prescriptive about specific IT standards. Rather, we proposed an approach that focuses on the functionality and capabilities of qualified CDSMs. The CDSM, EHR and health IT environments are constantly changing and improving and we want to allow room for growth and innovation. However, in the future, as more stakeholders and other entities including the ONC, AHRQ, and relevant standards development organizations come to consensus regarding standards for CDSMs, then we may consider pointing to such standards as a requirement for qualified CDSMs under this program. We believe standards would make it possible to achieve interoperability, allowing any CDSM to incorporate any standardized AUC and for sets of AUC to be easily interchangeable among various CDSMs. We will continue to work with the ONC and AHRQ to facilitate movement in this direction.

Recent work under the federally-sponsored Clinical Quality Framework (CQF) initiative has successfully developed an integrated approach that harmonizes standards for electronic clinical quality measurement with those that enable shareable clinical decision support artifacts (for example, AUC) using Fast Healthcare Interoperability Resources (FHIR). The CQF initiative is working to support semantically interoperable data exchange for (1) calling a service, sending patient data to a service for clinical decision support guidance and receiving clinical decision support guidance or quality measurement results in return, and (2) enabling a system to consume and internally execute decision support artifacts. The current implementation guide supports both approaches and could be used to successfully execute and share AUC as described in this program. As this standard is considered sufficiently mature for widespread adoption, the ONC may consider it for use in future editions of certification criteria for health IT. While the current regulation requires no specific standard, the CMS and ONC are supportive of this approach and additional information is available at *http://hl7-fhir.github.io/clinicalreasoning-module.html*. It should be noted that there are also existing deployed standards for clinical decision support and these and emerging standards can be found in the ONC Interoperability Standards Advisory (*https://www.healthit.gov/standards-advisory*).

At § 414.94(g)(1), we proposed to codify in regulations the seven requirements for qualified CDSMs set forth in section 1834(q)(3)(B)(ii) of the Act. The statute requires qualified CDSMs to make available to the ordering professional specified applicable AUC and the supporting documentation for the applicable imaging service ordered. We do not interpret this requirement to mean that every qualified CDSM must make available every specified applicable AUC. In the CY 2016 PFS final rule with comment period, we allowed for the

approval of massive libraries of AUC (resulting from approvals for qualified PLEs with comprehensive and extensive libraries), yet we expressed our intention to establish priority clinical areas. While there is a statutory requirement to consult AUC for each applicable imaging service, we recognize that ordering professionals may choose to thoroughly improve their understanding of, and focus their internal quality improvement (QI) programs on, those priority clinical areas; and these areas will in turn serve as the basis for future outlier calculations.

Consistent with that approach, we proposed to add a requirement in § 414.94(g)(1)(iii) that qualified CDSMs must make available to ordering professionals, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas. We encourage and expect some CDSMs, based on the needs of the professionals they serve, will choose to include a far more comprehensive set of AUC going above and beyond the minimum set as we understand many ordering professionals want such comprehensive access to AUC. When this Medicare AUC program is fully implemented, all ordering professionals must consult specified applicable AUC through a qualified CDSM for every applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system in order for payment to be made for the service. However, when identifying the outlier ordering professionals who will be subject to prior authorization beginning in 2020, we anticipate focusing on consultation with specified applicable AUC within priority clinical areas rather than the universe of specified applicable AUC. The concept of priority clinical areas will allow us to implement an AUC program that combines two approaches to implementation allowing clinicians flexibility to either engage with a rapid rollout of comprehensive specified applicable AUC or adopt a focused approach to consulting AUC. Thus, they can choose their approach and select a CDSM and AUC set(s) that fit their needs and preferences, while being sure that each qualified CDSM will include AUC that address all priority clinical areas.

We further proposed to add a requirement in § 414.94(g)(1)(iv) of our regulations that qualified CDSMs must be able to incorporate specified applicable AUC from more than one qualified PLE. We believe this approach ensures that CDSMs can expand the AUC libraries they can provide access to represent AUC across all priority clinical areas (consistent with the requirements under proposed § 414.94(g)(1)(iii)). We do not necessarily expect that a single qualified PLE will develop AUC addressing every priority clinical area domain, especially since we believe that over time and through future rulemaking, the list of priority clinical areas will expand and cross additional clinical domains. Ensuring that qualified CDSMs are not limited in their technology to incorporating AUC from only one qualified PLE will help to ensure that ordering professionals will not be in a position of consulting a CDSM that cannot offer them access to AUC that address all priority clinical areas. As stakeholders continue to advance CDSM technology, we look forward to standards being developed and widely accepted so that AUC are incorporated in a standardized format across CDSM platforms. Increasing standardization in this area will move the industry closer to the goal of interoperability across CDSMs and EHRs.

We also proposed to add a requirement in § 414.94(g)(1)(i) that specified applicable AUC and related documentation supporting the appropriateness of the applicable imaging service ordered must be made available within the qualified CDSM. For example, the ordering professional would have immediate access to the full appropriate use criterion, citations supporting the criterion and a summary of key evidence supporting the criterion.

We proposed to add a requirement in § 414.94(g)(1)(ii), consistent with section 1834(q)(3)(B)(ii)(II) of the Act, that the qualified CDSM must clearly identify the appropriate use criterion consulted if the tool makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario. We believe this is important since CDSMs that choose to incorporate a comprehensive AUC library may be offering the ordering professional access to AUC from multiple qualified PLEs. In such scenarios, it is important that the ordering professional knows which appropriate use criterion is being consulted and have the option to choose one over the other if more than one criterion accessible within the CDSM applies to the scenario.

We proposed to add a requirement in § 414.94(g)(1)(v), consistent with section 1834(q)(3)(B)(ii)(III) of the Act, that the qualified CDSM must provide to the ordering professional a determination, for each consultation, of the extent to which an applicable imaging service is consistent with specified applicable AUC or a determination of ''not applicable'' when the mechanism does not contain a criterion that would apply to the consultation. This determination would communicate the appropriateness of the applicable imaging service to the ordering professional. In addition to this determination, we also proposed that the CDSM provide the ordering professional with a determination of ''not applicable'' when the mechanism does not contain an appropriate use criterion applicable to that patient's specific clinical scenario.

We proposed to add a requirement in § 414.94(g)(1)(vi), consistent with section 1834(q)(3)(B)(ii)(IV) of the Act, that the qualified CDSM must generate and provide to the ordering professional certification or documentation that documents which qualified CDSM was consulted, the name and NPI of the ordering professional that consulted the CDSM and whether the service ordered would adhere to applicable AUC, whether the service ordered would not adhere to such criteria, or whether such criteria was not applicable for the service ordered. We proposed to require under § 414.94(g)(1)(vi)(A) that this certification or documentation must be issued each time an ordering professional consults the qualified CDSM. Since Medicare claims will be filed only for services that are rendered to beneficiaries, we will not see CDSM consultation information on the claim form specific to imaging services that are not ordered. We believe that for the CDSM to be able to provide meaningful feedback to ordering professionals, information regarding consultations that do not result in imaging is just as important as information on consultations that do result in an order for advanced imaging.

Thus, we proposed to require under § 414.94(g)(1)(vi)(B) that the documentation or certification provided by the qualified CDSM must include a unique consultation identifier. This would be a unique code issued by the CDSM that is specific to each consultation by an ordering professional. This type of unique code may serve as a platform for future collaboration and aggregation of consultation data across CDSMs. In addition, at some point in the future, this unique code may assist in more seamlessly bringing Medicare data together with CDSM clinical data to maximize quality improvement in clinical practices and to iteratively improve the AUC itself. We proposed in § 414.94(g)(1)(vii), consistent with section 1834(q)(3)(B)(ii)(V) of the Act, that the specified applicable AUC content within qualified CDSMs be

updated at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or to an individual appropriate use criterion. We proposed 12 months as the maximum acceptable time frame for updating content. We believed that in most cases it will be possible to update AUC content more frequently than every 12 months, particularly for cloud-based CDSMs. We further proposed in § 414.94(g)(1)(vii)(A) that qualified CDSMs have a protocol in place to more expeditiously remove AUC that are determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed.

In addition, we proposed in § 414.94(g)(1)(vii)(B) that qualified CDSMs must make available for consultation specified applicable AUC that address any new priority clinical areas within 12 months of the priority clinical area being finalized by CMS. We believe this would allow the CDSM sufficient time to incorporate the AUC into the CDSM. Thus, any new priority clinical areas finalized, for example, in the CY 2018 PFS final rule that would be effective January 1, 2018, would need to be incorporated into a qualified CDSM by January 1, 2019. To accommodate this time frame, we would accept a not applicable determination from a CDSM for a consultation on a priority clinical area for dates of service through the 12-month period that ends, in this example, on January 1, 2019. We note that all qualified CDSMs that are approved by June 30, 2017, should be capable of supporting AUC for all priority clinical areas that are finalized in the CY 2017 PFS final rule.

We proposed to add a requirement in § 414.94(g)(1)(viii), consistent with section 1834(q)(3)(B)(ii)(VI) of the Act, that the qualified mechanism must meet privacy and security standards under applicable provisions of law. Potentially applicable laws may include the HIPAA Privacy and Security rules.

We proposed to add a requirement in § 414.94(g)(1)(ix), consistent with section 1834(q)(3)(B)(ii)(VII) of the Act, that qualified CDSMs must provide ordering professionals aggregate feedback in the form of an electronic report on an annual basis (at minimum) regarding their consultations with specified applicable AUC. Our intent is to require records to be retained in a manner consistent with the HIPAA Security Rule. To provide such feedback, and to make detailed consultation information available to ordering professionals, furnishing professionals (when they have authorized access to the CDSM), auditors and CMS, we proposed in § 414.94(g)(1)(x) that a qualified CDSM must maintain electronic storage of clinical, administrative and demographic information of each unique consult for a minimum of 6 years. We believe CDSMs could fulfill this requirement in a number of ways, including involving a third party in the storage of information, as well as for providing feedback to ordering professionals. We recognize that these requirements represent a minimum floor that clinicians may choose to expand their local QI programs.

In the event requirements under § 414.94(g)(1) are modified through rulemaking during the course of a qualified CDSM's 5-year approval cycle, we proposed in § 414.94(g)(1)(xi) that the CDSM would be required to comply with the modification(s) within 12 months of the effective date of the modification.

The following is a summary of the comments we received on CDSM qualifications and requirements.

Comment: We received numerous comments both for and against including qualifying CDSMs that are freestanding, web-based and operating outside of a certified EHR environment. Some of those commenters pointed out CMS statements indicating that ideally a CDSM would be seamlessly integrated into the clinical workflow, which could be possible when the CDSM is completely integrated within an ordering professional's EHR. Those in favor of a freestanding CDSM cited the importance of allowing choice as there are some instances where a freestanding mechanism may be preferred, particularly in cases of practitioners who do not use EHR technology or when integration of a CDSM involves high costs or other problems.

Response: Particularly in the early stages of this program, we believe it is important to allow for the option of a freestanding mechanism that is independent of EHR technology, which is supported by section 1834(q)(3)(A)(iii)(II) of the Act. For some ordering professionals, this will allow compliance with the requirements of the program while still affording them time to make decisions regarding EHR-integrated CDSMs. In addition, as we understand the current marketplace, it is more likely that tools available free of charge may initially begin as web-based tools and, we note that, in accordance with section 1834(q)(1)(C) of the Act and as defined in § 414.94(b) of our regulations, an applicable imaging service is one for which there is one or more qualified CDSM available free of charge.

As noted, we believe examples of CDSMs that seamlessly integrate with EHRs, including those that operate outside of certified EHR technology, such as those that operate in the cloud, will likely be most effective in meeting clinicians' needs. As the market continues to mature, we would expect to see expanded availability of easily affordable tools that fully integrate AUC guidance with an efficient, clinician-friendly workflow within the interface of the primary health IT system they use in providing and documenting care.

Comment: Several comments addressed our approach to CDSM requirements and noted that we focused on functionalities and capabilities of a mechanism for flexibility as opposed to prescriptive and specific IT standards. Commenters overwhelmingly favored the approach we proposed. Commenters indicated that the current state of CDSM technology is varied and there are not yet accepted, mature standards available. Many of these commenters encouraged CMS to cooperate with ONC, Health Level Seven International (HL7) and other standards organizations to work toward identifying standards in the near future. Some commenters, however, pointed out that the lack of standards early in the program could lead to chaos in the market and increase costs since CDSM developers will not have a set of standards on which to build.

Response: We do not believe it is possible to require standards at this time due to the lack of agreement among stakeholders regarding which technical standards should be identified. We understand that some CDSM developers would prefer specific guidance from us to ensure they are building tools that meet the needs of the program; therefore, we will continue to work with stakeholders like ONC, HL7 and other standards organizations in an attempt to identify standards in the future. We will continue to actively encourage and welcome the input of stakeholders in this matter. As we expect that standards will continue to develop, evolve and gain acceptance, we believe that if we were to establish standards now for CDSMs, they would serve only as initial standards and may quickly become obsolete, potentially resulting in confusion for CDSM developers. We recommend that developers refer to ONC's Interoperability Standards Advisory (see *https://www.healthit.gov/standards-advisory*) for the most up-to-date standards available, which will likely be the basis of future development.

Comment: The majority of commenters addressed the proposal to

require qualified CDSMs to contain, at a minimum, AUC that encompass the entire clinical scope of priority clinical areas. Commenters were split regarding the proposed requirement. Some commenters suggested that establishing a minimum scope for CDSM AUC content would add cost and be unnecessary for CDSMs that serve specialists. They favored allowing qualified CDSMs to determine, along with the ordering practitioners they serve, what AUC content would be made available. Other commenters favored requiring every CDSM to contain comprehensive AUC. Those commenters said this was the intent of section 218(b) of the PAMA since ordering professionals must consult for every advanced diagnostic imaging order, and they believe a comprehensive AUC requirement would take into account the lessons learned from the MID, avoiding frustration of ordering practitioners who attempt to consult AUC for imaging services and do not find relevant AUC within their CDSM. Other commenters agreed in principle with the proposal to establish a minimum floor of AUC but expressed concerns about the way CMS proposed that the priority clinical areas must be addressed, stating that the requirement that AUC encompass the entire clinical scope of priority clinical areas is not preferred and would draw in AUC without a strong evidence base.

Response: We understand the significance of this aspect of the proposal, as well as the statements made by the commenters both for and against the requirement of an AUC floor, or the minimum AUC that must be available in a qualified CDSM, related to priority clinical areas. We reiterate that, in alignment with statute, ordering professionals must consult for each advanced diagnostic imaging service ordered. Therefore, we believe many professionals will choose a qualified CDSM that best fits their ordering patterns and clinical practice. Those ordering a wide array of imaging services or perhaps infrequently ordering imaging services across a broad clinical spectrum will align themselves with a mechanism that fits their needs and contains comprehensive specified applicable AUC in order to lessen the chances that they find no applicable AUC when they attempt to consult for a specific service.

Specialists may seek to align themselves with a qualified CDSM that contains AUC more exhaustive in one area of medicine to reflect the imaging services that they order most often.

We continue to believe that all tools should contain the specified applicable AUC needed by the ordering professionals they serve, as well as contain specified applicable AUC related to the priority clinical areas, to ensure that when an ordering professional needs to consult AUC for an imaging service, they will not have to go outside their regular qualified CDSM for the consultation. We reiterate that we envision choices for qualified CDSMs that allow efficient access by ordering professionals to one or more specialty-focused specified applicable AUC sets along with more comprehensive specified applicable AUC sets. We believe the determination of which AUC sets are made accessible through a given CDSM should be demand-driven by ordering professionals, who would be choosing from a marketplace of options for both CDSMs and AUC, all of which meet basic CMS qualifications to ensure implementation of the statutory requirements established under section 218(b) of the PAMA.

To balance the requirement for the minimum floor, we believe it is important to reconsider the extent to which specified applicable AUC encompass the entire clinical scope of priority clinical areas. We agree that requiring the entire clinical scope may not yield consultation of the highest quality specified applicable AUC and that ordering professionals, particularly specialists, may not have a need for specified applicable AUC addressing the entire clinical scope of a priority clinical area. We do not expect this requirement to be met by AUC that address only a narrow clinical aspect of a priority clinical area. We believe addressing less than the entire clinical scope should still result in AUC that robustly fill priority clinical areas. To avoid forcing the development of AUC based on poor evidence just for the sake of having AUC we modified this language and expect it will enable qualified PLEs to confidently develop AUC that represent a high level of evidence. Therefore, we agree with commenters' suggestions that we keep the AUC floor but allow the requirement to be fulfilled if specified applicable AUC address less than the entire scope of the priority clinical areas and instead reasonably address the common and important clinical scenarios within each priority clinical area. We have included this modified language in § 414.94(g)(1)(iii) and § 414.94(g)(1)(vii)(C).

Comment: We also received comments both for and against the proposed requirement that qualified CDSMs have the ability to incorporate specified applicable AUC from more than one qualified PLE. Some commenters agreed with the proposal while others suggested a more stringent requirement that the relationship between the CDSM and at least two PLEs already be established and formalized prior to qualifying a CDSM. Other commenters were against making this capability a requirement. They stated that CDSMs should have the flexibility to establish as many or as few relationships with PLEs as needed.

Response: We are concerned that removing the requirement for qualified CDSMs to have the ability to incorporate specified applicable AUC from more than one qualified PLE would not be in alignment with our intention to incorporate specified applicable AUC that reasonably address the common and important clinical scenarios within each priority clinical area. This is important since many qualified CDSMs will need to work with more than one qualified PLE to accomplish such a requirement and also to align with CMS' goal to maintain flexibility of qualified CDSMs to incorporate the best available AUC. We believe, for now, it is appropriate to keep this requirement as a capability as opposed to requiring that qualified CDSMs demonstrate or share with CMS that such contracts are in place.

In future years, as greater consensus emerges around common standards for interfacing with, uploading or otherwise referencing content that is not already in the system being used, we expect incorporation of AUC from a wide range of sources to become easier. We encourage systems to build standards-based mechanisms to incorporate external AUC and anticipate that such an approach would facilitate meeting this requirement.

Comment: Commenters were pleased with the requirement that the CDSM make available related documentation to specified applicable AUC supporting the appropriateness of the imaging service ordered, and indicated that having access to citations and evidence summaries would be helpful.

Response: We agree with commenters and have revised this requirement at § 414.94(g)(1)(i) to increase clarity and confirm commenters' expressed understanding that qualified CDSMs must make available specified applicable AUC and its related supporting documentation.

Comment: We received comments in favor of requiring the CDSM to identify which appropriate use criterion is being consulted in the event the mechanism includes AUC from more than one qualified PLE. Additionally, we received comments regarding who

makes the determination of which AUC within the mechanism is to be consulted. Some commenters wanted more freedom for the ordering professional to choose at the time of the consultation which AUC should be consulted in the event that there is more than one. Other commenters were in favor of more consistency and not allowing consultation of different AUC for the same clinical scenario.

Response: We agree with commenters that the capability to choose is critically important when more than one qualified PLE's AUC are made available within the qualified CDSM. However, we do not believe we should be involved in determining whether the qualified CDSM chooses which specified applicable AUC to display upon consultation or whether the ordering practitioner should have the ability to select the specified applicable AUC to consult.

Comment: Some commenters were concerned that the qualified CDSM should not be required to produce documentation when the result of a consultation is ''not applicable.'' In other words, the CDSM should not make the determination as to whether AUC available in the mechanism are relevant to the clinical scenario encountered by the ordering professional. Some suggested that the ordering professional should have the ability to notate that the result of a consultation with a CDSM was ''not applicable'' and that the programing required for a mechanism to accurately determine ''not applicable'' could be extremely difficult and possibly inaccurate. In contrast, other commenters believed this ability to produce a ''not applicable'' response was very important and suggested that such information should be provided back to the qualified PLE to encourage future development of AUC to address that clinical scenario. Other commenters questioned how this type of response from the CDSM would be implemented in a clinical workflow where the CDSM is embedded within the EHR system. In those situations, they believed it was unnecessary to interrupt the workflow of the ordering practitioner only to alert them that there are no AUC available.

Response: Due to the statutory requirement that AUC consultation occur with each advanced diagnostic imaging service ordered, we agree with commenters that it is important for the qualified CDSM to have the ability to return a ''not applicable'' result. This requirement will apply to document consistently that a consultation occurred and that no applicable AUC were found. Exactly how this ''not applicable'' response is formulated, we believe, can be somewhat flexible. ''Not applicable'' status could occur either when the AUC scope does not match the patient or their presentation or when no guideline exists that is appropriate to the patient or their presentation. If this situation is the case, it should be documented in the clinical or metadata around the particular application or attempted application of AUC.

For example, if the system only contains AUC for ''uncomplicated headache'' but the patient has presented with ''headache, fever, and altered mental status'' the practitioner could make the determination that no applicable AUC exists for the patient under consideration and document this using a text box, check box, or drop-down menu. The documentation that the search did not match the existing AUC and that the practitioner agreed that the existing AUC was not applicable should be retained. Furthermore, manual intervention by the practitioner might not be required in all cases in which the use of AUC is not applicable. We expect that there would be a legitimate clinical reason for declaring a relevant AUC ''not applicable'' to the patient and that this reason would be documented. Likewise, we expect that when no applicable AUC exists relevant to the patient that would be similarly documented. CDSMs should not be designed to permit the use of ''not applicable'' overrides without a documented reason. Ideally, systems would evaluate scenarios in which AUC were not available on a regular basis so qualified PLEs can seek to fill in these gaps. We agree with commenters who believe the ''not applicable'' response should be able to occur in the background of some qualified CDSMs, such as a qualified CDSM integrated within an EHR system. We do not foresee any problems with this method so long as documentation is produced as a result and the needed information is available to be provided by the ordering professional to the furnishing professional.

To allow flexibility for situations in which the ordering professional plays a role in the determination of ''not applicable,'' as well as those in which such determination is completely automated within the CDSM, we have revised our proposals in § 414.94(g)(1)(v) to require qualified CDSMs only to determine the extent to which the applicable imaging service is consistent with specified applicable AUC with the removal of language requiring the tool to make a determination of ''not applicable'' when it does not contain a criterion that would apply to the consultation.

We have also revised our proposals in § 414.94(g)(1)(vi) to allow for qualified CDSMs that are embedded seamlessly into the EHR system to provide documentation or certification of CDSM consultation without stopping the workflow of the ordering professional. This minor change in language requires the qualified CDSM to develop the documentation or certification at the time of the order but will no longer explicitly state that it has to be provided directly to the ordering professional.

For consistency, we have made a similar change to § 414.94(g)(1)(vi)(A) to allow for the documentation or certification to be generated but not necessarily issued directly to the ordering professional. This may be important to avoid workflow disruptions when an ordering professional is working within their EHR environment and the qualified CDSM working in the background does not alert the ordering professional when they have placed an order that is appropriate.

We have further modified § 414.94(g)(1)(vi) to more clearly state the requirements that the certification or documentation must document which CDSM was consulted; the name and NPI of the ordering professional that consulted the CDSM; whether the service ordered would adhere to specified applicable AUC or whether the specified applicable AUC consulted was not applicable to the service ordered.

Comment: Commenters generally favored requiring qualified CDSMs to issue unique consultation identifiers, with a few commenters opposed to the requirement until there is more interoperability. Some of the commenters in favor of the requirements suggested that CMS should establish a standard taxonomy so the identifier issued would be truly unique and not risk duplication across CDSMs. A subgroup of these commenters favored this approach to allow for CMS to match Medicare claims for advanced imaging services with their CDSM consultations.

Response: Although we agree that establishing a unique consultation identifier with standard taxonomy could facilitate adding more robust data to what is available on the Medicare claim, we do not have the repository and format for the identifiers that would be needed. We would further need to establish how the identifier could be meaningfully appended to the Medicare claim form. As such, it is not feasible at this time for CMS to require qualified CDSMs to create such a narrowly defined identifier. We are looking into options to determine possible future

roles for that identifier. In the interim, we believe the requirement should remain a functionality of qualified CDSMs. Furthermore, we are not yet certain which standard taxonomy is best suited to the needs of this program. We do, however, encourage stakeholders to work together and welcome qualified CDSMs to determine amongst themselves if they should begin issuing identifiers with an embedded taxonomy. It would seem as though this could be valuable in the future; having one number that provides information related to an individual CDSM consultation.

Comment: We received several comments regarding how frequently a qualified CDSM should be required to update AUC content. Some commenters stated that 12 months to update content was too long and we received the suggestion of 3 months while others were comfortable beginning with 12 months, but once the program is more established the time should be reduced. Other commenters suggested that adherence to the timing requirement is based primarily on the PLE and how quickly after updating AUC the PLE provides that updated content to the CDSM. Commenters also noted that the time it takes to update a CDSM is based on the format of the content delivered by qualified PLEs as some CDSMs will still have much work to do to translate the qualified PLE provided content for use in the CDSM.

Response: We thank commenters for pointing out that our 12-month requirement for qualified CDSMs to update AUC content was unclear with regard to when that 12-month period would begin. We agree that the time should begin when the qualified PLE provides updated specified applicable AUC content to the qualified CDSM and have modified language in § 414.94(g)(1)(vii). Such updates would only take place if there are new or updated AUC content. We understand commenters who believe a 12-month period is too long to update specified AUC and wish to clarify that the time begins when the specified applicable AUC content is updated. We had initially selected 12 months in an attempt to allow CDSMs to batch updates and integrate them into the CDSM. We will consider shortening this time period as the program continues and as CDSMs gain more experience. We note that this 12-month requirement for updating AUC is separate from the requirement that qualified PLEs review AUC at least every 12 months to confirm that the AUC reflect the latest clinical evidence.

Comment: Some commenters stated that having a protocol in place to expeditiously remove dangerous or harmful AUC is not enough and that this could be accomplished very quickly, even in a matter of a day.

Response: We agree that removing potentially harmful AUC is extremely important. At this time, we do not believe we have enough information about the types of CDSMs that will seek qualification to know their abilities to react quickly in these situations. Again, we believe expeditious removal is critical but we are not able to select a specific period of time at this point because there may be large differences in capabilities when removing AUC within one day, one week, or one month. We expect that CDSMs will remove potentially harmful AUC as expeditiously as possible, and will consider this issue for future rulemaking. Additionally, CDSMs may have differing components within their protocol to expeditiously remove potentially dangerous or harmful AUC which could include more timely communications with users regarding the removal through, for example, banner notices or push notifications.

Comment: Commenters proposed that CDSMs should contain AUC that address the priority clinical areas at the time they are qualified by CMS as opposed to allowing 12 months for CDSMs to make them available.

Response: We disagree with this comment and believe that, given the timing of the CY 2017 PFS final rule when the first priority clinical areas will be finalized, it is appropriate to allow for 12 months from the date of the final rule publication for qualified CDSMs to make available specified applicable AUC to address the priority clinical areas. There would otherwise not be enough time for qualified CDSMs to identify the needed specified applicable AUC and make them available within their mechanisms by March 1, 2017—the deadline for the first round of CDSM applications seeking CMS qualification.

Comment: We received comments requesting additional clarification regarding the privacy and security standards that CDSMs must meet with some commenters suggesting that CMS provide additional guidance through subregulatory vehicles.

Response: We are not the appropriate regulatory authority to specify privacy and security standards. However, there is existing guidance that we believe is instructive. For those CDSMs contained within certified EHR technology, or for which certification is sought for purposes of achieving ''meaningful use'', ONC provided the applicable privacy and security framework in its 2015 Edition Final Rule Health IT Certification. See the 2015 Edition Final Rule (80 FR 62705, October 16, 2015) describing the privacy and security certification framework and specifying standards. In addition, the privacy and security standards set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules and enforced by the Office for Civil Rights (OCR) are potentially applicable. CDSMs would also be subject to applicable state laws and regulations regarding privacy and security.

We are finalizing our proposals without change, but will continue to consult with other agencies and consider whether such standards may be specified in the future.

We are finalizing our proposals without change, but will continue to consult with other agencies and consider whether such standards may be specified in the future.

Comment: Commenters favored the requirement for CDSMs to provide aggregate feedback to ordering professionals. Some commenters suggested that CMS be prescriptive regarding the format and content of the reports providing feedback.

Response: We do not agree that we should establish standards in feedback reporting to ordering professionals at this time. We encourage qualified CDSMs and ordering professionals to work together to determine the information that would be most valuable.

Comment: We received several comments regarding the proposed requirement to electronically store CDSM consultation data for a minimum of 6 years. Some commenters stated that 6 years is an appropriate amount of time to store this information while others disagreed, stating that 6 years is overly burdensome. Some commenters are seeking greater detail surrounding exactly what data is required to be stored while others state that consultation information should be backed up by a third party or registry. These commenters were particularly concerned that data would be lost if a CDSM ceased operation.

Response: Generally, we agree that CDSM consultation data should be backed up to ensure that the data is not lost; however, we do not agree that we should be prescriptive at this time about how qualified CDSMs must go about ensuring their data is stored and available for 6 years. We believe 6 years is an appropriate amount of time across which ordering professionals will want to assess their ordering patterns. In

addition, as we discussed earlier our intent to require a unique consultation identifier, we believe there is the potential for consultation to be very valuable from a QI perspective if aggregated across qualified CDSMs, and provided to qualified PLEs and possibly to CMS. Regarding the data elements that must be stored, we have not required that qualified CDSMs collect specific data fields. Therefore, at this time, we only have a more general requirement that includes the storage of clinical, administrative and demographic information for each consultation.

Comment: A commenter suggested that qualified CDSMs ensure that ordering professionals have the opportunity to access content for educational purposes. This would allow ordering professionals to review information contained within the CDSM without having to link that consultation with an order for advanced imaging services.

Response: We agree that ordering professionals would benefit from being able to use qualified CDSMs to further their knowledge about the appropriateness of advanced imaging services.

In response to public comments, we are finalizing the following requirements at § 414.94(g)(1):

- Make available specified applicable AUC and its related supporting documentation.
- Identify the appropriate use criterion consulted if the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario.
- Make available, at a minimum, specified applicable AUC that reasonably address common and important clinical scenarios within all priority clinical areas identified in paragraph (e)(5) of this section.
- Be able to incorporate specified applicable AUC from more than one qualified PLE.
- Determine, for each consultation, the extent to which the applicable imaging service is consistent with specified applicable AUC.
- Generate and provide a certification or documentation at the time of order that documents which qualified CDSM was consulted; the name and national provider identifier (NPI) of the ordering professional that consulted the CDSM; whether the service ordered would adhere to specified applicable AUC; whether the service ordered would not adhere to specified applicable AUC; or whether the specified applicable AUC consulted was not applicable to the service ordered. Certification or documentation must be generated each time an ordering professional consults a qualified CDSM and include a unique consultation identifier generated by the CDSM.
- Modifications to AUC within the CDSM must comply with the following timeline requirements: make available updated AUC content within 12 months from the date the qualified PLE updates AUC; and have a protocol in place to expeditiously remove AUC determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed; and make available for consultation within 12 months of a priority clinical area being finalized by CMS specified applicable AUC that reasonably address common and important clinical scenarios within any new priority clinical area.
- Meet privacy and security standards under applicable provisions of law.
- Provide to the ordering professional aggregate feedback regarding their consultations with specified applicable AUC in the form of an electronic report on at least an annual basis.
- Maintain electronic storage of clinical, administrative, and demographic information of each unique consultation for a minimum of 6 years.
- Comply with modification(s) to any requirements under paragraph (g)(1) of this section made through rulemaking within 12 months of the effective date of the modification.
- Notify ordering professionals upon de-qualification.

d. Process for CDSMs To Become Qualified and Determination of Non-Adherence

We proposed that CDSMs must apply to CMS to be specified as a qualified CDSM. We proposed that CDSM developers who believe their mechanisms meet the regulatory requirements must submit an application to us that documents adherence to each of the requirements to be a qualified CDSM.

We proposed to require in § 414.94(g)(2) that CDSM developers must submit applications to CMS for review that document adherence to each of the CDSM requirements. Applications to be specified as a qualified CDSM must be submitted by January 1 of a year to be reviewed within that year's review cycle. For example, as proposed the first applications would be accepted from the date of publication of the PFS final rule until January 1, 2017. A determination on whether the applicants are qualified would be made by June 30, 2017. Applications must be submitted electronically to *ImagingAUC@cms.hhs.gov*. This process and timeline mirror the qualified PLE application and approval process and timeline. As we did for qualified PLEs, we will post a list of all applicants that we determine to be qualified CDSMs to our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html* by June 30. We proposed that all qualified CDSMs must reapply every 5 years and their applications must be received by January 1 during the 5th year that they are qualified CDSMs. It is important to note that, as with PLE applications, the application for qualified CDSMs is not a CMS form; rather it is created by the applicant. A CDSM that is specified as qualified for the first 5-year cycle beginning on July 1, 2017, would be required to submit an application for requalification by January 1, 2022. A determination would be made by June 30, 2022, and, if approved, the second 5-year cycle would begin on July 1, 2022.

An example of our proposed timeline for applications and the approval cycle is as follows:

- Year 1 = July 2017 to June 2018.
- Year 2 = July 2018 to June 2019.
- Year 3 = July 2019 to June 2020.
- Year 4 = July 2020 to June 2021.
- Year 5 = July 2021 to June 2022 (reapplication is due by January 1, 2022).

We believe it is important for us to have the ability to remove from the list of specified qualified CDSMs a CDSM that we determine fails to adhere to any of the qualification requirements, including removal outside of the proposed 5-year cycle. We proposed to state under § 414.94(h) that, at any time, we may remove from the list of qualified CDSMs a CDSM that fails to meet the criteria to be a qualified CDSM or consider this information during the requalification process. Such determinations may be based on public comment or our own review and we may consult with the National Coordinator for Health Information Technology or her designee to assess whether a qualified CDSM continues to adhere to requirements.

We invited comments on how we could streamline and strengthen the approval process for CDSMs in future program years. For instance, CMS may consider a testing framework for CDSMs that would validate adherence to specific standards that enable seamless incorporation of AUC across CDSMs.

The following is a summary of the comments we received on the process for CDSMs to become qualified and determination of non-adherence.

Comment: Some commenters requested that CMS review and approve qualified CDSMs more quickly. Some commenters suggested the list of qualified CDSMs be available by April 1, 2017, rather than June 30, 2017, so as to allow ordering professionals more time to prepare for implementation of consulting and reporting requirements on January 1, 2018. A commenter also suggested approval of certain types of systems, such as those intended specifically for use in the emergency department, be prioritized.

Response: We recognize and appreciate the desire to more quickly specify the first list of qualified CDSMs. However, given the detailed review that will be dedicated to each application along with agency internal processes, qualification of CDSMs before June 30, 2017 is not feasible. As with qualified PLE applications, which will be under review at the same time, we intend to treat each applicant with the same level of detail and attention and will not prioritize some over others.

Comment: Some commenters cited insufficient time for CDSMs to incorporate requirements between the release of the final CDSM requirements, on or around November 1, 2016, and the January 1, 2017 due date for qualified CDSM applications. These commenters requested that CMS delay the deadline and accept applications later into the year for this first round of applicants. Due to the limited time between finalization of CDSM requirements and the application deadline, another commenter recommended that CDSMs be qualified based on their commitment to support required functionality, rather than an attestation that the existing functionality is fully implemented in a CDSM.

Response: We recognize the challenge CDSM developers may have submitting applications by January 1, 2017, and have extended the deadline only for the first round of applications to March 1, 2017. To this end, CDSMs will become qualified if they provide evidence that supports that they meet all CDSM requirements at the time of application.

We further agree with commenters that qualification should be available to CDSMs that demonstrate a commitment to meeting the requirements. CDSM applicants whose applications are received by March 1, 2017 but who are not able to provide evidence that all requirements are met at the time of application will have the opportunity to receive preliminary qualification. Applicants eligible for a preliminary qualification must demonstrate a commitment to meeting the requirements by including expected dates by which each requirement is expected to be met and information documenting how they intend to meet them. Applicants that meet most but not all of the requirements at the time of application will be considered only for preliminary qualification.

CDSMs that receive preliminary qualification must achieve full qualification before the implementation of the consultation and reporting requirements. As CDSMs move from preliminary qualification to full qualification upon meeting the requirements, CMS will update the information on the AUC Web site. For those who are not able to achieve full qualification by the time of program implementation, preliminary qualification will terminate and they will be eligible to reapply in the next annual application cycle. For CDSMs that received preliminary qualification and are later converted to full qualification status, their preliminary period will be included as part of their 5-year approval period.

We encourage CDSMs to strive to meet all requirements by the March 1, 2017 application submission deadline, or as soon thereafter as possible, in order to receive full qualification status. We believe this policy strikes a balance between providing sufficient time for CDSMs to prepare for full implementation, while also providing ordering professionals information on CDSMs' qualification status to assist them in making procurement decisions.

Comment: Commenters recommended that CMS require CDSMs to have already demonstrated successful implementation of the mechanism and have established relationships in place with multiple PLEs whose AUC already populate the mechanism.

Response: We are finalizing section 414.94(g)(2) to state that CDSM developers must submit applications that document adherence to each CDSM requirement in § 414.94(g)(1). As such, we expect to receive applications from CDSMs that have already established these requirements and have experience with adhering to them. We believe that the final requirements largely address the above comment; however, we require that qualified CDSMs be able to incorporate specified applicable AUC from more than one qualified PLE. Therefore, we do not interpret this to require that qualified CDSMs must actually incorporate AUC from more than one qualified PLE in order to become qualified, provided concurrent requirements are also met.

Comment: A commenter suggested CMS use the qualification process to ensure AUC specific to the needs of the elderly are incorporated into qualified CDSMs. This commenter further recommended CMS engage stakeholders with expertise in geriatrics when selecting AUC and CDSMs.

Response: We are confident that qualified PLEs include relevant AUC within their libraries for the Medicare population and are supportive of multidisciplinary teams composed of members with expertise even beyond those required in § 414.94(c)(1)(ii). As indicated in the CY 2016 PFS final rule with comment period (81 FR 71106), we encourage teams to be larger and include other stakeholders.

Comment: Some commenters requested that CMS make all CDSM applications public. Commenters also suggested that CMS interact with applicants to communicate any questions or issues with the application prior to making a qualification determination.

Response: We appreciate the interest and contributions of all stakeholders as we implement this program and understand the desire to learn more about CDSM applicants; however, we will not systematically release this information. To encourage stakeholder interactions and to assist those seeking more information about qualified CDSMs, we intend to post basic information about each qualified CDSM on the AUC Web site once the list is finalized. This should enable stakeholders to research and reach out directly to qualified CDSMs to learn more about the mechanism in support of making well informed choices moving forward. During the review process, we intend to engage in the same type of dialogue with CDSM applicants as we have with PLE applicants. During the review of the first set of PLE applications, we held at least one conference call with each applicant, often held additional calls; and we also exchanged numerous emails to ensure questions and concerns from both parties involved, CMS and the applicant, were addressed, discussed and resolved as thoroughly as possible. We fully intend to engage in the same open and transparent process for CDSM applicants as well. We remind CDSM applicants that they may mark their applications as containing proprietary business information and we will protect that information to the full extent permitted by law.

Comment: Some commenters expressed concerns regarding CDSMs that either fail to requalify after the first 5-year qualification period or are found to no longer be adherent to CDSM requirements during the 5-year qualification period. A commenter

recommended that CDSMs be temporarily suspended before being disqualified. Other commenters recommended that CMS ensure ordering professionals using these mechanisms not be penalized while they seek a new mechanism for consultation. One commenter stated that the CDSM be required to notify ordering professionals of such a disqualification. Other commenters requested that qualification of CDSMs not be disrupted due to standard technical updates to CDSMs made during the 5-year qualification period.

Response: We agree that CDSM qualification should not be disrupted due to a standard update assuming no changes are made to functionality that result in non-adherence to the CDSM requirements in § 414.94(g)(1). We agree that qualified CDSMs should be required to notify ordering professionals in the event of disqualification and have added this requirement under § 414.94(g)(1)(xii).

Comment: Some commenters requested that CMS extend the amount of time qualified CDSMs are qualified to allow for more time to prepare for requalification. Other commenters recommended that CMS shorten the qualification period to better align with the pace of change to EHR security and interoperability standards with those of CDSMs.

Response: We believe that a 5-year qualification period for qualified CDSMs is an appropriate timeframe at this time. As the AUC program evolves, we could revisit this requirement through future rulemaking should we find that a modification is warranted.

Comment: Some commenters suggested and supported CMS developing a testing framework for CDSMs, focusing especially on interoperability, and/or convene stakeholders for the purpose of creating such a framework.

Response: We will continue to explore opportunities to develop a testing framework for qualified CDSMs with ONC and other standards groups.

Comment: Several commenters requested that CMS provide details on the free CDSM tool required under section 218(b) of the PAMA. Another commenter stated that all qualified CDSMs should have a free version available.

Response: As stated in the CY 2017 PFS proposed rule, the Secretary did not propose to establish any free CDSM at this time. Therefore, a free CDSM would need to apply for qualification just as any other CDSM. We disagree that all qualified CDSMs must have a free version available as section 1834(q)(1)(C) of the Act defines the applicable imaging services for which AUC consultation is required as those for which there is at least one free mechanism available for AUC consultation. There is not a requirement that every mechanism have a version available for free.

In response to the comments, we have added language to § 414.94(g)(2)(ii) delineating the process and requirements to include preliminary qualification. The first application cycle following the publication of this CY 2017 PFS final rule will be extended to March 1, 2017 for all CDSM applicants. As opposed to full qualification by which CDSMs have documented how all requirements are met at the time of application, preliminary qualification allows CDSMs to document, if not already met, how and when such requirements are reasonably expected to be met. The preliminary qualification period ends when we implement the consulting and reporting requirements under this program as specified in § 414.94(g)(2)(ii)(B). We have also added § 414.94(g)(1)(xii) to require qualified CDSMs to notify ordering professionals upon de-qualification.

e. Consultation by Ordering Professional and Reporting by Furnishing Professional

Although we continue to aggressively move forward to implement this AUC program, ordering professionals will not be expected to consult AUC using qualified CDSMs by January 1, 2017. At the earliest, the first qualified CDSM(s) will be specified on June 30, 2017. We anticipate that some ordering professionals could be able to begin consulting AUC through qualified CDSMs very quickly as some may already be aligned with a qualified CDSM.

We expect that furnishing professionals will be required to begin reporting January 1, 2018. This timeframe 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. While there will be further rulemaking next year, we are announcing this date because the agency expects physicians and other stakeholders/regulated parties to begin preparing themselves to begin reporting on that date. We will adopt procedures for capturing this information on claims forms and the timing of the reporting requirement through PFS rulemaking for CY 2018.

As we expect to implement the AUC consultation and reporting requirements under section 1834(q)(4)(A) and (B) of the Act on January 1, 2018, we requested feedback from the public to include a discussion of specific operational considerations that we should take into account and include in such rulemaking. For example, we noted that commenters could consider alternatives for reporting data on claims and for seeking exceptions, as discussed below. We also requested information on the barriers to implementation along this timeline that allows ordering and furnishing professionals to be prepared to consult AUC and report consultation information on the claims and whether separate rulemaking outside of the payment rule cycle would be preferred.

Under section 1834(q)(4)(B) of the Act, Medicare claims for applicable imaging services furnished in applicable settings can only be paid under the applicable payment systems if certain information is included on the claim including: which qualified CDSM was consulted by the ordering professional for the service; whether the service, based on the CDSM consultation, adheres to specified applicable AUC, does not adhere to specified applicable AUC or whether no criteria in the CDSM were applicable to the patient's clinical scenario; and, the national provider identifier (NPI) of the ordering professional. This section further allows payment for these services only if the claim contains such information beginning January 1, 2017. To develop and operationalize a meaningful solution to collecting new AUC consultation-related information on the claims, we must diligently evaluate our options taking into account the vast number of claims impacted and the limitations of the legacy claims processing system. Additionally, in the case of advanced imaging services, related claims are already required to append certain HCPCS modifiers and G codes for purposes of proper payments. In the recent implementation of section 218(a) of the PAMA, we established a HCPCS modifier for CT services rendered on machines that do not meet an equipment standard. It is important that we understand and evaluate how the additional requirements for AUC reporting would impact the information that is already required for advanced imaging services. Moving too quickly to satisfy the reporting requirement could inadvertently result in technical and operational problems that could cause delays in payments.

Section 1834(q)(4)(C) of the Act includes exceptions that allow claims to be paid even though they do not include the information about AUC consultation by the ordering 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 are considering the mechanisms for appending the AUC consultation information to various types of Medicare claims and expect to develop requirements for appending such information in the CY 2018 PFS rulemaking process. We encouraged stakeholders interested in sharing feedback related to reporting and claims processing to do so as part of the comment period to inform this final rule. We were particularly interested in receiving feedback on, for example, whether the information should be collected using HCPCS level II G codes or HCPCS modifiers.

The following is summary of the comments we received on consultation by ordering professionals and reporting by furnishing professionals.

Comment: In response to our request for information about how to reflect AUC consultation on the Medicare claim form, we received extensive feedback. In particular, we requested feedback on using HCPCS modifiers or HCPCS Level II G codes to identify the required information about the consultation on the Medicare claim form. Some commenters recognized that these options for reporting were feasible and could capture all information needed for the claim. Some commenters noted that the number of modifiers possible on a claim form was limited and questioned whether all information required for reporting could be captured by modifies. Some commenters noted that it would be difficult for G codes to include all required information for reporting which would necessitate multiple G codes and result in greater administrative burden for reporting.

Some commenters noted that modifiers and G codes were not ideal solutions and provided alternate suggestions. Several commenters addressed use of the UB04/837i for reporting. Some noted that such proposals would not work when more than one test is performed on the same date of service because the form does not allow reporting by line item. Others noted that the UB04/837i form would allow providers to report individual line item services, but limited space on the form prevents specific line items from being linked to other information like an ordering professional, diagnosis code or authorization code to each item.

Many commenters recommended the use of a specific code issued by the CDSM that would include alphanumeric characters to represent each of the required elements for reporting. Commenters suggested that this code could be placed in field 23 (prior authorization field) of the 837P claim form. Another commenter recommended placing a unique identifier in field 19 of the 1500 form. Two other suggestions included placing the unique identifier on both the professional component and technical component (or OPPS) claims, identifying field 63 on the 837i form, or submitting a ''dummy'' claim with the unique identifier to accompany all claims for applicable imaging services furnished.

A commenter suggested that the reporting requirement should apply to providers who submit claims on a 155/837P because line item reporting is available. We also received a comment suggesting CMS could work with X12 to add the data to the claim more quickly through the K3 segment of the electronic claim, which is reserved for new data required under legislation and regulation. A commenter suggested that the reporting requirements use a framework allowing for regular feedback to ordering professionals regarding their ordering patterns. Another commenter suggested a simple attestation that such information would be available to CMS upon request. A commenter recommended that codes be modified to reflect additional costs of CDSM services.

Response: We appreciate the extensive and thoughtful information provided in response to our request. These comments will be instrumental in our development of claims reporting requirements.

Comment: Many commenters requested the release of claims reporting information as quickly as possible and before rulemaking in CY 2017. Multiple commenters insisted that reporting requirements be provided before CDSMs apply for qualification as they need this information to design their mechanisms and comply with the program requirements. Some commenters requested responses to questions about precisely which codes will be required and their specific location on the claim form.

Response: Although we have been actively working with components throughout the agency to develop and establish claims processing instructions and reporting details for the AUC program, given the complexities of the Medicare legacy claims processing systems and the extensive interactions necessary to properly develop and implement these requirements, we intend to include them in rulemaking for the CY 2018 PFS and not earlier through subregulatory processes or alternate rulemaking cycles. While we appreciate that CDSMs could benefit from having information on claims reporting requirements, we note that the information to be submitted on the claim is identified in section 1834(q)(4)(B) of the Act and CDSMs may begin preparing themselves for reporting the following items: (1) Which qualified CDSM was consulted by the ordering professional for the service; (2) whether the service, based on the CDSM consultation, adheres to specified applicable AUC, does not adhere to specified applicable AUC or whether no criteria in the CDSM were applicable to the patient's clinical scenario; and (3) the NPI of the ordering professional. We remind CDSMs that § 414.94(g)(1)(vi) requires qualified CDSMs to generate and provide a certification or documentation at the time of order that documents which CDSM was consulted; the name and NPI of the ordering professional that consulted the CDSM; whether the service ordered would adhere to specified applicable AUC or whether the specified applicable AUC consulted was not applicable to the service ordered. The information qualified CDSMs must document encompasses information required for claims reporting under section 1834(q)(4)(B) of the Act.

Comment: Some commenters requested that CMS rigorously test the claims reporting requirements or facilitate a workgroup to engage in this testing before reporting requirements are established and effective. One commenter recommended that CMS have a way to account for orders that may appear to be appropriate based on AUC consultation but are actually duplicative and redundant.

Response: Thank you for this suggestion.

Comment: A commenter requested that CMS develop an appeals process, and share that information in a timely manner.

Response: Appeal rights will continue to apply to claims after implementation of this program. Changes to the appeals process are outside the scope of this rule.

Comment: Some stakeholders have requested CMS provide opportunities to involve and accept feedback from all stakeholders in the development of the claims reporting requirements. One commenter recommended that CMS create an agency-wide task force to work with claims standards organizations to address all demands that will be placed on the claim form due to AUC reporting.

Response: We appreciate the interest by stakeholders in contributing to the development of these requirements. We are happy to receive correspondence and feedback at any time through the AUC program email box *ImagingAUC@cms.hhs.gov*, and we encourage stakeholders to provide information to us as early as possible to help inform our proposals for requiring claims reporting starting January 1, 2018. We will continue to work with stakeholders as we develop reporting requirements.

We appreciate all information shared by commenters. We will use this feedback to inform CY 2018 rulemaking where we expect to establish the requirements for reporting under the AUC program.

f. Exceptions to Consulting and Reporting Requirements

Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements under section 1834(q)(4)(B) of the Act. First, the statute provides for an exception under section 1834(q)(4)(C)(i) of the Act where an applicable imaging service is ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. We believe this exception is warranted because there can be situations in which a delay in action would jeopardize the health or safety of individuals. Though we believe they occur primarily in the emergency department, these emergent situations could potentially arise in other settings. Furthermore, we recognize that most encounters in an emergency department are not for an emergency medical condition as defined in section 1867(e)(1) of the Act.

We proposed to provide for an exception to the AUC consultation and reporting requirements under § 414.94(i)(1) for an applicable imaging service ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. For example, if a patient, originally determined by the clinician to have an emergency medical condition prior to ordering an applicable imaging service, is later determined not to have had an emergency medical condition at that time, the relevant claims for applicable imaging services would still qualify for an exception. To meet the exception for an emergency medical condition as defined in section 1867(e)(1) of the Act, the clinician only needs to determine that the medical condition manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in: placing the health of the individual (or a woman's unborn child) in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Orders for advanced imaging services for beneficiaries with an emergency medical condition as defined under section 1867(e)(1) of the Act are excepted from the requirement to consult AUC. We intend through the CY 2018 PFS proposed rule to propose more details around how this exception will be identified on the Medicare claim.

The second exception is under section 1834(q)(4)(ii) of the Act for applicable imaging services ordered for an inpatient and for which payment is made under Medicare Part A. We proposed to codify this exception in new § 414.94(i)(2). While we are including this exception consistent with statute, we note that if payment is made under Medicare Part A, the service would not be paid under an applicable payment system, such that the AUC consultation and reporting requirements under § 414.94 would never apply.

The third exception is under section 1834(q)(4)(iii) of the Act for applicable imaging services ordered by an ordering professional who the Secretary determines, on a case-by-case basis and subject to annual renewal, that consultation with applicable AUC would result in a significant hardship, such as in the case of a professional practicing in a rural area without sufficient Internet access. We proposed to codify this exception in new § 414.94(i)(3) by specifying that ordering professionals who are granted a significant hardship exception for purposes of the Medicare EHR Incentive Program payment adjustment under § 495.102(d)(4)(i), (ii), or (iii)(A) or (B) of our regulations would also be granted a significant hardship exception for purposes of the AUC consultation requirement. We proposed, to the extent technically feasible, that the year for which the eligible professional is excepted from the EHR Incentive Program payment adjustment is the same year that the ordering professional is excepted from the requirement to consult AUC through a qualified CDSM. We proposed not to adopt the Meaningful Use significant hardship exception under § 495.102(d)(4)(iv)(C) as an exception for purposes of the AUC consultation requirement. Therefore, ordering professionals with a primary specialty of anesthesiology, radiology or pathology will not be categorically excepted from AUC consultation requirements.

We believe there is substantial overlap between the eligible professionals that would seek a hardship exception under the EHR Incentive Program and those ordering professionals that would seek a hardship exception under the AUC program and, as such, this proposal would be administratively efficient. Using an existing program is the most efficient and expeditious manner to implement the significant hardship exception under the Medicare AUC program. We also believe it is the only administratively feasible option for a national significant hardship identification process that can be implemented by January 1, 2018, though we intend to revisit this option for years after 2018 as the current EHR Incentive Program payment adjustment is set to expire after the 2018 payment adjustment year as the Merit-Based Incentive Payment System takes effect. In addition, below we discuss considerations for a supplemental process to account for hardships for ordering professionals that are not eligible to apply for a significant hardship under the EHR Incentive Program (for example, non-physician practitioners) and ordering professionals that incur a significant hardship outside of the EHR Incentive Program application deadline.

The criteria for significant hardships under the EHR Incentive Program relate to insufficient internet connectivity, extreme and uncontrollable circumstances that prevent the EP from becoming a meaningful EHR user, practicing for less than 2 years, practicing at multiple locations with the inability to control the availability of Certified EHR Technology, lack of face-to-face or telemedicine interaction with patients or a primary specialty designation of anesthesiology, radiology or pathology. We believe that most of these criteria would be relevant to demonstrate a significant hardship for ordering professionals to consult AUC. Regarding hardship exceptions for certain specialty designations, based on Medicare claims data for advanced imaging services from the first 6 months of 2014, approximately 1.2 percent of those claims were for advanced imaging services that had been ordered by a professional with one of the three

primary specialty designations. While their combined ordering volume is small, we do not believe that categorical exclusion of certain specialties of which the practitioner selected as their primary specialty designation for Medicare enrollment would necessarily be appropriate under the AUC program. Since eligible professionals in these three specialties are categorically excepted from the EHR Incentive Program payment adjustment, few of them would have applied for an exception on the other grounds. Therefore, we must consider another mechanism to evaluate whether ordering practitioners with these medical specialties experience a significant hardship for purposes of the AUC program.

We understand that there are differences between the purpose and timing of significant hardship exceptions for the EHR Incentive Program and the Medicare AUC program. Foremost, a significant hardship under the EHR Incentive Program is generally based on a hardship that occurred in a prior period, impacting meaningful EHR use that would affect payments in a subsequent calendar year. For example, a professional that submits an application in March 2017 and qualifies for the hardship exception under the EHR Incentive Program would be exempt from the EHR payment adjustment for calendar year 2018. Although significant hardship exceptions for the EHR payment adjustment year generally are based on the existence of a hardship in a prior period, we believe it would be appropriate for these professionals to also qualify for a significant hardship exception for purposes of the AUC consultation requirement during calendar year 2018. It is also our best, most efficient, administratively feasible means of determining significant hardships for ordering professionals for CY 2018.

We also recognize the possibility that an ordering professional could suffer a significant hardship during the AUC program year, and therefore, is immediately unable to consult AUC. In addition, while again we believe there is significant overlap, there may be circumstances where an ordering professional is not considered to be an eligible professional for purposes of the Medicare payment adjustmentsunder the EHR Incentive Program (for example, an ordering professional that is not a physician). We solicited feedback from commenters regarding processes that could be put in place to accommodate ordering professionals with primary specialties that categorically receive significant hardship exceptions under the EHR Incentive Program, real-time hardships that arise during a year, and ordering professionals that are not eligible to apply using the EHR Incentive Program significant hardship exception process and need to seek a significant hardship exception for the purposes of the AUC program. We believe this would involve only a small number of ordering professionals. To the extent technically feasible, some possibilities for implementing such hardship exceptions may include Medicare Administrative Contractors granting hardships on a case-by-case basis or establishing another mechanism to allow for self-attestation of a significant hardship for a defined period of time (for example, a calendar quarter or a calendar year). We intend to propose a process in the CY 2018 PFS proposed rule.

We invited the public to comment on our proposal for ordering professionals granted a hardship exception for the EHR Incentive Program for payment adjustment year 2018 to also be granted a hardship exception to the Medicare AUC program for those years. We proposed that the year the practitioner is excepted from the EHR Incentive Program payment adjustment is the same year that the practitioner would be excepted from consulting AUC.

The following is a summary of the comments we received on the proposed exceptions to consulting and reporting requirements:

Comment: Most commenters concurred that if an eligible professional is exempt from the EHR Incentive Program payment adjustment, then the ordering professional should also be exempt from AUC consultation for applicable imaging services. Commenters generally were concerned that CMS proposed a more limited set of hardship exceptions than what is currently available under the EHR Incentive Program. For example, we did not propose to allow certain medical specialty designations to be exempt from CDSM consultations even though they are automatically exempted from the EHR Incentive Program. One commenter observed that for the purposes of the AUC program only some EHR Incentive Program hardships may be applicable. One commenter suggested that the operation of this exceptions process be automatic for those already enrolled in the EHR Incentive Program hardship exception. Another commenter noted their observation that while making the EHR Incentive Program operational for the AUC program, it may not allow all ordering professionals (physicians and non-physician practitioners) with a significant hardship to seek such exceptions because the EHR Incentive Program is limited to physicians.

Response: We disagree with the commenters suggesting that we replicate under the AUC program all hardship exceptions under the EHR Incentive Program, including exceptions for three medical specialty designations. We do not believe our program is authorized to except ordering professionals based on their specialty. Therefore, we have decided at this time to proceed with finalizing the significant hardship exceptions under the AUC program as proposed. We remind all commenters that this proposal included a significant hardship exception for those ordering professionals that can demonstrate inability to control the availability of Certified EHR Technology.

We agree with the commenters that the agency need not create a separate process for granting a significant hardship exception where practitioner overlap is available but we understand that a separate process will need to be established to handle significant hardship requests from non-physician practitioners that order advanced imaging tests as they are not currently included in the EHR Incentive Program. However, we remind all commenters that we intend to revisit this option for years after 2018 as the current EHR Incentive Program payment adjustment is set to expire after the 2018 payment year as the Merit-Based Incentive Payment System takes effect.

Comment: A few commenters urged CMS to consider additional exceptions for ordering professionals that may encounter hardship in attempting to consult of specified applicable AUC for an applicable imaging service. The additional exceptions submitted by commenters included (1) ordering professionals who lack control over the availability of CEHRT for more than 50 percent of patient encounters, such as in the case of some hospital-based physicians; (2) any physician who does not have access to a low-cost integrated CDSM; (3) ordering professionals within a small practice or with a low-volume of advanced imaging services; (4) those who participate in either alternative payment models or accountable care organizations; (5) physicians who practice in a patient-centered medical home; (6) any professional using a qualified CDSM that is either disqualified or not re-qualified; (7) any group or institution in the process of implementing a new electronic medical record and billing system; (8) clinicians who receive a 0% weighting for the advancing care information performance

category under the MIPS; and (9) claims for patients in clinical trials.

Response: We appreciate the additional feedback received about additional categories of hardship that could be excepted from the consulting and reporting requirements. Although we did not propose additional hardship categories outside of the EHR Incentive Program in this year's rule, we will take these comments into account as we consider hardship exceptions in the CY 2018 PFS proposed rule.

Comment: Other commenters were not concerned with the determination of the hardship exceptions for ordering professionals, and instead raised concerns that a furnishing professional may not be able to accurately determine whether an ordering professional qualifies for a hardship exception. Another commenter proposed a potential solution to the other commenters' concerns and recommended to CMS that any ordering professional with a hardship exception should have a special NPI designation. Other commenters did not propose such mechanisms and encouraged CMS to address this concern in future rulemaking.

Response: We will work internally to consider this concern and may address it in future rulemaking.

Comment: Commenters generally supported exceptions to AUC consultation and reporting requirements for applicable imaging services ordered for an individual with an emergency medical condition; however, there was disagreement on how best to implement this exception. Commenters stated that ambiguity regarding whether an emergency medical condition is present could cause a delay in the delivery of emergency services to patients and requested clarification on the application of the AUC program in emergency departments and exceptions for certain emergency services. A few commenters offered an alternative exception from AUC consultation for all emergency departments. One commenter proposed a simple attestation process that does not further divert physician time away from patients. Some commenters expected that to operationalize this exception, any service with revenue codes in the range of 045X or 0516 or place of service code 23 would be exempt. Other commenters recognized and remarked to CMS that encounters that may occur outside the emergency department may also be ordered for an individual with an emergency medical condition. Another commenter explained that one problem with creating an exception for individuals with an emergency medical condition is that the ordering professional may not be in a position to make such a determination. As an alternative recommendation, one commenter suggested that a ''reasonable person'' should make the determination as to whether an emergency medical condition exists. The commenter states that the ''reasonable person'' standard is used by private health insurance coverage in emergency situations and would include scenarios when the patient himself has a reasonable belief that he has an emergency medical condition. A few commenters disagreed as to how many encounters in an emergency department are outside the definition of an emergency medical condition.

Response: We do agree that exceptions granted for an individual with an emergency medical condition include instances where an emergency medical condition is suspected, but not yet confirmed. This may include, for example, instances of severe pain or severe allergic reactions. In these instances, the exception is applicable even if it is determined later that the patient did not in fact have an emergency medical condition. We appreciate the offer from stakeholders to work with us to determine how best to capture this exception on claims. We do not have a reason at this time to believe that a categorical exception granted to emergency departments would foster inappropriate use of advanced imaging services. However, we believe such a categorical exception would not be consistent with the statutory requirement under section 1834(q)(4)(C)(i) of the Act, which is framed in terms of individual services.

In response to the comments, we have made no changes to the proposed exceptions and have finalized our proposals.

6. Summary

Section 1834(q) of the Act includes rapid timelines for establishing a Medicare AUC program for advanced diagnostic imaging services. The number of clinicians impacted by the scope of this program is massive as it will apply to every physician or other practitioner who orders or furnishes applicable imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite broad.

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 proposed to continue a stepwise approach, adopted through notice and comment rulemaking. We proposed this second component to the program to specify qualified CDSMs, identify the initial list of priority clinical areas, and establish requirements related to CDSMs, as well as consulting and reporting exceptions. However, we also recognize the importance of moving expeditiously to accomplish a fully implemented program. Under this proposal, the first list of qualified CDSMs will be posted no later than June 30, 2017, allowing ordering professionals to begin aligning themselves with a qualified CDSM. We expect that furnishing professionals will be required to begin reporting AUC information starting January 1, 2018, and will address this requirement through PFS rulemaking for CY 2018, including how to report that information on claims.

In summary, we proposed definitions of terms and processes necessary to implement the second component of the AUC program. We invited the public to submit comments on these proposals. We were particularly seeking comment on the proposed priority clinical areas and the requirements that must be met by CDSMs to become qualified. We believe the proposed requirements for qualified CDSMs will allow for flexibility so mechanisms can continue to reflect innovative concepts in decision support and develop customer-driven products to ultimately provide information to the ordering professional in such a manner that will maximize appropriate ordering of advanced diagnostic imaging while seamlessly integrating into workflow. As the stakeholders continue to move to a place of consensus-based standards deemed ready for deployment, we may become more prescriptive in future requirements for CDSMs. We also solicited comment on the exceptions to the requirements to consult applicable AUC using CDSMs.

The following is a summary of the other of the comments we received specific to the Medicare AUC program but not directly related to our proposals.

Comment: Overall, commenters expressed their general support for the use of AUC in diagnostic imaging.

Response: We appreciate the support and stakeholder involvement throughout the implementation process.

Comment: Most commenters supported our staged approach to implementing this program and most commenters supported the longer time period before requiring ordering

professionals to consult AUC in qualified CDSMs and furnishing professionals to report consultation information on claims. Many commenters requested additional time to comply with the consultation and reporting requirements under this program. Some recommended an additional 6-months until July 1, 2018, and others encouraged waiting until 2019 noting that providers will not have time to choose a CDSM once the qualified CDSM list is posted by June 30, 2017. Many commenters urged us to allow for 18 months between the release of the list of qualified CDSMs and the start of the reporting requirement. Commenters also supported additional time for implementation by stating that the program implementation date should be dictated by the availability of CDSMs, their integration into EHR systems, physician readiness, and sufficient testing. One commenter suggested, in the absence of additional time, we could ask physicians to annually attest, subject to audit, that they are consulting a CDSM prior to ordering relevant advanced imaging services.

Response: We appreciate the challenges that the aggressive timeline, established in section 218(b) of the PAMA, creates for all of us, and have taken steps to alleviate these challenges by phasing in components of this program as necessary for meaningful implementation. We continue to expect that furnishing professionals will be required to begin reporting January 1, 2018, and will address this requirement through PFS rulemaking for CY 2018.

Comment: One commenter cautioned CMS to ensure ordering professionals and furnishing professionals are not penalized due to phase-in of the consulting and reporting requirements under the AUC program or any other quality program.

Response: We do not foresee any situations where professionals would be penalized as a result of our decision to phase in the consulting and reporting requirements.

Comment: Several commenters noted that practitioners will have to comply with the requirements of the Merit-Based Incentive Payment System (MIPS) (under the Quality Payment Program) at the same time they will have to comply with the AUC consultation and reporting requirements which is overly burdensome. Some commenters recommended alignment of the AUC program with the Quality Payment Program requirements so as not to further increase burden on practitioners, and one commenter recommended alignment of the AUC program with MIPS rather than creating a standalone AUC program.

Response: We will continue to explore avenues for alignment of the AUC program and the Quality Payment Program. CMS issued a final rule with comment period to implement the QPP, including MIPS. The rule can be accessed at *https://qpp.cms.gov/education*.

Comment: Some commenters requested that CMS confirm that consulting and reporting will be required starting January 1, 2018, and stated that due to the availability of CDSMs and AUC, this start date is reasonable and feasible. One commenter expressed concern with the January 1, 2018 implementation date for consultation and reporting due to the cost and patient harm resulting from inappropriate imaging. The commenter urged CMS to work diligently to implement these requirements as quickly as is feasible. Another commenter suggested using a pilot period or starting voluntary consulting and reporting on January 1, 2018, during which information on the Medicare claim would not be considered for outlier determinations. Some commenters also suggested that the program first start with health systems and larger group practices and be rolled out to smaller settings over time.

Response: We continue to expect that furnishing professionals will be required to begin reporting January 1, 2018, and will address this requirement through PFS rulemaking for CY 2018.

Comment: Some commenters requested that CMS continue to implement the AUC program through rulemaking separate from the PFS so as to establish more programmatic components sooner, particularly related to consulting and reporting requirements and how this information will be documented on Medicare claims. Other commenters stated that the PFS is the appropriate cycle for establishing the AUC program and is important to ensure all stakeholders are aware of proposals and have the opportunity to comment.

Response: We believe that the PFS is the most appropriate rulemaking vehicle for implementing the AUC program and will continue to use the PFS annual rulemaking process to establish future components.

Comment: Many comments were submitted specific to qualified PLEs. Commenters requested both clarification and modifications to the definition of PLE finalized through rulemaking in the CY 2016 PFS final rule with comment period. Specifically, some commenters requested that we clarify that radiology benefit management (RBM) companies cannot be involved in any way with qualified PLEs and in the development of specified applicable AUC. Some commenters further stated that RBMs should not be involved because they do not use the same rigorous AUC development process as medical specialty societies, clinicians and providers and are focused on limiting utilization rather than assisting providers in making optimal medical decisions. Other commenters requested that we better explain the third party interaction permissible between qualified PLEs and RBMs.

Response: As finalized in the CY 2016 PFS final rule with comment period, the definition of PLE refers to organizations comprised primarily of providers or practitioners who, either within the organization or outside of the organization, predominantly provide direct patient care. This definition of PLE includes health care collaboratives and other similar organizations such as the National Comprehensive Cancer Network and the High Value Healthcare Collaborative. We further clarify that qualified PLEs may collaborate with third parties that they believe add value to their development of AUC, provided such collaboration is transparent. It is our expectation that PLEs will develop or modify AUC consistent with all regulations in § 414.94(c)(1). If commenters are interested in learning more about the AUC development process of any individual qualified PLE, then we remind the commenters that qualified PLEs disclose the parties external to the organization when such parties have involvement in the AUC development process.

Comment: Another commenter noted that the definition of qualified PLE restricts independent, evidence-based content solutions from inclusion. The commenter further requested that we remove language from the preamble they believe adds criteria to the definition of PLE. Specifically they requested removal of language discussing expectations of qualified PLEs ''to have sufficient infrastructure, resources, and the relevant experience to develop and maintain AUC. . .'' and identified this language as an ''evolving definition'' that is ''highly problematic'' and requested revision to more accurately reflect the language in the CY 2016 PFS final rule with comment period.

Response: We are not changing the requirements of qualified PLEs and disagree that the cited language adds criteria to the existing definition of PLE. The language in the background section of the CY 2017 PFS proposed rule

referenced above is not intended to build upon or provide more criteria to the definition of PLE in § 414.94(b). In fact this language was being used to describe the requirements of qualified PLEs under § 414.94(c)(1) and not to further explain the definition of PLE.

Comment: Some commenters requested that we provide more information about qualified PLEs and facilitate interactions between qualified PLEs and other stakeholders perhaps in the form of a tool or resource containing more detailed information or by coordinating a meeting for qualified PLEs and other stakeholders to interact.

Response: We do not believe we are best equipped to facilitate stakeholder interactions as suggested; however, we will continue to build out the information on the AUC Web site to enable stakeholders to research and reach out directly to qualified PLEs to learn more about their AUC libraries and processes.

Comment: A commenter requested that we wait to implement the AUC program until a broader list of qualified PLEs is available.

Response: On June 30, 2016, a list of 11 qualified PLEs was posted to the AUC Web site (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html*). Together these qualified PLEs include a large volume of AUC and we do not agree that it is necessary to wait to implement the program to further expand the list of qualified PLEs. Furthermore, we expect more applications from organizations seeking specification as qualified PLEs for 2017 so we expect the list to grow again in June of 2017.

Comment: Several commenters requested that all applications submitted by organizations seeking qualification as a PLE be made public.

Response: We appreciate the interest and contributions of all stakeholders as we implement this program and understand the desire to learn more about qualified PLEs, however we will not systematically release this information. To encourage stakeholder interactions and to assist those seeking more information about qualified PLEs, we posted general information about each qualified PLE on the AUC Web site. We intend to add more information about each qualified PLE to the AUC Web site which should enable stakeholders to research and reach out directly to qualified PLEs. We remind PLE applicants that they may mark their applications as containing proprietary business information and we will protect that information to the fullest extent permitted by law.

Comment: In response to our request for feedback regarding how appropriateness ratings provided by CDSMs could be interpreted and recorded for the purposes of this program, we received numerous comments. Commenters identified several ways appropriateness ratings are presented in CDSMs including: binary yes, appropriate or no, not appropriate; color coded using green for appropriate, yellow for may be appropriate and red for not appropriate; numerical ranges from 1 through 9/10 where 1–3 are not appropriate, 4–6 may be appropriate and 7–9/10 are appropriate, and a combination of color coded and numerical ratings. Commenters also used varying terminology including not appropriate, rarely appropriate, may be appropriate, usually appropriate, indicated and not indicated. Commenters recommended that appropriateness ratings that are not in a binary form need to be translated into binary values, only values equivalent to not appropriate equal no and values equal to may be appropriate and appropriate equal yes. Some commenters recommended that CDSMs be required to present appropriateness ratings in binary formats as this information will be required on the claim, while others stated that a binary appropriateness rating should not be required. Some commenters recommended CMS define standards for appropriateness ratings.

Response: We appreciate the extensive and thoughtful information provided in response to our request. These comments will be instrumental in operationalizing the AUC program.

Comment: We received numerous comments addressing the future outlier determinations. Many commenters agreed with using priority clinical areas to inform the outlier identifications. Other commenters questioned how we will be able to identify outliers starting in 2020 when priority clinical areas include AUC that conflict with one another. Some commenters suggested that outlier determinations be based upon the percentage of orders for which AUC consultation resulted in a recommendation of 1–3 (based on the 1–9 appropriateness level determinations). More specifically, ordering professionals ''with an ordering pattern in 'Red Rate' percentage two standard deviations higher than the median should be considered outliers.'' One commenter suggested that the outlier calculation use AUC compliance for priority clinical areas as the numerator and total AUC as the denominator. Some commenters encouraged us to focus outlier identification where wide variance in appropriate imaging patterns appears. Commenters also recommended that ordering professionals should be made aware of ordering patterns before being subject to prior authorization under the AUC program.

Some commenters opposed a strict application of all priority clinical areas for the purposes of outlier identification. Commenters requested that only ordering professionals with ordering patterns significantly misaligned with AUC be subject to prior authorization. Commenters also requested criteria used to make outlier determination be adjusted over time to allow for innovation in ordering. One commenter requested that ordering professionals not be subject to AUC consultation and prior authorization at the same time.

Response: We appreciate the extensive and thoughtful information provided in response to our request. We will consider these comments when determining how to operationalize the outlier determination component of this program.

Comment: Some commenters recommended that we require data submission to CMS directly or to a third party registry. Such reporting would enable professionals to track ordering patterns, especially in relation to priority clinical areas and subsequent outlier determinations.

Response: We will consider this recommendation as we implement the future components of this program.

Comment: Several comments focused on the communication for the image order from ordering professionals to furnishing professionals. Some commenters requested we include requirements in the final rule, and some requested that we require electronic communications. Commenters recommended that the furnishing professional be allowed to consult specified applicable AUC through a qualified CDSM if the ordering professional fails to provide consultation information to the furnishing professional to avoid claims denials. Others suggested that furnishing professionals be able to identify whether an ordering professional is considered an outlier under the AUC program and others recommended we develop a verification mechanism that would be required of the ordering professional.

Response: We are not establishing requirements regarding the communication of the imaging order from the ordering professional to the

furnishing professional. These professionals currently send and receive orders successfully via various vehicles (within EHR, fax, etc.), and we do not believe it is appropriate at this time to place further constraints or requirements on the systems for communications between these professionals. We also note that section 1834(q)(4) of the Act clearly specifies that AUC consultation is required for ordering professionals and does not provide for instances where consultation by furnishing professionals is an acceptable alternative, even if only for the purpose of avoiding claims denials. We do not believe the statute affords us the authority to allow furnishing professionals to consult in lieu of or in the absence of consultation by ordering professionals. For all other purposes, we remind commenters that furnishing professionals are not specifically prohibited from consulting specified applicable AUC through a CDSM.

Comment: Some commenters requested clarification regarding the role of local coverage determinations (LCDs) and national coverage determinations (NCDs) under the AUC program. Commenters requested that CMS identify whether LCDs and NCDs take precedent over specified applicable AUC, or if advanced diagnostic imaging orders that are considered appropriate based on consultation with specified applicable AUC would be covered under Medicare if such order was not covered by an LCD or NCD. Some commenters requested that AUC be the only criteria for medical necessity of advanced imaging services and other commenters insisted that we instruct MACs to retire LCDs for advanced imaging services once the AUC program is implemented. One commenter also recommended that we instruct qualified PLEs to adhere to NCD requirements when developing AUC.

Response: At this time we consider LCDs and NCDs to be active and binding policies detailing the criteria upon which Medicare coverage or non-coverage is based. For the purposes of this program, consulting with AUC is not a replacement for a determination of medical necessity. Consultation with AUC that conflict with an LCD or NCD does not modify the applicability of the LCD or NCD. Specified applicable AUC do not override LCDs or NCDs.

Comment: Some commenters stated that the disproportionate burden of the AUC program is on primary care physicians. Many commenters noted in general the additional burden, both administratively and financially, the AUC program will create for providers. While other commenters stated that the added burden is outweighed by the cost savings and quality improvements resulting from a properly implemented AUC program and is significantly less than traditional prior authorization programs.

Response: We understand that primary care physicians will be significantly impacted by the AUC program and have acknowledged this throughout implementation of this program. We are making every effort to implement a program that does not impart excess levels of burden but still includes all statutorily required provisions and is designed to achieve goals of the PAMA.

Comment: Some commenters noted that since AUC consultation information will be required on the claim for the imaging service ordered, only the furnishing professional, often including the hospital where imaging services are provided, will be held accountable if AUC are not consulted. Because the ordering professional is required to consult and their action, or inaction, impacts payment for the furnishing professional, commenters stated that we should find a way to hold the ordering professional accountable as well.

Response: The fourth component of the AUC program in section 1834(q)(5) of the Act includes the identification of outlier ordering professionals, which we believe will distinguish and provide consequences for those ordering professionals that fail to comply with AUC. Through facilitation of a prior authorization requirement for such identified professionals, as specified under section 1834(q)(6) of the Act, we believe we will fulfill the shared goal of assisting both ordering and furnishing professionals in making the most appropriate treatment decisions for Medicare beneficiaries. Although we did not propose to implement these sections in the CY 2017 PFS proposed rule, we continue to expect that consultations with physicians, practitioners and other stakeholders will serve as part of the process to hold accountable outlier ordering professionals, and believe that such dialogues will yield meaningful results. We recognize that this response does not address those ordering professionals that consistently fail to consult AUC at all, and we will continue to discuss internally the extent to which such professionals would be impacted by this AUC program and other Medicare programs.

Comment: Some commenters requested that we ensure that AUC consultation requirements do not create issues with patient access to care due to the additional administrative burden this program will place on providers. Commenters also requested that we ensure that AUC consultations do not interfere with physicians' clinical judgment when treating patients.

Response: We disagree with the idea that AUC consultation creates new barriers for Medicare beneficiaries, and believe that while technology itself cannot improve care coordination or patient outcomes, the use of that technology can be a tool for practitioners to use in working toward improving care for Medicare beneficiaries. To this end, CDSMs can provide efficiencies in administrative processes which support clinical effectiveness, leveraging automated patient safety checks, supporting clinical decision making, enabling wider access to health information for patients, and allowing for dynamic communication between providers. We believe that as ordering professionals continue to engage with qualified PLEs, qualified CDSMs and CMS, AUC consultations will complement the practice of medicine.

Comment: Some commenters questioned the overall approach we are taking in implementing this program. Commenters noted that the program should not be set in place until it is determined that use of AUC actually improves utilization of diagnostic imaging. Other commenters reiterated their opposition to using the AUC consultation requirement to withhold payment for rendered services.

Response: Section 1834(q) of the Act as amended by section 218(b) of the PAMA identifies specific requirements for the implementation of the Medicare AUC program. The program must be implemented and must include all detailed components in the statute. We believe the approach we are taking is consistent with the requirements in the PAMA.

Comment: Some comments focused on requests for practitioner and patient education efforts. Commenters requested that we educate practitioners and allow for adequate time to do so. Another commenter recommended that we inform patients on the AUC program and explain both the need for the program and supposed benefits. This commenter also recommended that we encourage other payers to use the same criteria as the Medicare AUC program to avoid additional administrative burden on providers. This commenter recommended that we inform clinicians of the expected cost associated with compliance with the AUC program requirements.

Response: We plan to develop and provide educational materials about the AUC program before implementation of this program. We also expect many stakeholders will work to educate and inform providers and the public and other interested parties about the program. We do not have control over what other payers choose to implement and do not have cost projections associated with implementation of this program at this time as they relate to regulations yet to be proposed through notice and comment rulemaking.

Comment: One commenter noted that different terminology is used in the two proposed rules with the CY 2017 OPPS proposed rule using the term ''imaging supplier'' and the CY 2017 PFS proposed rule using ''furnishing professional.'' The commenter noted that the PAMA uses the term ''furnishing professional'' and asks that CMS use consistent terminology for the parties furnishing the radiology service and more clearly define the parties/entities that would fall into the standard term.

Response: We understand commenters' confusion. All components of the Medicare AUC program are being implemented through the PFS. The use of ''imaging supplier'' in the OPPS is not relevant to the AUC program. Under the AUC program and as specified in section 1834(q)(1) of the Act, the term ''furnishing professional'' is defined as a physician (as defined in section 1861(r) of the Act) or a practitioner described in section 1842(b)(18)(C) of the Act who orders an applicable imaging service which we codified in § 414.94(b) as discussed in the CY 2016 PFS final rule.

Comment: Several commenters made various recommendations and suggestions regarding the development of AUC, the type of AUC that should be used under this program and their involvement in identifying and/or developing AUC for use under this program.

Response: We remind readers that through the CY 2016 PFS final rule with comment period, we established new § 414.94 and included requirements regarding the development of AUC and who can be qualified to develop, modify and endorse AUC. We will not be developing specified applicable AUC for consultation under this program. Rather specified applicable AUC, that ordering professionals will be required to consult, are those developed, modified or endorsed by qualified PLEs. The first list of qualified PLEs was released in June of 2016 and can be found on the CMS AUC program Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html*.

Comment: Many commenters communicated their appreciation of efforts by CMS to actively engage with stakeholders to implement this program as mandated by the section 218(b) of the PAMA amending section 1834(q) of the Act. Other commenters asked how they can become involved and when CMS will reach out directly to them.

Response: We have found the extensive interactions we have had with a wide range of stakeholders over the past several years to be highly instrumental and essential to the development of this program. Many stakeholders reached out to us from early on and we have reached out to other organizations when issues particularly relevant to their areas of focus arise. We have also expanded our stakeholder interactions through numerous conferences and meetings held by various organizations. Furthermore we receive regular email inquiries that create an open dialogue with more stakeholders and are always happy to interact with any individual or organization with an interest in the AUC program. The best way to contact the CMS AUC Team is through the AUC program resource box: *ImagingAUC@cms.hhs.gov*. We check the resource box regularly and respond to all inquiries.

These additional comments will assist us in further building out the AUC program as we move into the next component for implementation in future rulemaking and have not resulted in any changes to our proposals. We have discussed above, throughout the preamble, our changes in response to public comment. We thank the public for their comments and appreciate the detailed feedback and recommendations from stakeholders. We believe the changes based on public comments have improved the identified priority clinical areas and the qualified CDSM requirements and process for qualification. We are finalizing without change the proposals for the determination of non-adherence and the exceptions under this program. We will continue to post information on our Web site for this program accessible at *www.cms.gov/Medicare/Quality-Initiatives/Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program*.

D. Reports of Payments or Other Transfers of Value to Covered Recipients: Summary of Public Comments

1. Background

In the February 8, 2013 **Federal Register** (78 FR 9458), we published the ''Transparency Reports and Reporting of Physician Ownership or Investment Interests'' final rule (Open Payments Final Rule) which implemented section 1128G of the Act, as added by section 6002 of the Affordable Care Act. Under section 1128G(a)(1) of the Act, manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) are required to submit, on an annual basis, information about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Section 1128G(a)(2) of the Act requires applicable manufacturers and applicable group purchasing organizations (GPOs) to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. The Open Payments program creates transparency around the nature and extent of relationships that exist between drug, device, biologicals and medical supply manufacturers, and physicians and teaching hospitals (covered recipients and physician owner or investors). The implementing regulations are at 42 CFR part 402, subpart A, and part 403, subpart I.

In addition to the Open Payments final rule, we issued final regulations in the CY 2015 PFS final rule with comment period (79 FR 67758) that revised the Open Payments regulations. Specifically, we: (1) Deleted the definition of ''covered device''; (2) removed the continuous medical education (CME) exclusion; (3) expanded the marketed name reporting requirements to biologicals and medical supplies; and (4) required stock, stock options, and any other ownership interests to be reported as distinct forms of payment.

Since the publication and implementation of the Open Payments Final Rule and the CY 2015 PFS, various stakeholders have provided feedback to us regarding a variety of aspects of the Open Payments program. As a result, we have identified areas of the rule that might benefit from revision or subregulatory clarification. To consider the views of all stakeholders,

in the CY 2017 PFS proposed rule (81 FR 46395 through 46396), we solicited public comments regarding policy and operational issues related to the Open Payments program.

Examples of subject matter areas for which we solicited public comments included: (1) Expansion of the nature of payment categories; (2) length of continued reporting obligations; (3) length of time in which Open Payments data remains relevant to users; (4) mandatory registration for applicable manufacturers and GPOs; (5) pre-vetting of payment information with physicians and teaching hospitals prior to submission; (6) definition of a teaching hospital; (7) new teaching hospital reporting elements; (8) option for early or continuous data submission; (9) the impact of mergers, acquisitions, and other business dealings on reporting; (10) clarification on the definitions of ownership and investment interest terms; and (11) definition of, and collection of data from, Physician Owned Distributors (PODs).

In response to our solicitation, we received 136 timely comments, 95 of which were deemed relevant to the solicitation in that they suggested matters to consider in future rulemaking and system enhancements. The majority of the comments focused on:

- Expanding or clarifying the nature of payment categories enumerated in § 403.904(e)(2).
- Changing the continued reporting obligation to a specific period of time, such as 5 years after the payment or transfer of value was made.
- Publishing or refreshing the Open Payments data so that it is accessible to stakeholders for an appropriate period of time, such as 5 years or the number of years in which an applicable manufacturer or GPO is required to report.
- Streamlining the Open Payments registration process and maintaining voluntary registration for those applicable manufacturers or GPOs that do not report.
- Requiring applicable manufacturers and GPOs to pre-vet financial information with physicians and teaching hospitals before it is reported to Open Payments.
- Clarifying the regulatory definition of a teaching hospital.
- Adding non-public data elements that allow additional detail about the specific recipient or department of a teaching hospital that received a payment or transfer of value.
- Expanding the timeframe in which the Open Payments program can accept data submissions from applicable manufacturers and GPOs, such as by implementing multiple submission windows.
- Implementing flexible reporting requirements so that applicable manufacturers and GPOs can properly and easily represent changes resulting from mergers, acquisitions, and other business dealings.
- Clarifying the definition of PODs and how Open Payments requirements apply to PODs.

These comments, submitted by a variety of parties, broadly supported our effort to engage the program's stakeholders before revising or creating new reporting requirements. We appreciate the commenters' views and recommendations and we will consider the public comments received in the future through possible rulemaking or publication of subregulatory guidance. No Open Payments program changes are being proposed or finalized within this final rule.

E. Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D Medical Loss Ratio (MLR) Data

1. Overview of Proposed Rule

In the CY 2017 PFS proposed rule (81 FR 46162) we proposed to release certain data related to the bids submitted annually by Medicare Advantage Organizations (MAOs) and certain Medical Loss Ratio (MLR) data submitted annually by MAOs and Part D plan sponsors. In general, we proposed to release the data submitted by MAOs in the Medicare Advantage (MA) Bid Pricing Tool (BPT), subject to a 5-year delay; and to release data submitted by MAOs and Part D sponsors in accordance with MLR requirements, subject to an 18-month delay. In both cases, the proposed release is subject to specified exclusions.

2. Release of Bid Pricing Data

a. Summary of Proposed Rule

The proposed rule included a discussion of both the statutory and regulatory authority for collecting bids, as well as an overview of how the information is collected. Each year, MAOs submit bids to CMS for participation in the Medicare Advantage program. Information from these bids is primarily collected through the MA BPT, which was developed by CMS. The data collected in the BPT demonstrates the actuarial bases of the plan bid. Each MA plan bid is an estimate of the plan's revenue requirement to cover plan benefits for a projected population, including benefit costs net of cost-sharing, non-benefit expenses, and gain/loss margin.

The following summary describes the types of data collected in the BPT, which we described in greater detail in the proposed rule at 81 FR 46397–99:

- Base period experience data.
- Trend assumptions.
- Manual rates and credibility assumptions.
- Projected allowed costs.
- Effective value of a plan's cost-sharing.
- Projected administrative expenses and information related to the plan's gain/loss margin.
- Plan-specific bid and benchmark, based on projected enrollment and risk scores.
- Beneficiary rebate and beneficiary premium for the plan.
- Rebate allocations to MA mandatory supplemental benefits and buy down of the Part D basic premium, the Part D supplemental premium, and/or the Part B premium.
- Actuarial pricing elements for any optional supplemental benefit packages.

In addition to these categories of data collected in the BPT, MAOs must submit supporting documentation to substantiate the actuarial basis of pricing and an actuarial certification of the bid.

We described the proposed regulatory changes to allow for the release of MA bid pricing data, along with the manner in which we proposed to make the release. We proposed to codify the requirements for release of MA bid pricing data by adding new § 422.272 to subpart F of part 422. We proposed to release to the public each year, after the first Monday in October, MA bid pricing data for MA plan bids that we accepted or approved for a contract year at least 5 years prior to the upcoming calendar year, subject to specific exclusions described in proposed § 422.272(c). We proposed to amend the regulation text at § 422.504 by adding a new paragraph (n)(2), which would require that an MAO acknowledge the release of MA bid pricing data as provided in § 422.272 as a mandatory contract provision; we also proposed certain technical changes to § 422.504(n). The proposed rule did not discuss these changes to § 422.504(n) in detail as part of the proposal to release MA bid data, but they were reflected in the proposed regulation text at 81 FR 46471. Specifically, we proposed to move the existing provisions regarding the release of summary CMS payment data at existing paragraph (n) to paragraph (n)(1) and to redesignate the existing paragraphs (n)(1)(i) through (iv) and (n)(2) as (n)(1)(i)(A) through (D) and (n)(1)(ii), respectively.

We also described the data that would be subject to exclusion from release. We proposed not to include any Part D bid pricing data, or any information pertaining to the Part D prescription drug bid amount for an MA plan offering Part D benefits. We also proposed to exclude any narrative information included in the MA BPT, MSA BPT, and ESRD–SNP BPT regarding base period factors, manual rates, cost-sharing methodology, optional supplemental benefits, or other topics for which narratives are required by us under § 422.254. We proposed to exclude supporting documentation that is provided outside of the BPT template. We proposed to exclude any information identifying Medicare beneficiaries or other individuals. Regarding other individuals, we explained that our proposal would exclude the names and contact information of certifying actuaries and MAO contacts from the releases. Finally, we proposed to exclude any bid review correspondence between us or our contractors and the MAO.

We detailed the rationale for the proposed releases. We discussed how the release of this data is in support of the Administration's commitment to transparency. We indicated that release of MA bid pricing data could support public research into the MA program that could support the agency's goals for the program, including the delivery of better healthcare. We also suggested the data release would promote public accountability of the program.

We also addressed past and ongoing attempts to achieve release of this data under the Freedom of Information Act, 5 U.S.C. 552 (FOIA). We have received several requests under the FOIA for the type of MA bid pricing data we proposed to release. Under the FOIA, we are required to make available any data released under the FOIA that the agency determines are likely to become the subject of subsequent requests, or that have been requested by three or more requesters. As a result of one such FOIA request, we have already released publicly a limited set of MA bid pricing data. This data, from 2011, is available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/DataRequests.html*. This data was posted in June 2013.

We solicited comments on the scope of the proposed release of MA BPT worksheets and data elements. We were particularly interested in comments on whether the MA bid pricing data we proposed to release contains proprietary information, and if so, we requested detailed explanations of good cause for its redaction from public availability and suggestions for what safeguards might be implemented to appropriately protect those portions of the data. We noted that detailed explanations should contain specific examples which show how this information disclosure could cause substantial competitive harm to MAOs. Specific examples should have (1) cited the particular information proposed to be released and explained how that information differs from publicly available data; (2) pointed to the particular entity or entity type that could gain an unfair competitive advantage from the information release; and (3) fully explained the mechanism by which the release of that particular information would create an unfair competitive advantage for that particular entity. Similarly, we were interested in comments that our proposed scope for release was too narrow and unnecessarily protects data that is not confidential and should not be protected.

We also solicited comments on the proposed 5-year delay and its effect with respect to any competitive disadvantages to MAOs that could result from the disclosure of MA bid pricing data. We solicited comments on whether a shorter period would suffice to protect MAOs from competitive harm associated with the disclosure of confidential commercial information or if a longer period is necessary to adequately protect the information.

b. Comments

We received 30 comments from the public, some in support and some in opposition to our proposed release of MA bid pricing data. We reviewed these comments closely, and we appreciate the concerns identified in comments on our proposed release. These comments are addressed below.

Comment: About half of the commenters expressed support for the proposal to release MA bid pricing data.

Response: We appreciate the support.

Comment: A number of commenters stated that the release of MA bid pricing data would result in substantial competitive harm to MAOs and to the MA program. Commenters expressed concern that release of plan-level financial data, even with the 5-year delay, would provide current and future competitors with sensitive information such as gain/(loss) margin and the profitability of serving beneficiary populations in specific markets, which could expose business strategies, reduce innovation, and undermine the functioning of a competitive marketplace. These commenters stated that the detailed claims cost, cost sharing, and utilization information collected in the MA BPT could be used by a competitor to derive not only future bid amounts in the aggregate, but also to derive components of future bids for specific benefits contained in the bid. Some commenters remarked that this could incent the gaming of bids, cause MAOs to exit markets, and create disincentives for new market entrants.

Response: We share the commenters' interest in the continued success of the MA program. In recent years, enrollment has grown while plan quality has demonstrated continued improvement. Our goal is to continue to make the MA program a strong and healthy one.

As discussed in the proposed rule, we believe this disclosure is consistent with Presidential directives to make information available to the public, and with our goals of allowing public evaluation of the MA program, encouraging research into better ways to provide health care, and reporting to the public regarding federal expenditures and other statistics involving this program. Analysis of this data could inform future bidding and payment policies. Further, releasing MA bid pricing data, particularly in conjunction with information already released under § 422.504(n), will provide insight into the use of public funds for the MA program, providing appropriate transparency about the administration of the program.

We discussed the need to balance these goals with the need to protect the proprietary information of the MAOs that submit this bid pricing information to us. Our proposed time lag of 5 years prior to the upcoming calendar year was an important element in our decision to release the MA bid pricing data.

As part of our efforts to balance our mission to effectively administer federal health care programs and increase data transparency with MAOs' proprietary interests, we requested that commenters who oppose release of MA bid pricing data provide a ''detailed explanation of good cause'' for the redaction of some or all MA bid data from public release. As noted in section III.E.2.a of this final rule (''Summary of Proposed Rule''), we stated that detailed explanations should contain specific examples which show how this information disclosure could cause substantial competitive harm to MAOs. Specific examples should have (1) cited the particular information proposed to be released and explained how that information differs from publicly available data; (2) pointed to the particular entity or entity type that could gain an unfair competitive advantage from the information release;

and (3) fully explained the mechanism by which the release of that particular information would create an unfair competitive advantage for that particular entity (81 FR 46402).

We believe that commenters did not provide data analysis that met this requested standard of specificity to help us determine that release of the data as proposed would cause unfair competitive harm or negative consequences for the MA program. We did not receive specific examples that illustrated how the structure of a particular healthcare market (for example, a particular county or multi-county healthcare market), combined with universal access to certain 5-year-old data elements in the MA BPT, could create an unfair competitive advantage.

A number of commenters expressed concern about the use of MA bid pricing data to reverse-engineer provider payment rates, stating that this could cause competitive harm, especially in highly consolidated markets in which there are a limited number of providers for a specific service. A few commenters stated that a provider might determine whether its payment rates were higher or lower than the average in such a consolidated market (especially for MA bids for single-county MA plans) by comparing its negotiated rate to the average unit price reported in the BPT, in order to increase its leverage in future negotiations with the MAO.

We understand this concern and appreciate the sensitivity of the negotiations between private health plans and healthcare providers. We discuss these comments a greater length below. However, as discussed in more detail throughout this final rule, we believe that the 5-year delay in the release of MA bid pricing data would make any information about payment rates that could be obtained from an examination of plan bids stale and no longer commercially sensitive.

Finally, in 2013, we released certain 2009 actual costs (worksheet 1) from the 2011 MA bid pricing data, as required by the U.S. District Court for the District of Columbia in *Biles* v. *Dep't of Health and Human Services,* 931 F. Supp. 2d 211 (D.D.C. 2013). (Discussion of this case is at 81 FR 46403 of the proposed rule.) Given that this information has been released to the public, and we have not been made aware of any instances of competitive harm, we do not see any reason why the release of 5-year-old data could cause competitive harm.

In the absence of any evidence or analysis demonstrating that competitive harm would result from the proposed release of MA bid pricing data, and in consideration of the important policy goals that we believe will be served by publicly releasing MA bid pricing data, discussed above, we are finalizing our proposal to release MA bid pricing data after a 5-year delay, subject to certain specified exclusions.

Comment: A few commenters expressed skepticism that the release of MA bid pricing data will cause competitive harm to MAOs, and stated that there is no real competition among MAOs for government approval of bids because we approve multiple reasonable bids. Another commenter stated that if MA bid pricing data is publicly released, there cannot be competitive harm or unfair commercial gain because each MAO would have the same information about its competitors and would be equally capable of using that information. The commenter stated that such symmetrical access to data obviates the potential for any unfair commercial gain for one MAO over another, and that only asymmetric disclosure can be a condition for substantial competitive harm.

Response: We do not agree entirely with the comments stating that the public release of MA bid pricing data cannot cause competitive harm or unfair commercial gain. We note that the public release of MA bid pricing data could give new market entrants information on competitors' MA plan bids while such information about their own bid(s) would not have been released, allowing them to potentially benefit from asymmetric disclosure. However, we believe that our proposed time lag of 5 years prior to the upcoming calendar year is an important element in mitigating competitive harm to MAOs or the potential for unfair commercial gain for new market entrants when releasing MA bid pricing data.

Comment: Many commenters stated that MA bid pricing data could be used to calculate an MA plan's negotiated provider payment rates. Several commenters cited a Federal Trade Commission (FTC) letter (at *https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-amendments-minnesota-government-data-practices-act-regarding-health-care/150702minnhealthcare.pdf*) stating that the public disclosure of competitively sensitive pricing information may be used in an anticompetitive manner that increases costs and adversely impacts consumers. The commenters stated that when a provider knows that another provider is receiving a higher payment rate for a service, the provider will demand at least the same rate as the higher-paid provider, thereby raising the ''price floor'' for the service. Some commenters stated that with knowledge of MA bid pricing data, lower-priced providers would negotiate for known higher rates, and that providers may be less likely to agree to lower-cost arrangements if the details will be shared with their competitors, which leads to higher unit prices for healthcare services across the MA program and thus higher total costs.

Several commenters also described, at a general level, various methods for reverse engineering provider payment rates using certain information that MAOs submit in their bids. A few commenters stated that the release of an MA plan's average historical cost per unit could be used to calculate negotiated rates by service category and market, particularly where health care markets are highly concentrated.

Response: A negotiated rate between an MAO and a provider (facility, physician, or other provider) refers to the payment rate that an MAO has established by contract with a provider. Typically negotiated rates are specified at a unit of payment such as per person per month, per diem rate, per service rate, or a global capitation rate (for example, a physician is paid a negotiated rate for managing all services received by a beneficiary under a specific health plan).

We do not have access to these negotiated rates between an MAO and its contracted network of providers, so we cannot determine how closely an entry in the BPT may represent negotiated rates in provider contracts. Since payment figures in the MA BPTs are grouped into general service categories (such as ''Inpatient Facility'' and ''Skilled Nursing Facility'') and represent average costs across multiple providers, beneficiaries, services, and sites of service, we believe that the BPT information is unlikely to give more than high-level insight into contractual negotiated rates.

Even if reverse engineering of provider rates were possible, the 5-year delay renders that information even less competitively useful or relevant. We do not believe that any commenters established that a provider who uses MA bid data to estimate the negotiated rate that a competitor was receiving 5 years earlier would be greatly advantaged by this information.

Delivery of health care is constantly evolving and MAOs are continually seeking ways to gain efficiency in providing care. For example, the number of providers, the cost of services, and utilization patterns associated with an MAO are very likely to change over a 5-year period; we believe that these changes—particularly

as the health care industry moves toward alternative payment methodologies—mitigate any risk associated with reverse engineering of historical payment rates. As such, we remain unconvinced that releasing this information has potential to cause harm to the marketplace as a whole or to the competitive position of MAOs.

Comment: Some commenters stated that our proposal to release multiple years of data initially, followed by the release of more recent bid data on an annual basis, would make it possible for providers and competitors to analyze cost trends, which could inform negotiations and adversely impact competition by providing insight into profit objectives and growth strategies. One commenter noted that the *Biles* court indicated that its conclusion (that the MA bid pricing data requested by the plaintiff could be released without impacting market conditions) was specific to the request for a single year's data, and that a request for second year's data that could be trended creates a distinguishable factual situation that requires a new and separate analysis. 931 F.Supp.2d at 227 n.22. The commenter stated that, if the proposal to release bid data after a 5-year delay is finalized, we should deny FOIA requests for more recent data, both because this data is precluded under Exemption 4 as ''trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential,'' and because this data could be analyzed in combination with the bid data that we are proposing to release after a 5-year delay to potentially reveal competitively sensitive trend information. Finally, one commenter stated that we did not explain the rationale for our assumption that the MA bid data is no longer commercially sensitive after 5 years.

Response: We appreciate the commenters' concerns about how bid data for multiple years can both reveal actual trends in the past and can be trended into the future to predict an MAO's projected gains and losses, which could give competitive insight into business strategies. However, as we stated in the proposed rule at 81 FR 46400, we believe that our proposed 5-year delay renders multi-year comparisons of pricing trends less relevant to the current year of MA plan pricing.

We selected a 5-year delay, in part, due to the requirements associated with projected margins in the bids submitted by MAOs, particularly when the margin is projected to be negative. MAOs with negative margins in their bids are expected to achieve profitability within 5 years (that is, bids should not have negative margins for more than 4 consecutive years). Absent the 5-year delay, we were concerned that the public might be able to use this margin rule to deduce competitively sensitive information from a plan's bids.

We also believe that 5 years is sufficient time for competitively sensitive bid data to become no longer competitively sensitive. The time lag represents a buffer between the development and implementation of pricing strategies that can be distilled from multiple years of data and the observed relationship and trend from 1 year to the next, and we believe that this buffer mitigates any competitive disadvantage that might otherwise result from the disclosure of multiple years of bid data. As an example, we noted that an MAO looking to enter a new market is significantly less likely to gain an unfair commercial advantage from being able to examine and trend 5-year-old bid pricing data than if the MAO were able to examine and trend more recent bid pricing data (81 FR 46400).

We continue to believe that the proposed exclusion of MA BPT narrative fields and supporting documentation is appropriate because MAOs provide information in narrative fields and supporting documentation that is commercially sensitive information in a way that the cost and enrollment estimates in the BPT are not. MA BPT narrative fields and supporting documentation can include sensitive information such as multi-year regional or national-level information on an MAO's approach to cost-sharing methodology or projection factors, which can provide insight into longer-term strategies, or they may include information on provider contracting, such as fee schedules or summaries of provider contract terms. Provider contract terms and actual fee schedules, for example, would be more competitively sensitive than the estimated provider payment rates that could be generated from 5-year-old bid figures at the broad service level categories in the MA BPT. In addition, we believe that supporting documentation could cause misinterpretation of the MA bid pricing data that we proposed to release. We proposed to release only the MA bid pricing data for MA plan bids that were accepted or approved by CMS. However, MAOs often upload multiple versions of each plan bid in response to our requests for further information or corrections. Given the volume of supporting documentation submitted by MAOs, it may be difficult for a member of the public to identify clearly which documents support the final accepted version of the bid. We proposed, and finalize here, that these documents will not be included in the data that we release under this rule.

We agree that more recent MA bid data is more competitively sensitive than bid data that is at least 5 years old, and we recognize that, even if the release of bid pricing data for a single, more recent year would not itself create a risk of substantial competitive harm, there could be an increased likelihood of substantial competitive harm resulting from the release of a more recent year's bid pricing data when that data can be analyzed in combination with publicly-released bid data for previous years and trended forward to predict current or future bids.

If a FOIA request is received, we will follow our ordinary FOIA procedures and not release data the agency determines are trade secrets, or commercial or financial information protected by Exemption 4 to the FOIA (5 U.S.C. 552(b)(4)). We also note that we do not view data releases made under the authority of the new § 422.272 as FOIA releases. These releases are discretionary disclosures of data to the public, rather than in response to a request under the FOIA. Section 422.272 permits the release of data, but does not require it. As noted in the proposed rule (81 FR 46396–97), we believe that these releases are consistent with the principles of transparency in government that underlie the FOIA and that regular release of this data might mitigate the number of FOIA requests and the associated need for repeated analyses of this data.

Comment: A number of commenters suggested that bid pricing data is inherently proprietary, and therefore, should not be released. A few commenters stated that pricing data is confidential, proprietary information covered by Exemption 4 of the FOIA.

Response: We disagree with the commenters. Absent detailed analytical evidence, which we solicited in the rulemaking process but did not receive, as discussed above, we do not believe the release of bid pricing data on a 5-year lag poses a threat of competitive harm.

Specifically, regarding the comment that MA bid pricing data is proprietary and covered by Exemption 4 of the FOIA, we restate here that we are finalizing our proposal to expand the basis and scope of our regulations on MA bidding to incorporate section 1106(a) of the Act (42 U.S.C. 1306(a)), which authorizes disclosure of information filed with this agency in accordance with regulations adopted by

the agency. A substantive regulation issued following rulemaking provides the legal authorization for government officials to disclose commercial information that would otherwise be required to be kept confidential in accordance with 18 U.S.C. 1905. *See Chrysler Corp.* v. *Brown,* 441 U.S. 281, 306–08 (1979). We note as well that under 45 CFR 401.105(a), we have adopted a regulation that permits publication and release of data that would not be exempt from disclosure under the FOIA or prohibited from disclosure under other law, even if a request has not been submitted.

Comment: Many commenters offered alternative ideas for what MA bid pricing data to release. These commenters stated that the data should be aggregated above the level of the MA plan bid, such as at the contract level because it would be more difficult to reverse-engineer provider payment rates and other proprietary information. Another commenter suggested releasing only an aggregate financial measure that reflects the sum of non-benefit expenses and gain/(loss) margin. Some commenters recommended additional data exclusions, for example, that all plan-level financial data should be excluded because it would provide current and potential future competitors with proprietary, competitively sensitive information such as profitability of specific beneficiary populations. One commenter stated that information used to project an MA plan's revenues and costs, such as enrollment and population projections, should not be released at granular levels (for example, county-level details). Commenters stated their concern that the 5-year timeline we proposed for releasing the MA bid data is too short, and one commenter stated that bid data should be released only after 10 years and that any release after that time exclude all plan-identifying information.

Response: We appreciate the concerns raised by the commenters. However, based on our analysis of the comments we received, we did not find that any commenter provided sufficiently detailed evidence of competitive harm associated with the release of any of the fields proposed for release after the proposed 5-year delay. As such, we do not consider these exclusions or any further aggregation of bid data to be necessary.

Comment: Several commenters recommended that the MA bid pricing data not be released to the public on the CMS Web site, but be made available through other mechanisms. One commenter suggested that, to avoid any competitive use of the MA bid pricing data, the data should be released only through the ResDAC portal for researchers as Research Identifiable Files (RIFs). Another commenter urged us to aggregate the MA bid pricing data and release it through our established methodology of public data release, the Public Use File (PUF), which generally can be understood by technical audiences after a review of supporting documentation.

Response: We appreciate the recommendation that the bid pricing data be released through ResDAC. CMS' Research Data Assistance Center (ResDAC at *www.resdac.org*) is a critical part of the Administration's commitment to transparency, and has been a valuable resource for researchers (in releasing RIFs) and the public (in releasing PUFs). However, we do not agree that this release should be through the ResDAC resource or require the signing of a Data Use Agreement (DUA) that restricts use and disclosure of the data (which is required for use of RIFs). Because commenters did not identify a specific competitive harm associated with the public release of the bid data, we will publish it without restriction on the CMS Web site (*www.cms.gov*), subject to the exclusions as finalized in this rule.

Comment: Several commenters stated that bid pricing data should not be released because such data is not useful to beneficiaries, and it has a high risk of being misinterpreted. One commenter stated that beneficiaries will likely find bid data confusing and less informative than our Star Ratings, which are considered a more accessible and straightforward measure by which to compare plan value and quality. One commenter stated that we should refrain from releasing bid data to the public ''until there is a proven case that the release would lead to improvements in the quality of care overall in the Medicare program.''

Response: We appreciate the concerns that were raised regarding the possibility that the bid data we proposed to release could be misinterpreted. We intend to release with each year's bid data the BPT instructions and data dictionary for that year to minimize confusion and the possibility of misinterpretation of the data. Further, as noted in the proposed rule at 81 FR 49396, we anticipate that researchers, as well as other members of the public will have use for this information and that research based on the data may provide important insights for future MA policy development and for developing health care policy. Disclosing MA bid pricing data will allow the public to better understand how public dollars are spent in the MA program. Beneficiaries may or may not seek to use this data to make plan choices and we did not identify that as a specific reason for the release of MA bid pricing data.

Comment: Some commenters stated that the release of the MA bid pricing data would likely result in an increase in the cost of MA plan basic benefits and supplemental services (for example, dental benefits) as MAOs respond to a new competitive situation. Commenters stated that this would harm beneficiaries because it will cause MA plans to offer fewer supplemental benefits, increase cost-sharing, or both.

Response: We expect that the MA program will continue providing affordable and comprehensive health plan options to Medicare beneficiaries. We did not receive any detailed analysis to demonstrate that releasing 5-year-old MA bid pricing data is likely to have the harmful impact on beneficiaries raised by the commenters.

Comment: Commenters expressed support for our proposal to not release Part D bid pricing data. Two commenters argued against the release of Part D bid pricing or manufacturer's rebate data, and one commenter stated that the release of Part D bid pricing or rebate data would violate the Takings Clause of the U.S. Constitution, as well as the Part D noninterference clause (section 1860D–11(i) of the Act). One commenter expressed concern that our broad interpretation of our authority to release MA bid data through notice-and-comment rulemaking could cause us to ignore legal barriers to the release of Part D pricing data.

Response: We appreciate the support. Since we proposed to exclude Part D bid data from our proposed release of MA bid pricing data and are finalizing those exclusions in this final rule, we consider the comments arguing against the release of Part D bid pricing and rebate data to be beyond the scope of the proposed rule. To the extent that these comments support the exclusion in our rule, we appreciate the support.

Comment: Several commenters expressed support for the proposed release of MA bid pricing data, but stated that the 5-year lag in release was too long for timely analysis that would still be beneficial to informing future policymaking and reforms. Some commenters stated that MA organizations are paid with public funds to provide a public benefit, and transparency should outweigh the concern of competitive harm, in part because there is limited competition in the program in that we approve multiple

reasonable bids, not merely the lowest bidders. Some commenters also stated that significant changes in the health care landscape can occur over the course of 5 years, and bid pricing data that is 5 years old will constrain researchers' ability to do meaningful policy analysis. Finally, one commenter suggested a 3-year lag instead of a 5-year lag in release of MA bid pricing data.

Response: We appreciate the comments, and the interest in having access to more recent data. Through notice and comment rulemaking, we have sought to balance an interest in transparency with the need to protect proprietary information. We received comments on both sides of this issue, and have reviewed these comments critically. In this case, we believe it is important to maintain the 5-year delay we originally proposed. As discussed above, data more recent than 5 years old may impose substantial competitive harm on market participants, such as by providing an unfair competitive advantage to new market entrants, who could use more recent data to determine current pricing arrangements between existing plans and providers and undermine their negotiation strategies. Such information would not be similarly available about new market entrants to existing plans.

Comment: One commenter stated that, if we release MA bid data without including MAO names or plan IDs, it is likely that some plan sponsors with unique internal cost structures will be publicly identifiable while other competitors may not be identifiable, giving certain plan sponsors serious competitive advantage over others.

Response: All MA plan sponsors will be identifiable in the bid data that we will release through the field labeled ''Organization Name.'' While there are some organization names in MA bids that differ from the name of the parent organization, a link can be established through an internet search if a member of the public is interested in making that connection.

Comment: Several commenters expressed skepticism about the necessity of using bid data for health policy research. One commenter stated that the proposed bid data release is unnecessary for purposes of ensuring program oversight or development of health policy; the commenter noted that MA bids are already subject to our review and approval and a bid audit process, and MedPAC analyzes bid data and issues an annual report describing program-wide trends. Another commenter expressed skepticism about the ability of researchers to use the data we proposed to release in an effective, appropriate way; the commenter supported our proposed exclusion of narrative information from the proposed release of MA bid pricing data but argued that researchers would find it extremely challenging if not impossible to fully understand a plan's bid without this excluded information. Finally, one commenter noted that we have made available on our Web site MA bid data that was requested under the FOIA, and asked whether this data had proven useful to researchers.

Response: As stated in the proposed rule, we believe that facilitating public research using MA bid pricing data could lead to better understanding of the costs and utilization trends in MA and support future policymaking for the MA program. We do not believe that it is possible for one researcher or one set of researchers to address all policy questions regarding the MA program. We expect that a wide range of research studies could complement the work published by MedPAC. We believe that MA bid data could be useful to researchers even without access to the narrative fields or supporting documentation, and we have not received any comments that demonstrate convincingly or with specific examples to change our position.

Finally, regarding the usefulness of currently available MA bid pricing data to researchers, one commenter pointed to research conducted by Dr. Brian Biles on behalf of the Commonwealth Fund, and his work to examine costs in MA. We believe that the data may be accessed again in the future for further research.

After consideration of the public comments received, we are choosing to finalize the proposed MA bid pricing data release, codified at § 422.272, and the proposed contractual acknowledgment of the release, codified at § 422.504(n)(2), without modification. We also finalize our proposal to amend § 422.504 by moving the existing provisions regarding the release of summary CMS payment data at existing paragraph (n) to paragraph (n)(1) and redesignating existing paragraphs (n)(1)(i) through (iv) and (n)(2) as (n)(1)(i)(A) through (D) and (n)(1)(ii), respectively. We appreciate the concerns raised by some commenters, and we believe that these concerns are addressed by our decision to delay our release of MA bid data by 5 years and to exclude certain information from release, as discussed above. We continue to believe that the release of MA bid pricing data is consistent with the Administration's directives regarding the transparency of program data, and will support public research that can potentially strengthen the program.

While we are not modifying any of the proposed exclusions, we note that we will withhold certain fields within the BPT where necessary to comply with our current cell size suppression policy. This policy stipulates that no cell (for example, admissions, discharges, patients, services, etc.) 10 or less may be displayed. For example, a plan with more than 11 enrollees may have fewer than 11 beneficiaries who receive benefits that fall under one of the BPT's service categories. The policy is designed and implemented in order to protect against disclosure of individually identifiable data as our analysis has indicated the potential to identify individuals where the information in the cell is based on 10 or fewer individuals. We interpret the regulation text in this final rule (that protects against and excludes from these disclosures ''information that could be used to identify Medicare beneficiaries or other individuals'') to support this suppression policy. Further, to the extent that the suppression policy is revised in the future for these purposes to apply to cell sizes based on more than 10 individuals, we will apply that updated policy under this rule. In order for our release of MA bid pricing data to be consistent with our cell size suppression policy, we may determine that certain fields in the BPT should be withheld or redacted.

c. Summary of Proposed Technical Change and Response to Public Comments

We proposed to amend § 422.250 on the basis and scope of the MA program to add a reference to section 1106 of the Act. As discussed in the proposed rule (81 FR 46396), section 1106(a) of the Act (42 U.S.C. 1306(a)) addresses requirements, including rulemaking, for the agency to release information filed with it by outside parties.

We received a few comments on the proposed technical change, summarized below with our response.

Comment: A few commenters expressed concern that we proposed releasing MA bid pricing data in the CY 2017 PFS proposed rule, rather than through a Part C and D rulemaking process. The commenters stated that this approach increased the likelihood that many stakeholders would have been unaware of our proposal in time to provide detailed analysis of the impacts of the proposed data releases, and one commenter suggested reissuing this proposal in a Parts C and D rulemaking.

Response: The Administrative Procedure Act (APA) and section 1871 of the Act generally require that rules be published in the **Federal Register** in proposed form, with a basis and purpose statement explaining the proposal, and then published in the **Federal Register** in final form, with revisions based on comments received, and responses to such comments. There is no requirement governing how proposed or final rules are packaged or organized, as long as the public is given proper notice. The proposed rule (81 FR 46162) clearly listed all Parts of the Medicare regulations that would be affected by the proposed regulations (including part 422) and its title included a reference to release of Medicare Advantage data (''. . . Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low [sic] Ratio Data Release . . .''), so there was adequate notice to the public of the content of the proposed rule. That fully satisfies the requirements of the APA and section 1871 of the Act.

The presence of this rider was clearly discussed in the title of the proposed rule, and was also discussed in the Fact Sheet we released to the public at the time of the rule's display. We received many comments from across the industry, including a number of comments from MAOs and their trade associations. This further demonstrates that adequate notice was provided.

After consideration of the public comments we received on the proposed technical amendment, we are finalizing the amendment as proposed.

3. Release of MLR Data

a. Summary of Proposed Rule

The proposed rule provided background on the Part C and Part D Medical Loss Ratio requirements, including the statutory and regulatory authority. An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. In the May 23, 2013 final rule (78 FR 31284), we codified the MLR requirements for MAOs and Part D sponsors in the regulations at 42 CFR part 422, subpart X, and part 423, subpart X, respectively.

For contracts beginning in 2014 or later, MAOs and Part D sponsors are required to report their MLRs and are subject to financial and other penalties for failure to meet the statutory requirement that they have an MLR of at least 85 percent (see § 422.2410 and § 423.2410). Section 1857(e)(4) of the Act requires several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination.

Under the regulations at § 422.2410 and § 422.2460, with respect to MAOs, and § 423.2410 and § 423.2460, with respect to Part D sponsors, for each contract year, each MAO and Part D sponsor is required to submit a report to us, in a timeframe and manner that we specify, which includes the data needed to calculate and verify the MLR and remittance amount, if any, for each contract. For each contract year beginning in 2014 or later, MAOs and Part D sponsors are required to enter their MLR data and upload their MLR Reports to our Health Plan Management System (HPMS). The MLR Report is on our Web site at *https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/medicallossratio.html,* accompanied by instructions on how to populate the Report.

In the proposed rule, we summarized the information collected in conjunction with the MLR requirement. We described the categories of information, including:

- Revenue.
- Claims.
- Federal and State Taxes and Licensing or Regulatory Fees.
- Health Care Quality Improvement Expenses.
- Non-claims Costs.
- Member Months.

We also described the process used to calculate the MLR with this information, including the numerator and denominator.

We explained the proposed regulatory changes to provide for the release of Part C and Part D MLR data, along with the manner in which we proposed to make the release. We proposed to codify the new requirements for the release of Part C and Part D MLR data by adding new regulations at § 422.504 (related to contract terms) and § 422.2490 (related to the details of the MLR data release) of part 422, with respect to Part C MLR data, and § 423.505 (related to contract terms) and § 423.2490 (related to the details of the MLR data release) of part 423, with respect to Part D MLR data. We proposed to define Part C MLR data at § 422.2490(a), and Part D MLR data at § 423.2490(a), as the data the MAOs and Part D sponsors submit to us in their annual MLR Reports, as required under existing § 422.2460 and § 423.2460. At § 422.2490(b) and § 423.2490(b), we proposed certain exclusions to the definitions of Part C MLR data and Part D MLR data, respectively. We proposed at § 422.2490(c) and § 423.2490(c) to release the Part C MLR data and Part D MLR data, respectively, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year.

We proposed to amend the regulation text at § 422.504 by adding a new paragraph (n)(2), which would require that an MAO acknowledge the release of Part C MLR data as provided in § 422.2490 as a mandatory contract provision. We also proposed to amend the regulation text at § 423.505(o) by adding a new paragraph (o)(2), which would require that a Part D sponsor acknowledge the release of Part D MLR data as provided in § 423.2490 as a mandatory contract provision. We proposed certain technical changes to § 422.504(n) and to § 423.505(o). The proposed rule did not discuss these changes to § 422.504(n) and § 423.505(o) in detail as part of the proposal to release Part C and Part D MLR data, but they were reflected in the proposed regulation text at 81 FR 46471–72. Our proposed technical changes to § 422.504(n) are described in section III.E.2.a of this final rule (''Summary of Proposed Rule''). With respect to § 423.505(o), we proposed to move the existing provisions regarding the release of summary CMS payment data at existing paragraph (o) to paragraph (o)(1) and to redesignate the existing paragraphs (o)(1) through (5) as (o)(1)(i) through (v).

We also explained the rationale for the proposed data release. As with our release of MA bid pricing data, discussed in section III.E.2.b of this final rule (''Comments''), our release of Part C and Part D MLR data is consistent with Administration initiatives to improve federal management of information resources by increasing data transparency and access to federal datasets. We also noted in the proposed rule that we already publicly release MLR data that issuers of commercial health plans submit each year as required by section 2718 of the Public Health Service Act. This data is listed publicly at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.* In releasing Part C and Part D MLR data, we are seeking to align with the disclosure of commercial MLR data.

Finally, we discussed our belief that Part C and Part D MLR data could be a valuable tool for consumers, researchers, and the public. We believe that the release of this data will facilitate public evaluation of the MA and Part D programs by providing insight into the efficiency of health insurers' operations. In addition, we believe that the release of certain MLR

data will provide beneficiaries with information that can be used to assess the relative value of Medicare health and drug plans. We acknowledged in the proposed rule that the commercial MLR varies from the Part C and Part D MLR in certain ways. For example, commercial MLR data is collected from issuers at the state level, aggregated by market, while Part C and Part D MLR data is collected at the contract level. Although the data is reported differently, we do not believe these differences are significant enough to merit a different approach to the public disclosure of data.

We also believe that the availability of Part C and Part D MLR data will enhance the competitive nature of the MA and Part D programs. The proposed access to data will support potential new plan sponsors in evaluating their participation in the Part C and Part D programs and will facilitate the entry into new markets of existing plan sponsors. With knowledge of historical MLR data, new business partners might emerge, and better business decisions might be made by existing partners. As a result, we believe that releasing Part C and Part D MLR data as proposed is both important and appropriate for the effective operation of these programs.

Further, we believe that the release of Part C and Part D MLR data, as described in this final rule, strikes the appropriate balance between our goals for the release of Part C and Part D MLR data and safeguarding information that could be commercially sensitive or proprietary. Costs in the MLR numerator are aggregated across providers, beneficiaries, and sites of service. Costs and revenues are further aggregated across all plans under the contract. We do not believe that there is a realistic possibility that the MLR data we release could be disaggregated or reverse engineered to reveal commercially sensitive or proprietary information.

We described the data we proposed to exclude from the public release. We stated that we would exclude the following four categories of data from release: narrative information, plan-level information (Part C MLR data and Part D MLR data that we will release is aggregated at the contract level), any information identifying beneficiaries or other individuals, and any MLR review correspondence.

First, at proposed § 422.2490(b)(1) and § 423.2490(b)(1), we proposed to exclude from release any narrative information that MAOs and Part D sponsors submit to support the amounts that they include in their MLR Reports, such as descriptions of the methods used to allocate expenses. MAOs and Part D sponsors are required to describe the methods they used to allocate expenses, including incurred claims, quality improvement expenses, federal and state taxes and licensing or regulatory fees, and other non-claims costs. A detailed description of each expense element is provided, including how each specific expense meets the criteria for the type of expense in which it is categorized. MAOs and Part D sponsors may provide information that is pertinent to more than the individual MA or Part D contract for which the MLR Report is being submitted (see, for example, § 422.2420(d)(1)(ii) and § 423.2420(d)(1)(ii), which requires that expenditures that benefit multiple contracts, or contracts other than those being reported, be reported on a pro rata share), such as an MAO's or Part D sponsor's approach to setting payment rates in contracts with providers, or its strategies for investing in activities that improve health quality. We proposed to exclude this narrative information because we believe that it is more competitively sensitive than the contract-level figures that are used to populate the non-narrative fields in the MLR Report. We are concerned that MAOs and Part D sponsors would be reluctant to submit narrative descriptions that include information that they regard as proprietary or confidential if they know that it will be disclosed to the public, which could impair our ability to assess whether their allocation methods are appropriate.

Second, at proposed § 422.2490(b)(2) and § 423.2490(b)(2), we proposed to exclude from release any plan-level information that MAOs and Part D sponsors submit in their MLR Reports. Some of the plan-level data in MAO's and Part D sponsors' MLR Reports is also included in their plan bids as base period experience data, such as plan IDs, plan member months, and Medicaid per member per month gain/loss. As discussed in our proposal to release certain MA bid pricing data, we believe bid data would no longer be competitively sensitive after 5 years; however, we do not believe that bid data becomes no longer competitively sensitive within the 18-month timeframe for our proposed release of MLR data. Therefore, we proposed to exclude from release plan-level data that is included as base period experience data in plan bids. We also proposed to exclude the plan-level information submitted in MLR Reports because we do not regard it as relevant to the purposes of our proposed release of Part C and Part D MLR data, which include giving the public access to data that can be used to evaluate the efficiency of MAOs and Part D sponsors and providing enrollees with information that can be used to compare the relative value of health plans. For example, our proposed release excludes MAOs' and Part D sponsors' responses to questions in the MLR Report that ask whether each plan under a contract is a Special Needs Plan for beneficiaries who are dually eligible for both Medicare and Medicaid (D–SNP), or whether the plan's defined service area includes counties in one of the territories.

Third, at proposed § 422.2490(b)(3) and § 423.2490(b)(3), we proposed to exclude from release any information identifying Medicare beneficiaries or other individuals. This exclusion was proposed for the same reason we proposed to exclude similar information from MA bid submission data that will be released: we believe that it is important to protect the privacy of individuals identified in these submissions, particularly Medicare beneficiaries. We explained that, consistent with our longstanding data release policy for protecting individually identifiable information, if a data field in the MLR Report for an MA or Part D contract is calculated based on figures associated with fewer than 11 enrollees (or 132 member months, assuming each individual is counted for 12 months), we would suppress all the data from such fields in the public release file for that contract.

Regarding other individuals, we require that MAOs and Part D sponsors provide in their MLR Reports the names and contact information of individuals who can answer questions about the data submitted in an MLR Report. We proposed to exclude this information from release. We do not believe that the release of this information serves the purposes of our proposed release of certain MLR data, which are to provide the public with data that can be used to evaluate MA and Part D contracts' efficiency, and to provide beneficiaries with information that can be used to compare the relative value of Medicare plans. Further, release of this identifying and contact information appears to be an unnecessary intrusion into information about private individuals.

Fourth, at proposed § 422.2490(b)(4) and § 423.2490(b)(4), we proposed to exclude from release any MLR review correspondence. In the course of the MLR review process, our reviewers may engage in correspondence with MAOs and Part D sponsors in order to validate amounts included in their MLR Reports. Such correspondence may include

requests for evidence of amounts reported to us. Responses to these requests could include proprietary or confidential information, such as MAOs' and Part D sponsors' negotiated rates of reimbursement. We believe that such information is more competitively sensitive than the contract-level figures that are used to populate the non-narrative fields in the MLR Report. Further, we are concerned that, if we were to publicly release this correspondence, it could cause MAOs and Part D sponsors to be less forthcoming in the information provided to us or our reviewers, which would impede our access to information that would we could use to verify the information submitted by MAOs and Part D sponsors.

We proposed to release the MLR data specified in this rule for each MA and Part D contract on an annual basis no earlier than 18 months after the end of the contract year to which the MLR data applies. We proposed to follow the commercial MLR approach in making the data we receive in MLR Reports available to the public. For Part C and Part D MLR reporting, the data is due about 12 months after the end of the contract year. After we receive MAOs' and Part D sponsors' MLR Reports, we anticipate that it will take approximately 6 months for us to review and finalize the data submitted by MAOs and Part D sponsors.

We recognize that the 18-month time lag time for the release of Part C and Part D MLR data differs from the 5-year delay used for the release of MA bid pricing data (discussed in section III.E.2.a of this final rule (''Summary of Proposed Rule'')). This difference in the length of the delay that applies to each of these data releases reflects key differences between the MA bid pricing data that we proposed to release in accordance with § 422.272 and the Part C and Part D MLR data that we proposed to in accordance with § 422.2490 and § 423.2490. Most importantly, the Part C and Part D MLR data that we proposed to release is aggregated at the contract level, and we are excluding any plan-level data. The MA bid pricing data that we proposed to release includes plan-level information. We believe that contract-level information is sufficiently aggregated such that it would be difficult to obtain an unfair competitive advantage from its review. For example, we do not believe it is possible to reverse-engineer provider rates from contract-level information.

Finally, we proposed to amend § 422.2400, which identifies the basis and scope of the MLR regulations for MAOs, and § 423.2400, which identifies the basis and scope of the MLR regulations for Part D sponsors, to add a reference to section 1106 of the Act, which governs the release of information gathered in the course of administering our programs under the Act.

We solicited comment on the release of MLR data as outlined above. We also solicited comment on whether the Part C and Part D MLR data we proposed to release contain proprietary information, and if so, what safeguards might be appropriate to protect those data, such as recommended fields to be redacted, the minimum length of time that such data remains commercially sensitive, and any suggestions for publishing aggregations of Part C and Part D MLR data in lieu of publishing the MLR data as submitted by MAOs and Part D sponsors. We invited commenters to provide analysis and explanations to support comments that information should be protected for a longer—or shorter—period of time so that we could properly evaluate our proposal in adopting a final rule. Analysis and explanations were requested to (1) cite the particular information proposed to be released and explain how that information differs from publicly available data; (2) point to the particular entity or entity type that could gain an unfair competitive advantage from the information release; and (3) fully explain the mechanism by which the release of that particular information would create an unfair competitive advantage for that particular entity. We requested this level of detail in order to substantiate the positions taken by commenters and to better inform our rulemaking and decisions (81 FR 46403).

b. Comments

The following is summary of the comments we received on our proposed regulatory changes providing for the release of Part C and Part D MLR data.

Comment: Several commenters expressed support for our proposal to release Part C and Part D MLR data, noting the benefits of transparency and advancing research, and improving healthcare delivery, as well as the cost of healthcare. A number of commenters also stated that release of Part C and Part D MLR data would help beneficiaries make informed choices when choosing between health plans. Two commenters added that releasing Part C and Part D MLR data would allow the public to see how MAOs and Part D sponsors administer Medicare and supplemental benefits in an effective and efficient manner.

Response: We appreciate the support.

Comment: Some commenters suggested that Part C and Part D MLR data would be unhelpful to the public, including researchers and beneficiaries, because it could be misconstrued. A few commenters stated that release of Part C and Part D MLR data as proposed would lead to misinterpretation and inappropriate comparisons across MA or Part D contracts, causing erroneous conclusions and misinformed policy decisions. Many commenters questioned whether the MLR data would be valuable or useful to Medicare beneficiaries.

Response: We appreciate the concerns raised. However, we continue to believe that releasing the MLR data is consistent with the Administration's commitment to transparency. In addition, while Medicare beneficiaries have multiple tools available to assist them in evaluating MA and Part D plans, we continue to believe that beneficiaries should have the opportunity to review Part C and Part D MLR information as an additional tool. We continue to believe that making the MLR data available to the research community will spur research that could support the goals of federal policymakers. Furthermore, we believe it is important to mirror the transparency created by the commercial MLR to the extent possible. As commercial MLR data is already being released, our proposal to release Part C and Part D MLR data is the next step in maintaining consistency.

Comment: Some commenters indicated that the commercial MLR data that we release each year is substantively different from the Part C and Part D MLR data, making the decision to release Part C and Part D MLR data one that should not be tied to the current disclosure of commercial MLR data. Two commenters noted that because the MLR Reports for MAOs and Part D sponsors are contract-based and MLR Reports for issuers in the commercial market are state-based, the Part C and Part D MLR Reports could be confusing to consumers and subject to misinterpretation.

Response: We acknowledge that there are differences between Part C and Part D MLR data and commercial MLR data. However, we do not believe these differences are substantial enough to merit withholding the Part C and Part D MLR data from public consumption when commercial MLR data is released annually. Although there are some differences between how the Part C and Part D MLR is reported in comparison with the commercial MLR, in all cases, the data is used to produce a final MLR

ratio, and we continue to believe that this data can be a valuable tool for beneficiaries and researchers, as discussed earlier in this rule.

Comment: Several commenters expressed support for our proposed exclusions of certain data from our proposed release of Part C and Part D MLR data, stating that aggregation and exclusions would help safeguard against the release of proprietary information.

Response: We appreciate the support.

Comment: Several commenters stated that the proposed release of Part C and Part D MLR data would cause significant competitive harm to plans in the MA and Part D markets through the disclosure of confidential and proprietary information. Some commenters suggested the data in the proposed release could provide insight into a plan's strategies related to provider agreements, pricing, or quality improvement activities.

Response: We appreciate the concerns raised by the commenters with respect to protecting proprietary information. We take very seriously the need to safeguard proprietary and confidential business information shared with the agency for purposes of participation in the MA and Part D programs. However, we do not believe that the information included in the proposed MLR release represents a threat to the competitive position of MAOs and Part D sponsors particularly as comparable data is already released for commercial plans. Through the comment period and rulemaking process, we provided MAOs and Part D sponsors the opportunity to offer specific, detailed examples of how the release of MLR data could lead to competitive harm. We do not believe any of the commenters provided such examples. Further, we believe that the exclusions described in the final rule will help protect plans' proprietary information.

However, to address concerns raised by commenters, we are expanding the data that would be subject to exclusion. First, we are revising our proposed exclusion of plan-level data at proposed § 422.2490(b)(2) and § 423.2490(b)(2) to state that we will not be releasing any MLR data submitted for contracts that consist of only one plan. Contract-level data for single-plan contracts is equivalent to plan-level data, which we regard as more competitively sensitive because it is at a lower level of aggregation. In expanding the exclusion at proposed § 422.2490(b)(2) and § 423.2490(b)(2) to include MLR data submitted for single-plan contracts, we are confirming our commitment not to release any plan-level MLR data. Second, we are excluding from release any MLR data for a contract in a contract year that the contract is determined to be non-credible, as defined in accordance with § 422.2440(d) for MA contracts and § 423.2440(d) for Part D contracts. Although, as we explain more fully below, we are adopting this new exclusion of non-credible contracts' MLR data for reasons other than the protection of proprietary information, we expect that this exclusion will address concerns about competitive harm for MAOs or Part D sponsors operating contracts with limited enrollment.

Comment: Several commenters asked us to aggregate the data further or expand the list of exclusions before release, in order to protect plans' proprietary and confidential information. One commenter suggested that we limit the release of MLR data to the aggregate categories that we listed in the preamble of the proposed rule at 81 FR 46404 (that is, ''Revenue,'' ''Claims,'' ''Federal and State Taxes and Licensing or Regulatory Fees,'' ''Health Care Quality Improvement Expenses,'' and ''Non-Claim Costs'') and the MLR calculation itself, without releasing the data for the component fields that make up each of these categories. Another commenter requested that we exclude any part of the MLR substantiation, including but not limited to the narrative included in the substantiation. In addition, we received two comments requesting that we not release Part C and Part D MLR data at a more granular level than the contract level. This would exclude the ''Plan-Specific Data'' section of the MLR Report. Another commenter stated that if we believe it is important for the public to further understand the breakdown of how revenue is spent, then we could consider releasing only the percent of revenue associated with incurred claims, quality improvement activities, and Part B premium rebates, in order to limit potential competitive harm.

Response: We appreciate the concerns raised by commenters, along with the proposed alternatives. We believe that the list of exclusions provided in the final rule is sufficient to protect plans against competitive harm. Where possible, we have sought to mirror the release policies for the commercial MLR, and we are not aware of any evidence demonstrating that the release of commercial MLR data has caused any competitive harm. We have also broadened the data subject to exclusion, as discussed above.

Comment: Several commenters urged us to not release Part C or Part D MLR data for single-plan contracts. One commenter requested further clarification regarding the plan-level information that we are proposing to exclude. The commenter asked that we state whether plan-level means at the plan benefit package (PBP) level or something else.

Response: We appreciate the comments submitted, and have expanded the data exclusions to not release data for single-plan contracts, since single-plan contract level data is functionally the same as plan-level data. The exclusion of plan-level data would also apply to data that is captured by the section of the MLR Report that is labeled ''Plan-Specific Data.'' We described the information collected in this section of the MLR Report in the proposed rule at 81 FR 46404. We explain above why the release of plan-level data that is as recent as 18 months old could cause substantial competitive harm.

Comment: One commenter expressed concern about the release of MLR data for contracts with a limited number of beneficiaries. This commenter suggested that we not release data for a contract in a year that the contract does not meet the minimum credibility threshold of 2,400 member months for MA contracts or 4,800 member months for Part D contracts.

Response: We agree with the commenter's concern about releasing Part C and Part D MLR data for contracts that have non-credible experience. We believe that publishing the MLR data for a contract in a contract year in which it has non-credible experience may be misleading and cause incorrect assumptions. As such, we have added an exclusion to our proposed release of Part C and Part D MLR data to specify that we will not release the MLR data for a contract in any contract year in which the contract is determined to be non-credible. This exclusion is added at § 422.2490(b)(5), with respect to Part C MLR data, and at § 423.2490(b)(5), with respect to Part D MLR data.

Currently, MA contracts are considered to be non-credible if they have fewer than 2,400 member months, and Part D contracts are considered non-credible if they have fewer than 4,800 member months. In the February 23, 2013 proposed rule (78 FR 12428, 12438–40), we explained our rationale for taking into account the number of enrollees under a contract when assessing Part C and Part D MLRs, stating, ''To avoid requiring MA organizations and Part D sponsors to pay remittances due to random claim variation, rather than due to their underlying pricing and benefits structure, it is necessary to assess MLRs

on sufficient numbers of member months for statistical credibility.'' In excluding from release MLR data submitted for contracts with non-credible experience, we recognize that these contracts' MLRs are more vulnerable to the effects of random variations in claims experience and may fail to reflect their efficiency or relative value. We wish to release MLR data that accurately and meaningfully reflects the value of MA and Part D plans; we do not believe that pro-active public release of MLR Reports for contracts that have non-credible experience furthers that goal. Therefore, we are finalizing the rule with an exclusion for any MLR data submitted for a contract in a year that the contract is determined to be non-credible.

Comment: A small number of commenters asked that we only release the final MLR for MA and Part D contracts (that is, the ratio that is calculated by dividing the MLR numerator by the MLR denominator), instead of the additional data included with MLR submissions. They stated that this would fulfill our goal of increased transparency, while protecting beneficiaries and researchers from drawing incorrect conclusions, and would safeguard confidential and proprietary information that could hurt competition.

Response: We appreciate the suggestion. Given that we already release annually the MLR data submitted by commercial plans, we believe that it would be inconsistent to release only the final MLR for MA and Part D contracts. As previously discussed, we do not believe that differences between the Part C and Part D MLRs and the commercial MLR are significant enough to merit a different approach to the public disclosure of data.

We have proposed appropriate exclusions and safeguards to protect proprietary business strategies. Completely excluding other information would not be consistent with the Administration's commitment to transparency.

Comment: Several commenters expressed support for our proposal to release MLR data on an annual basis no earlier than 18 months after the end of the contract year to which the MLR data applies. A few commenters stated that the proposed 18-month delayed release of MLR data would help balance the need for transparency and the potential for competitive harm.

Response: We appreciate the support.

Comment: We received one comment encouraging us to consider releasing MLR data that is more recent, and therefore, more useful to beneficiaries and researchers.

Response: We appreciate the commenter's concern. The decision to follow an 18-month delay was not intended only for the purpose of protecting proprietary interests. Part C and Part D MLR data is typically not collected until the end of the year following the contract year (for example, contract year 2014 data was not collected until December 2015). We must then review all submitted data for completeness and accuracy before determining whether MLRs are final. We continue to believe that the 18-month delay is appropriate, given these operational constraints.

Comment: Several commenters expressed concern that 18 months was not a sufficient period of time to ensure the release of data would not cause competitive harm. One commenter pointed out that because our revenue settlement is 8 months after the close of the year, and Part C and Part D MLR Reports are submitted at the end of that calendar year, MLR data would end up being released only 6 months after the data is filed with CMS, not the 18 months envisioned by the policy. Another commenter stated that data generally does not change significantly from year-to-year or across plans within a contract, and therefore, neither aggregation at the contract level nor an 18-month delay of release will provide sufficient protection. Several commenters asked that we release Part C and Part D MLR data using the same 5-year delay that was proposed for the release of bid data. A few commenters added that releasing such competitively sensitive information sooner than the 5-year lag could potentially injure plans and the program by harming competition among MA plans and driving up costs.

Response: We believe that the proposed 18-month delay of release of Part C and Part D MLR data will balance the need to make sure the data is complete with the desire to provide beneficiaries and researchers with data that is meaningful and helpful in plan selection and research. We selected a 5-year delay for bid pricing data because much of that data is collected at the plan level. Part C and Part D MLR data is aggregated to the contract level, and also includes a more limited range of information. Further, as we have noted, we do not believe that there will be competitive harm to MAOs or Part D plan sponsors as a result of the release of MLR reports as provided under this rule. Contract-level data is, as described above, sufficiently aggregated to avoid creating an unfair competitive advantage for particular entities, such as new market entrants, who would have access to such data without having to release such data themselves. It is not likely that entities, such as new market entrants, could use aggregated data to reverse-engineer pricing strategies, payments rates, or other competitively sensitive information.

Comment: One commenter urged us to utilize established public data release methodologies for the release of Part C and Part D MLR data. A few commenters also asked that we only release data through ResDAC to researchers.

Response: Through the Administration's continued commitment to transparency, we have significantly increased the amount of Medicare data available to the public in recent years, in part through the ResDAC portal. While we agree that ResDAC is a valuable resource, we believe that it is more appropriate in this instance to post the data directly to our Web site (*cms.gov*) for broader consumption. Because the data is aggregated to the contract level, we do not believe there is a significant risk associated with making the data more widely available.

Comment: A few commenters expressed concern that we proposed releasing Part C and Part D MLR data in the CY 2017 PFS proposed rule, rather than through a Part C and Part D rulemaking process. The commenters stated that this approach increased the likelihood that many stakeholders would have been unaware of our proposal in time to provide detailed analysis of the impacts of the proposed data releases, and one commenter suggested reissuing this proposal in a Parts C and D rulemaking.

Response: The Administrative Procedure Act (APA) and section 1871 of the Act generally require that rules be published in the **Federal Register** in proposed form, with a basis and purpose statement explaining the proposal, and then published in the **Federal Register** in final form, with revisions based on comments received, and responses to such comments. There is no requirement governing how proposed or final rules are packaged or organized, as long as the public is given proper notice. The proposed rule here clearly listed all Parts of the Medicare regulations that would be affected by the proposed regulations (including parts 422 and 423) and its title included a reference to release of Medicare Advantage and Part D data (''. . . Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low [sic] Ratio Data Release

. . .''), so there was adequate notice to the public of the content of the proposed rule (81 FR 46162). That fully satisfies the requirements of the APA and section 1871 of the Act.

The presence of this rider was clearly discussed in the title of the rule and in the Fact Sheet that we released publicly at the time of the rule's display. We received 26 comments on our proposed release of Part C and Part D MLR data from across the industry, including a number of comments from MAOs, Part D sponsors, and their trade associations. This further demonstrates that adequate notice was provided.

We also proposed to amend § 422.2400, which identifies the basis and scope of the MLR regulations for MAOs, and § 423.2400, which identifies the basis and scope of the MLR regulations for Part D sponsors, to add a reference to section 1106 of the Act, which governs the release of information gathered in the course of administering our programs under the Act. After consideration of public comments received on the technical changes, we are finalizing these technical changes to § 422.2400 and § 423.2400 as proposed.

After reviewing the comments we received, we are choosing to finalize the proposed MLR data release with two modifications. First, we will revise the exclusion at § 422.2490(b)(2), with respect to Part C MLR data, and at § 423.2490(b)(2), with respect to Part D MLR data, to exclude from release any MLR data submitted for a single-plan contract. Second, we add a new exclusion at § 422.2490(b)(5), with respect to Part C MLR data, and at § 423.2490(b)(5), with respect to Part D MLR data, to exclude from release any MLR data submitted for a contract in a contract year for which the contract is determined to be non-credible, as defined in accordance with § 422.2440(d) for MA contracts and § 423.2440(d) for Part D contracts. We continue to believe that the release of MLR data is consistent with the Administration's directives regarding the transparency of program data, and we support public research that can potentially strengthen the program.

F. Prohibition on Billing Qualified Medicare Beneficiary Individuals for Medicare Cost-Sharing

As we stated in the CY 2017 proposed rule, we remind all Medicare providers (including providers of services defined in section 1861 of the Act and physicians) that federal law prohibits them from collecting Medicare Part A and Medicare Part B deductibles, coinsurance, or copayments, from beneficiaries enrolled in the Qualified Medicare Beneficiaries (QMB) program (a Medicaid program which helps certain low-income individuals with Medicare cost-sharing liability). In July 2015, we released a study finding that confusion and inappropriate balance billing persist notwithstanding laws prohibiting Medicare cost-sharing charges for QMB individuals, Access to Care Issues Among Qualified Medicare Beneficiaries (QMB) (''Access to Care'') *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Access_to_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf*.

These findings underscore the need to re-educate providers about proper billing practices for QMB enrollees.

In 2013, approximately 7 million Medicare beneficiaries were enrolled in the QMB program. State Medicaid programs are liable to pay Medicare providers who serve QMB individuals for the Medicare cost-sharing. However, as permitted by federal law, states can limit provider payment for Medicare cost-sharing to the lesser of the Medicare cost-sharing amount, or the difference between the Medicare payment and the Medicaid rate for the service. Regardless, as stated in the CY 2017 proposed rule, Medicare providers must accept the Medicare payment and Medicaid payment (if any, and including any permissible Medicaid cost sharing from the beneficiary) as payment in full for services rendered to a QMB individual. Medicare providers who violate these billing prohibitions are violating their Medicare Provider Agreement and may be subject to sanctions. (See sections 1902(n)(3), 1905(p), 1866(a)(1)(A), and 1848(g)(3) of the Act.)

Additionally, as we stated in the CY 2017 proposed rule, Medicare providers should take steps to educate themselves and their staff about QMB billing prohibitions and to exempt QMB individuals from impermissible Medicare cost-sharing billing and related collection efforts. For more information about these requirements, steps to identify QMB patients and ways to promote compliance, see *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se1128.pdf*.

Given that original Medicare providers may also serve Medicare Advantage enrollees, we again note that the CY 2017 Medicare Advantage Call Letter reiterates the billing prohibitions applicable to dual eligible beneficiaries (including QMBs) enrolled in Medicare Advantage plans and the responsibility of plans to adopt certain measures to protect dual eligible beneficiaries from unauthorized charges under § 422.504(g). (See pages 181–183 at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf*).

Although we did not solicit comments on this statement of current law and policy, we appreciate the comments received, which included comments from national beneficiary advocacy organizations, and professional, insurance, and medical billing associations.

Comment: Commenters concurred that confusion and improper QMB billing problems remain pervasive and affirmed their negative toll on beneficiaries. Commenters were supportive of CMS's expanded efforts to educate providers regarding QMB billing rules to reduce the incidence of improper QMB billing. Some commenters also noted that Medicare providers encounter difficulties discerning which patients are QMBs and advised CMS to adopt strategies to help providers ascertain this information. Additionally, one commenter noted that the variation in state policies to pay providers for Medicare cost-sharing fuels confusion, frustration and compliance problems.

Response: We continue to pursue opportunities to educate providers and welcome partnering with commenters and others in these efforts. Currently, Medicare providers must determine a patient's QMB status through information from State Medicaid agencies, including online eligibility systems and beneficiary identification cards. We are actively exploring additional mechanisms for Medicare providers to readily identify the QMB status of patients.

G. Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number

1. Overview and Background

Medicare payments to providers and suppliers may be offset or recouped, in whole or in part, by a Medicare Administrator Contractor (MAC) if the MAC or CMS has determined that a provider or supplier has been overpaid. Historically, we have used the Medicare provider billing number or National Provider Identifier (NPI) to recoup overpayments from Medicare providers and suppliers until these debts were paid in full or eligible for referral to the Department of Treasury (Treasury) for further collection action under the Debt

Collection Improvement Act of 1996 and the Digital Accountability and Transparency Act of 2014. Once an overpayment is referred to Treasury, the Treasury's Debt Management Services uses various tools to collect the debt, including offset of federal payments against entities that share the same provider Taxpayer Identification Number (TIN). Hence, Treasury has the ability to collect our overpayments using the provider TIN and we pay a fee for every collection made.

On March 23, 2010, the Affordable Care Act (ACA) was enacted. Section 6401(a)(6) of the Affordable Care Act established a new section 1866(j)(6) of the Act. Section 1866(j)(6) of the Act allows the Secretary to make any necessary adjustments to the payments to an applicable provider of services or supplier to satisfy any amount due from an obligated provider of services or supplier. The statute defines an applicable provider of services or supplier (applicable provider) as a provider of services or supplier that has the same taxpayer identification number as the one assigned to the obligated provider of services or supplier. The statute defines the obligated provider of services or supplier (obligated provider) as a provider of services or supplier that owes a past-due overpayment to the Medicare program. For purposes of this provision, the applicable and obligated providers must share a TIN, but may possess a different billing number or National Provider Identifier (NPI) number than one another.

For example, a health care system may own a number of hospital providers and these providers may share the same TIN while having different NPI or Medicare billing numbers. If one of the hospitals in this system receives a demand letter for a Medicare overpayment, then that hospital (Hospital A) will be considered the obligated provider while its sister hospitals (Hospitals B and C) will be considered the applicable providers. This authority allows us to recoup the overpayment of the obligated provider, Hospital A, against any or all of the applicable providers, Hospitals B and C, with which it, Hospital A, shares a TIN.

2. Provisions of the Proposed Regulations

If CMS or a Medicare contractor has decided to put into effect an offset or recoupment, then § 405.373(a) requires the Medicare contractor to notify the provider or supplier in writing of its intention to fully or partially offset or recoup payment and the reasons for the offset or recoupment. Currently, the written demand letter sent by the Medicare contractor to a provider or supplier serves as notification of the overpayment and intention to recoup or offset if the obligated provider, Hospital A, fails to repay the overpayment in a timely manner.

With the passage of section 1866(j)(6) of the Act, the requirements in § 405.373(a) could be interpreted to require the Medicare contractor to provide notification to both the obligated provider, Hospital A, and the applicable provider, Hospital B, of its intention to recoup or offset payment. Because we don't think it is necessary to provide separate notice to both the obligated provider and the applicable provider, we proposed to amend the notice requirement in § 405.373. Specifically, we proposed to create a new paragraph (f) in § 405.373 to state that § 405.373(a) does not apply in instances where the Medicare Administrative Contractor intends to offset or recoup payments to the applicable provider of services or supplier to satisfy an amount due from an obligated provider of services or supplier when the applicable and obligated provider of services or supplier share the same Taxpayer Identification Number.

Before the effective date of this rule, we intend to notify all potentially affected Medicare providers of the implementation of section 1866(j)(6) of the Act through Medicare Learning Network (MLN) or MLN Connects Provider eNews article(s). We also intend to update the current Internet Only Manual instructions including, the Medicare Financial Management Manual, and the addition of clarifying language in the demand letters issued to obligated providers. We believe these actions would provide adequate notice to providers and suppliers sharing a TIN, if they choose, provide the opportunity to implement a tracking system of Medicare overpayments on the corporate level for the affected providers. We also believe these actions are sufficient because of Treasury's analogous practice of offsetting using a TIN without furnishing notice to all potentially affected providers and suppliers. It has been a long standing practice for Treasury to offset federal payments using the TIN and Treasury currently does not issue a notice of intent to recoup or offset to applicable providers and suppliers when Treasury recoups CMS overpayments.

Additionally, in our review of § 405.373(a) and (b), we proposed to replace the terms intermediary and carrier with the term Medicare Administrative Contractor as intermediaries and carriers no longer exist.

The following is a summary of the comments we received on recoupment or offset of payments to providers sharing the same taxpayer identification number.

Comment: One commenter disagreed with our assertion that there is no need for its contractors to notify either party when such a recoupment will be made. The commenter recommended that CMS should not finalize its proposal to eliminate notice to the applicable provider and the obligated provider in the event of a recoupment of an overpayment.

Response: We continue to believe it is not necessary to provide separate notice to both the obligated provider and the applicable provider. We believe that updating the Medicare Financial Management Manual, as well as including clarifying language in the demand letters issued will provide sufficient notification to providers and suppliers sharing a TIN. In addition, we believe the publication of this rule and notification through a Medicare Learning Network article provides sufficient notice to providers and suppliers sharing the same TIN and allows these providers and suppliers sufficient time to implement a tracking system of Medicare overpayments on a corporate level, should they choose. Finally, offsetting using a TIN without furnishing notice to all potentially affected providers and suppliers is a long standing practice used by Treasury to collect Medicare overpayments.

Comment: One commenter recommended CMS recoup payments based upon the combination of the TIN and individual NPI.

Response: We do not believe the intent of section 1866(j)(6) of the Act is to use a combination of the TIN and individual NPI to offset Medicare overpayments. We view section 1866(j)(6) of the Act as giving the agency the authority to recoup payments from an applicable provider or supplier that are due from an obligated provider or supplier that shares the same TIN. Accordingly, we will finalize the rule as proposed.

H. Accountable Care Organization (ACO) Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately

The Affordable Care Act gives the Secretary authority to incorporate reporting requirements and incentive payments from certain Medicare programs into the Shared Savings Program, and to use alternative criteria to determine if payments are warranted.

Specifically, section 1899(b)(3)(D) of the Act affords the Secretary discretion to incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848 of the Act, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848, and permits the Secretary to use alternative criteria than would otherwise apply (under section 1848 of the Act) for determining whether to make such payments.

Current Shared Savings Program regulations at § 425.504(c) do not allow eligible professionals (EPs) billing through the Taxpayer Identification Number (TIN) of an Accountable Care Organization (ACO) participant to participate in PQRS outside of the Shared Savings Program, and these EPs and the ACO participants through which they bill may not independently report for purposes of the PQRS apart from the ACO. This policy was designed to ease reporting burden for individual EPs and group practices and promote integration of providers and suppliers within the ACO in order to help achieve the Shared Savings Program goals of improving quality and coordination of care. While over 98 percent of ACOs satisfactorily report their quality data annually, if an ACO fails to satisfy the PQRS reporting requirements, the individual EPs and group practices participating in that ACO will receive the PQRS payment adjustment along with the automatic VM downward payment adjustment.

We proposed to amend the regulation at § 425.504 to permit EPs that bill under the TIN of an ACO participant to report separately for purposes of the 2018 PQRS payment adjustment when the ACO fails to report on behalf of the EPs who bill under the TIN of an ACO participant. Specifically, we proposed to remove the requirement at § 425.504(c)(2) so that, for purposes of the reporting period for the 2018 PQRS payment adjustment (that is, January 1, 2016, through December 31, 2016), EPs who bill under the TIN of an ACO participant have the option of reporting separately as individual EPs or group practices. If the ACO fails to satisfactorily report on behalf of such EPs or group practices, we proposed to consider this separately reported data for purposes of determining whether the EPs or group practices are subject to the 2018 PQRS payment adjustment. We also proposed to amend § 425.504(c)(2) to apply only for purposes of the 2016 payment adjustment. We proposed revised requirements for the 2017 and 2018 PQRS payment adjustments under the Shared Savings Program at § 425.504(d). We refer readers to section III.K.1.e. of this final rule for a more detailed discussion of the proposed revisions to the requirements at § 425.504 and the policies that are being finalized in this final rule.

In the proposed rule, we noted that the registration deadline for participating in the PQRS Group Practice Reporting Option (GPRO) is June 30 of the applicable reporting period. Since affected EPs are not able to register for the PQRS GPRO by the applicable deadline for the 2018 PQRS payment adjustment, we proposed that such EPs would not need to register for the PQRS GPRO for the 2018 PQRS payment adjustment, but rather could mark the data as group-level data in their submission. Thus, we proposed to eliminate a registration process for groups submitting data using third party entities. When groups submit data utilizing third party entities, such as a qualified registry, qualified clinical data registry (QCDR), direct Electronic Health Record (EHR) product, or EHR data submission vendor, we are able to obtain group information from the third party entity and discern whether the data submitted represents a group-level submission or an individual-level submission once the data is submitted. In addition, we proposed that an affected EP may utilize the secondary reporting period either as an individual EP using one of the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options or as a group practice using one of the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options. We noted that this would exclude, for individual EPs, the claims reporting option and, for group practices, the Web Interface and certified survey vendor reporting options.

Furthermore, we recognized that certain EPs are similarly situated with regard to the 2017 PQRS payment adjustment, which will be applied beginning on January 1, 2017. We stated that we believe it is appropriate and consistent with our stated policy goals to afford these EPs the benefit of this proposed policy change. Accordingly, as noted above, we proposed to permit EPs that bill through the TIN of an ACO participant to report separately for purposes of the 2017 PQRS payment adjustment if the ACO failed to report on behalf of the EPs who bill under the TIN of an ACO participant. Specifically, we proposed to remove the requirements at § 425.504(c)(2) so that, for purposes of the reporting period for the 2017 PQRS payment adjustment, EPs who bill under the TIN of an ACO participant have the option of reporting separately as individual EPs or group practices. As noted in this final rule, we proposed to amend § 425.504(c)(2) to apply only for purposes of the 2016 payment adjustment. We proposed to include the revised requirements for the 2017 and 2018 PQRS payment adjustments under the Shared Savings Program at § 425.504(d). We refer readers to the discussion of this proposal and the final policies that we are adopting in section III.K.1.e. of this final rule.

The previously established reporting period for the 2017 PQRS payment adjustment is January 1, 2015, through December 31, 2015. To allow affected EPs that participate in an ACO to report separately for purposes of the 2017 PQRS payment adjustment, we proposed at § 414.90(j)(1)(ii) to establish a secondary PQRS reporting period for the 2017 PQRS payment adjustment for individual EPs or group practices who bill under the TIN of an ACO participant if the ACO failed to report on behalf of such individual EPs or group practices during the previously established reporting period for the 2017 PQRS payment adjustment. We proposed that this option would be limited to EPs that bill through the TIN of an ACO participant in an ACO that failed to satisfactorily report on behalf of its EPs and would not be available to EPs that failed to report for purposes of PQRS outside the Shared Savings Program.

In addition, we proposed that these affected EPs may utilize the secondary reporting period either as an individual EP using the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options or as a group practice using one of the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options. We noted that this would exclude, for individual EPs, the claims reporting option and, for group practices, the Web Interface and certified survey vendor reporting options.

We note that the registration deadline for the participating in the PQRS GPRO is June 30 of the applicable reporting period. Since the applicable deadline for the 2017 PQRS payment adjustment has passed, we proposed that such EPs would not need to register for the PQRS GPRO for the 2017 PQRS payment adjustment, but rather would be able to report as a group practice via the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options. Therefore, we proposed at § 414.90(j)(4)(v) that sections

§ 414.90(j)(8)(ii), (iii), and (iv) would apply to affected EPs reporting as individuals using this secondary reporting period for the 2017 PQRS payment adjustment. In addition, we proposed at § 414.90(j)(7)(viii) that sections § 414.90(j)(9)(ii), (iii), and (iv) would apply to affected EPs reporting as group practices using this secondary reporting period for the 2017 PQRS payment adjustment. Further, we proposed at § 414.90(k)(4)(ii) that § 414.90(k)(5) would apply to affected EPs reporting as individuals or group practices using this secondary reporting period for the 2017 PQRS payment adjustment.

We also proposed that the secondary reporting period for the 2017 PQRS payment adjustment would coincide with the reporting period for the 2018 PQRS payment adjustment (that is, January 1, 2016 through December 31, 2016). In addition, for operational reasons and to minimize any additional burden on affected EPs (who are already required to report for CY 2016 for purposes of the 2018 PQRS payment adjustment), we proposed to assess the individual EP or group practice's 2016 data using the applicable satisfactory reporting requirements for the 2018 PQRS payment adjustment (including, but not limited to, the applicable PQRS measure set). We invited comment on any 2018 requirements that might need to be modified when applied for purposes of the 2017 PQRS payment adjustment.

As a result, individual EP or group practice 2016 data could be used with respect to the secondary reporting period for the 2017 PQRS payment adjustment or for the 2018 PQRS payment adjustment or for both payment adjustments if the ACO in which the affected EPs participate failed to report for purposes of the applicable payment adjustment. We explained that we believe this change to our program rules is necessary for affected individual EPs and group practices to be able to take advantage of the additional flexibility proposed for the Shared Savings Program (81 FR 46426 through 45427). If an affected individual EP or group practice decides to use the secondary reporting period for the 2017 PQRS payment adjustment, we explained that this EP or group practice should expect to receive a PQRS payment adjustment for services furnished in 2017 until CMS is able to determine that the EP or group practice satisfactorily reported for purposes of the 2017 PQRS payment adjustment. First, we would need to process the data submitted for 2016. Second, we would need to determine whether or not the individual EP or group practice met the applicable satisfactory reporting requirements for the 2018 PQRS payment adjustment. Third, we would need to update the individual EP or group practice's status so that the EP or group practice stops receiving a negative payment adjustment on claims for services furnished in 2017 and reprocess all claims that were previously paid. In addition, as discussed in the proposed rule, the EP or group practice would also avoid the automatic downward VM adjustment, but would not qualify for an upward adjustment since the ACO failed to report (81 FR 46446).

Since EPs and group practices taking advantage of this secondary reporting period for the 2017 PQRS payment adjustment will have missed the deadline for submitting an informal review request for the 2017 PQRS payment adjustment, we proposed that the informal review submission periods for these EPs or group practices would occur during the 60 days following the release of the PQRS feedback reports for the 2018 PQRS payment adjustment.

We requested comments on these proposals.

The following is summary of the comments we received on ACO participants who report PQRS quality measures separately.

Comment: The majority of commenters supported CMS's proposal to allow affected EPs or group practices to use CY 2016 as a secondary reporting period for purposes of the 2017 PQRS payment adjustment, in which case such EPs or group practices should expect to receive a PQRS payment adjustment for services furnished in 2017 until CMS is able to determine that the EP or group practice satisfactorily reported for purposes of the 2017 PQRS payment adjustment. In addition, the commenters supported CMS's proposal to allow EPs or group practices that bill under the TIN of an ACO participant to report separately for purposes of the PQRS payment adjustment if the ACO fails to report on their behalf; the commenters believed this proposal provides flexibility for EPs and group practices to avoid penalties under PQRS and VM when ACOs fail to report the data. Another commenter supported the proposal to retain the requirement that an ACO satisfactorily report on behalf of the EPs who bill under the TIN of an ACO participant for purposes of the PQRS payment adjustment. One commenter stated that they appreciated the elimination of the registration process for groups using third party entities.

Response: We would like to clarify that the elimination of the GPRO registration process would only apply to EPs and groups that participate in ACOs that fail to report on their behalf.

Comment: One commenter stated that affected EPs or group practices would not be aware that the ACO did not satisfactorily report for purposes of the 2018 PQRS payment adjustment and, absent such information, would not choose to report outside the ACO during the CY 2016 reporting period. Another commenter noted that many EPs in an ACO will not report data separately during the reporting period if they are operating under the assumption that their ACO is reporting on their behalf. In addition, other commenters urged CMS to invest in strategies to prevent these situations from occurring in the first place, such as providing ACOs with more frequent feedback on their reporting compliance throughout the year.

Response: We expect that any ACO that is unable to meet satisfactory reporting requirements for any reason would inform the EPs participating in the ACO in a timely and transparent manner to allow the EPs to report separately using the registry, QCDR, direct EHR or EHR data submission vendor reporting options. Therefore, if an EP or group practice has reason to believe their ACO may not report on their behalf in 2016, they have the ability to report separately for purposes of the 2018 PQRS payment adjustment. In regards to providing ACOs with more frequent feedback on their reporting compliance, we provide many opportunities for ACOs to monitor their progress toward the satisfactory reporting requirement while the Web Interface is open for data collection. Throughout the data collection period, and when the ACO has finished its abstraction, ACOs may use reports available in the Web Interface to confirm whether or not the Web Interface reporting requirements have been met. Leading up to the data collection period and during the data collection period, we provide frequent reminders to ACOs on the importance of reporting and how to satisfactorily report. We also provide targeted outreach to ACOs who have not entered data into the Web Interface in the final weeks of the data collection period, in an effort to ensure that all ACOs completely report.

Comment: One commenter acknowledged the difficulty in adding a second reporting period for affected EPs and group practices, and therefore, urged flexibility on the part of CMS to determine a way to provide an

additional reporting period in 2017 for purposes of the 2018 PQRS payment adjustment for EPs and group practices that participate in ACOs that fail to report for purposes of the 2018 PQRS payment adjustment. Another commenter encouraged CMS to allow affected EPs and group practices to report PQRS data separately during the year following the CY 2016 reporting period in order for them to avoid penalties during the 2018 payment year.

Response: As discussed in section III.K.1.e. of this final rule, we are finalizing our proposal to remove the requirement at § 425.504(c)(2) so that, for purposes of the reporting periods for the 2017 and 2018 PQRS payment adjustments, EPs who bill under the TIN of a Shared Savings Program ACO participant have the option of reporting separately as individual EPs or group practices. We disagree with the commenter's suggestions to establish a secondary reporting period for the 2018 PQRS payment adjustment, in addition to the 2017 PQRS payment adjustment. We believe there is adequate time for EPs or group practices to report separately for the 2018 payment adjustment given that this final rule will be issued more than a month prior to the end of the reporting period for the 2018 payment adjustment (that is, January 1, 2016 through December 31, 2016).

Comment: Several commenters stated their support for CMS's recognition of the individual commitment to quality improvement of EPs in ACOs and CMS's proposals that would enable them to avoid penalties in situations where their ACO fails to meet satisfactory reporting requirements. The commenters stated that individual EPs and group practices are not in direct control of decisions or actions taken by the larger ACO, and therefore, should not be penalized. In fact, the commenters stated that many EPs do not even know they are part of an ACO and prefer instead to report more directly relevant measures, such as those available through a QCDR. As an alternative to giving these EPs another opportunity to report data, a few commenters believed that EPs should instead be held harmless or provided a waiver from a negative payment adjustment if the ACO fails to report.

Response: We appreciate the commenters' support. However, we do not believe that EPs should be held harmless or provided a waiver if the ACO fails to report on their behalf. As discussed above, we believe it is reasonable and appropriate to expect that any ACO that is unable to meet satisfactory reporting requirements for any reason would inform the EPs participating in the ACO in a timely and transparent manner to allow the EPs to report separately using the registry, QCDR, direct EHR or EHR data submission vendor reporting options. However, if an EP or group practice has reason to believe their ACO may not report on their behalf in 2016, they have the ability to report separately for purposes of the 2018 PQRS payment adjustment. In addition, by permitting EPs and group practices to report separately from the ACO in such cases, we are giving them flexibility to report more directly relevant measures if they so choose.

Comment: One commenter supported CMS's proposal to allow affected EPs to report separately via a registry, QCDR, direct EHR or EHR data submission vendor.

Response: We appreciate the commenter's support for our proposal.

Comment: One commenter recommended that for the CY 2016 reporting period: (1) In cases where measures data are submitted by both the EP and the ACO, the best performance should be counted and the EP should be eligible for a positive payment adjustment; or (2) in cases where the EP does not opt to report outside the ACO, and the ACO fails to report, the EP should receive a neutral payment adjustment (that is, the EP should be held harmless from a negative payment adjustment and be ineligible for a positive payment adjustment).

Response: PQRS only assesses whether or not an EP or group practice satisfactorily reported quality data or satisfactorily participated in a QCDR. PQRS does not apply positive payment adjustments or adjust payments based on an EP or group practice's performance on the quality measures. However, the VM does apply positive payment adjustments and adjust payments based on the EP or group practice's performance. We refer readers to section III.L.3.b. of this final rule for a discussion of the VM policies in this scenario.

Comment: One commenter stated that reporting the previous year's data is burdensome, particularly for registry measures. The commenter believed that requiring EPs to report separately from the ACO effectively penalizes the EP for the ACO's error. Instead, the commenter suggested that CMS impose a negative payment adjustment on the ACOs when they fail to report. For the 2017 PQRS payment adjustment, the commenter recommended that affected EPs be held harmless by receiving no payment adjustment. The commenter stated that retroactive reporting would be burdensome to the EPs and would require information reported using QCDRs and EHRs to simultaneously meet the reporting requirements and measures of multiple years.

Response: We would like to clarify that we are not requiring affected EPs or group practices to report the previous year's data. EPs or group practices that are taking advantage of the secondary reporting period for the 2017 PQRS payment adjustment would be reporting data from CY 2016 and would be assessed using the applicable reporting requirements for the 2018 PQRS payment adjustment (including, but not limited to, the applicable PQRS measure set). In addition, we note that the PQRS payment adjustment does not apply to ACOs, and therefore, we cannot impose a negative payment adjustment on the ACOs when they fail to satisfactorily report.

Out of Scope Comments

We received a few comments for this section that are out of scope for this final rule. We received comments pertaining to the following: (1) Support for CMS' proposal that EPs participating in an ACO under the Shared Savings Program that satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when the EP extracts data necessary for the ACO to satisfy the quality reporting requirements under the Shared Savings Program from CEHRT and when the ACO reports the ACO GPRO measures through the CMS Web Interface; (2) recommendation that under MIPS, CMS use the PQRS data (either submitted by the ACO or separately by the ACO participant) which would generate the highest score for the quality performance category; and (3) requested guidance in the final rule for EPs, such as rehabilitation therapists, who are currently subject to PQRS, but will not be subject to MIPS until 2021 at the earliest.

After consideration of the comments received regarding our proposed policies for EPs and group practices participating in ACOs that report PQRS quality measures separately from the ACO, we are finalizing the policies as proposed. At § 414.90(j)(1)(ii), we are finalizing our proposal to establish a secondary PQRS reporting period for the 2017 PQRS payment adjustment for individual EPs or group practices who bill under the TIN of an ACO participant if the ACO failed to report on behalf of such individual EPs or group practices during the previously established reporting period for the 2017 PQRS payment adjustment. This option is limited to EPs and group practices that bill through the TIN of an

ACO participant in an ACO that failed to satisfactorily report on behalf of its EPs and would not be available to EPs and group practices that failed to report for purposes of PQRS outside the Shared Savings Program. We are finalizing our proposal that these affected EPs may utilize the secondary reporting period either as an individual EP or as a group practice using one of the registry, QCDR, direct EHR product, or EHR data submission vendor reporting options. We are also finalizing our proposal that such EPs do not need to register for the PQRS GPRO for the 2017 PQRS payment adjustment. In addition, we are finalizing at § 414.90(j)(4)(v) our proposal that sections § 414.90(j)(8)(ii), (iii), and (iv) would apply to affected EPs reporting as individuals using this secondary reporting period for the 2017 PQRS payment adjustment. Further, we are finalizing at § 414.90(j)(7)(viii) our proposal that sections § 414.90(j)(9)(ii), (iii), and (iv) would apply to affected EPs reporting as group practices using this secondary reporting period for the 2017 PQRS payment adjustment. We are finalizing at § 414.90(k)(4)(ii) our proposal that § 414.90(k)(5) would apply to affected EPs reporting as individuals or group practices using this secondary reporting period for the 2017 PQRS payment adjustment. We are finalizing our proposal that the secondary reporting period for the 2017 PQRS payment adjustment would coincide with the reporting period for the 2018 PQRS payment adjustment (that is, January 1, 2016 through December 31, 2016). In addition, we are finalizing a policy under which we will assess the individual EP or group practice's 2016 data using the applicable satisfactory reporting requirements for the 2018 PQRS payment adjustment (including, but not limited to, the applicable PQRS measure set). If an affected individual EP or group practice decides to use the secondary reporting period for the 2017 PQRS payment adjustment, the EP or group practice should expect to receive a PQRS payment adjustment for services furnished in 2017 until we are able to determine that the EP or group practice satisfactorily reported for purposes of the 2017 PQRS payment adjustment. Further, we are finalizing our proposal that the informal review submission periods for these EPs or group practices would occur during the 60 days following the release of the PQRS feedback reports for the 2018 PQRS payment adjustment.

I. Medicare Advantage Provider Enrollment

1. Background

a. General Overview

The Medicare program is the primary payer of health care for approximately 54 million beneficiaries and enrollees. Section 1802(a) of the Act permits beneficiaries to obtain health services from any individual or organization qualified to participate in the Medicare program. Providers and suppliers furnishing items or services must comply with all applicable Medicare requirements stipulated in the Act and codified in the regulations. These requirements are meant to promote quality care while protecting the integrity of the program. As a major component of our fraud prevention activities, we have increased our efforts to prevent unqualified individuals or organizations from enrolling in Medicare.

The term ''provider of services'' is defined in section 1861(u) of the Act as a hospital, a critical access hospital (CAH), a skilled nursing facility (SNF), a comprehensive outpatient rehabilitation facility (CORF), a home health agency (HHA), or a hospice. The term ''supplier'' is defined in section 1861(d) of the Act as, unless context otherwise requires, a physician or other practitioner, facility or other entity (other than a provider of services) that furnishes items or services under title XVIII of the Act. Other supplier categories may include, for example, physicians, nurse practitioners, and physical therapists.

Providers and suppliers that fit into these statutorily defined categories may enroll in Medicare if they meet the proper screening and enrollment requirements. This final rule will require providers and suppliers in MA organization networks and other designated plans (hereafter including MA–PD plans, FDRs, PACE, Cost HMOs or CMPs, demonstration programs, pilot programs, locum tenens suppliers, and incident-to suppliers) to be enrolled in Medicare in an approved status. We generally refer to an ''approved status'' as a status whereby a provider or supplier is enrolled in, and is not revoked from, the Medicare program. For example, a provider or supplier that has submitted an application, but has not completed the enrollment process with their respective Medicare Administrative Contractor (MAC), is not enrolled in an approved status. The submission of an enrollment application does not deem a provider or supplier enrolled in an approved status. A provider or supplier that is currently revoked from Medicare is not in an approved status. Out-of network or non-contract providers and suppliers are not required to enroll in Medicare to meet the requirements of this final rule with respect to furnishing items and services to MA enrollees.

b. Background

To receive payment for a furnished Medicare Part A or Part B service or item, or to order, certify, or prescribe certain Medicare services, items, and drugs, a provider or supplier must enroll in Medicare. The enrollment process requires the provider or supplier to complete, sign, and submit to its assigned Medicare contractor the appropriate Form CMS–855 enrollment application. The CMS–855 application form captures information about the provider or supplier that is needed for CMS or its contractors to screen the provider or supplier, verify the information provided, and determine whether the provider or supplier meets all Medicare requirements. This screening prior to enrollment helps to ensure that unqualified individuals and entities do not bill Medicare and that the Medicare Trust Funds are accordingly protected. Data collected and verified during the enrollment process generally includes, but is not limited to: (1) Basic identifying information (for example, legal business name, tax identification number); (2) state licensure information; (3) practice locations; and (4) information regarding ownership and management control.

We strive to further strengthen the provider and supplier enrollment process to prevent problematic providers and suppliers from entering the Medicare program. This includes, but is not limited to, enhancing our program integrity monitoring systems and revising our provider and supplier enrollment regulations in 42 CFR 424, subpart P, and elsewhere, as needed. With authority granted by the Act, including provisions in the Affordable Care Act, we have revised our provider and supplier enrollment regulations by issuing the following:

• In the February 2, 2011 **Federal Register** (76 FR 5861), we published a final rule with comment period titled, ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers.'' This final rule with comment period implemented major Affordable Care Act provisions, including the following:

++ A requirement that institutional providers and suppliers must submit application fees as part of the Medicare, Medicaid, and CHIP provider and supplier enrollment processes.

++ Establishment of Medicare, Medicaid, and CHIP provider and supplier risk-based enrollment screening categories and corresponding screening requirements.

++ Authority that enabled imposition of temporary moratoria on the enrollment of new Medicare, Medicaid, and CHIP providers and suppliers of a particular type (or the establishment of new practice locations of a particular type) in a geographic area.

• In the April 27, 2012 **Federal Register** (77 FR 25284), we published a final rule titled, ''Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements and Changes in Provider Agreements.'' The rule implemented another major Affordable Care Act provision and required, among other things, that providers and suppliers that order or certify certain items or services be enrolled in or validly opted-out of the Medicare program.

++ This requirement was expanded to include prescribers of Medicare Part D drugs in the final rule published in the May 23, 2014 **Federal Register** (79 FR 29844) titled, ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs.''

Through improved processes and systems, since March 2011 we have:

• Saved over $927 million by revoking Medicare Part A and B providers and suppliers that did not comply with Medicare requirements;

• Avoided over $2.4 billion in costs by preventing further billing from revoked and deactivated Medicare Part A and B providers and suppliers;

• Deactivated more than 543,163 Medicare Part A and B providers and suppliers that did not meet Medicare enrollment standards;

• Revoked enrollment and billing privileges under § 424.535 for more than 34,888 Medicare Parts A and B providers and suppliers that did not meet Medicare enrollment standards, and

• Denied 4,949 applications for providers and suppliers in Medicare Parts A and B that did not meet Medicare enrollment standards within a recent 12-month period.[14]

The public may review the Annual Report to Congress on the Medicare and Medicaid Integrity Programs each year for more information on program integrity efforts, including how we calculate savings to the Medicare and Medicaid programs. The Department of Health and Human Services (HHS), Office of Inspector General (OIG), Government Accountability Office (GAO), and other federal agencies routinely review Medicare's provider and supplier enrollment processes and systems, including a recent study stating that ''as part of an overall effort to enhance program integrity and reduce fraud risk, effective enrollment-screening procedures are essential to ensure that ineligible or potentially fraudulent providers or suppliers do not enroll in the Medicare program.'' (GAO–15–448) The enrollment screening authorities granted in the Affordable Care Act and used to prevent and detect ineligible or potentially fraudulent providers and suppliers from enrolling in the Medicare program are working to protect beneficiaries and the Medicare Trust Funds.

Under applicable provisions of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, Medicare began to pay health plans on a prospective risk basis for the first time. The Balanced Budget Act of 1997 (BBA) modified these provisions and established a new Part C of the Medicare program, known as Medicare+Choice (M+C), effective January 1999. As part of the M+C program, the BBA authorized us to contract with public or private organizations to offer a variety of health plan options for enrollees, including both traditional managed care plans (such as those offered by HMOs, as defined in section 1876 of the Act) and new options not previously authorized.

The M+C program was renamed the Medicare Advantage (MA) program under Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), which was enacted on December 8, 2003. The MMA updated the choice of plans for enrollees under MA and changed how benefits are established and payments are made. In addition, Title I of the MMA established the Medicare prescription drug benefit (Part D) program and amended the MA program to allow most types of MA plans to offer prescription drug coverage.

All Medicare health plans, with the exception of PACE organizations, operating in geographic areas that we determine to have enough qualified providers and suppliers with which to contract in order for enrollees to have access to all Medicare Part A and Part B services, must develop a network of qualified providers and suppliers that meet our network adequacy standards. As a condition of contracting with us, the health plans' contracted network of providers and suppliers must be approved by us as part of application approval (§ 417.406). PACE organizations must furnish comprehensive medical, health, and social services that integrate acute and long-term care in at least the PACE center, the participant's home, or inpatient facilities, and must ensure accessible and adequate services to meet the needs of its participants.

Individuals receiving care through MA organizations are typically referred to as enrollees, while in other parts of the Medicare program, benefit recipients are referred to as beneficiaries. This rule does not change the proper meaning of either term; however, for ease of reading, the terms ''beneficiary'' and ''enrollee'' are used synonymously throughout the preamble of this final rule.

2. Provisions of the Proposed Regulation

a. Need for Regulatory Action

This final rule will require providers or suppliers that furnish health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization to be enrolled in Medicare and be in an approved status. The term ''MA organization'' refers to both MA plans and also MA plans that provide drug coverage, otherwise known as MA–PD plans. This final rule creates consistency with the provider and supplier enrollment requirements for all other Medicare (Part A, Part B, and Part D) programs. We believe that this final rule is necessary to help ensure that Medicare enrollees receive items or services from providers and suppliers that are fully compliant with the requirements for Medicare enrollment and that are in an approved enrollment status in Medicare. This final rule will assist our efforts to prevent fraud, waste, and abuse and to protect Medicare enrollees by carefully screening all providers and suppliers, especially those that potentially pose an elevated risk to Medicare, to ensure that they are qualified to furnish Medicare items and services. Out-of-network or non-contract providers and suppliers are not required to enroll in Medicare to meet the requirements of this final rule.

[14] Taken from Shantanu Agrawal, M.D. testimony to Congress on July 22, 2015 *http://www.aging.senate.gov/imo/media/doc/CMS%20_Agrawal_7_22_15.pdf.*

We consider provider and supplier enrollment to be the gateway to the Medicare program and to beneficiaries. Requiring enrollment of those that wish to furnish items or services to MA beneficiaries gives us improved oversight of the providers and suppliers treating beneficiaries and the Medicare Trust Funds dollars spent on their care. However, Medicare has not historically had direct oversight over all providers and suppliers in MA organizations. We note that § 422.204 requires MA organizations to conduct screening of their providers. We believe that we, through our enrollment processes, can further ensure that only qualified providers and suppliers treat Medicare beneficiaries by conducting rigorous screening and rescreening of providers and suppliers that includes, for example, risk-based site visits and, in some cases, fingerprint-based background checks. We also have access to information and data not available to MA organizations, making oversight to ensure compliance with all federal and state requirements more robust. We also continually review provider and supplier enrollment information from multiple sources, such as judicial and law enforcement databases, state licensure databases, professional credentialing sources, and other systems of record. In short, we collect and carefully review and verify information prior to the provider's or supplier's enrollment and, of great importance, continue this monitoring throughout the period of enrollment. Section 422.204, on the other hand, neither requires MA organizations to, for instance, review a provider or supplier's final adverse action history (as defined in § 424.502), nor to verify a provider or supplier's practice location, ownership, or general identifying information.

We believe that MA organization enrollees should have the same protections against potentially unqualified or fraudulent providers and suppliers as those afforded to beneficiaries under the fee-for-service (FFS) and Part D programs. Indeed, Medicare beneficiaries and enrollees, the Medicare Trust Funds, and the program at large, are at risk when providers and suppliers that have not been adequately screened, furnish, order, certify, or prescribe Medicare services and items and receive Medicare payments. For instance, a network provider with a history of performing medically unnecessary tests, treatments, or procedures could threaten enrollees' welfare, as could a physician who routinely overprescribes dangerous drugs. Lack of sufficient oversight could also result in improper Medicare payments, harming the Medicare Trust Funds and taxpayers. Requiring enrollment allows us to have proper oversight of providers and suppliers, making it more difficult for these types of providers and suppliers to enroll in Medicare and remain enrolled in Medicare. Furthermore, it allows us to remove a enrolled provider or supplier that does not comply with our rules across Medicare (Part A, Part B, MA, and Part D).

Information regarding a provider or supplier's enrollment status is housed in our enrollment repository called the Provider Enrollment, Chain and Ownership System (PECOS). A link to that information is located on the CMS Web site. Initial data show a large percent of MA providers and suppliers are already enrolled in Medicare. We do not believe that this final rule will have a significant impact on MA organizations' ability to establish networks of contracted providers and suppliers that meet CMS' MA network requirements. However, we solicited industry comment on the potential impact of this final rule on MA organizations ability to establish or maintain an adequate networks of providers and suppliers. To clarify, this rule only requires the enrollment of providers and suppliers that are of a provider or supplier type eligible to enroll in Medicare. Categorically-eligible providers and suppliers unable to meet the specific enrollment requirements are not exempt from this rule. For example, if a clinical social worker cannot meet an education requirement as required by § 410.73, the clinical social worker cannot enroll because he or she fails to meet program requirements. Therefore, this clinical social worker may not provide items and services to beneficiaries that receive items and services through FFS, MA, MA–PD, PACE, and Cost plans, as well as demonstration and pilot programs, regardless of whether the provider or supplier is listed on a specific claim for payment.

We believe that preventing questionable providers or suppliers from participating in the MA program and removing existing unqualified providers and suppliers will help ensure that fewer enrollees are exposed to risks and potential harm, and that taxpayer monies are spent appropriately. Such a policy will also help comply with the GAO's recommendation that we improve our provider and supplier enrollment processes and systems to increase the protection of all beneficiaries and the Medicare Trust Funds. (GAO–15–448). The additional resources and oversight that we provide in our processes for enrolling providers and suppliers will enhance and complement the screening processes that MA organizations already are required to perform.

b. Statutory Authority

The following are the principal legal authorities for these provisions:

- Section 1856(b) of the Act provides that the Secretary shall establish by regulation other standards for Medicare+Choice organizations and plans consistent with, and to carry out, this part. In addition, section 1856(b) states that these standards supersede any state law or regulation (other than those related to licensing or plan solvency) for all MA organizations.
- Sections 1102 and 1871 of the Act, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1866(j) of the Act, which provides specific authority with respect to the enrollment process for providers and suppliers in the Medicare program.

3. Major Provisions

Given the foregoing and the need to safeguard the Medicare program and its enrollees, we are finalizing most provisions included in the proposed rule, with limited exceptions and explained herein.

Although existing regulations at § 422.204 address basic requirements for MA provider credentialing, we are finalizing the requirement in § 422.204(b)(5) to require plans to verify that they are compliant with the provider and supplier enrollment requirements. We believe this addition would help facilitate MA organizations' compliance.

In §§ 422.222, 417.478, 460.50, 460.70, and 460.71 we are finalizing the provisions requiring providers and suppliers to enroll in Medicare and be in an approved status in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. This requirement would apply to network providers and suppliers; first-tier, downstream, and related entities (FDR); providers and suppliers participating in the Program of All-inclusive Care for the Elderly (PACE); suppliers in Cost HMOs or CMPs; providers and suppliers participating in demonstration programs; providers and suppliers in pilot programs; locum tenens suppliers; and incident-to suppliers. Based on a comment we received, we made a change from the proposed rule when

finalizing a specific provision relating to the PACE program. Commenters were concerned that the requirement to update PACE program agreements with the name and NPIs of all enrolled providers and suppliers was extremely burdensome based on the nature of the agreements and it imposed more of a burden than was established for other plans and programs required to comply with this rule. Instead of requiring PACE organizations to update the program agreement with the name and NPI of all providers and suppliers (§ 460.32), we added language to § 460.70 and § 460.71 that better reflect the enrollment requirements imposed on MA organizations. We agree that we can achieve the same program integrity goals, without the added burden of having PACE organizations reflect this information in the program agreement. Based on a comment we received, we also moved the requirement for PACE that was included in 422.222 and relocated it to better align with the PACE program. The requirements remain the same; however, the enrollment requirements are now contained in part 460.

We are finalizing the provisions in § 422.510, § 422.752, § 460.40, and § 460.50 stating that organizations and programs that do not ensure that providers and suppliers comply with the provider and supplier enrollment requirements may be subject to sanctions and termination. Considering the serious risks to the Medicare program and enrollees from fraudulent or unqualified providers and suppliers, we believe that these are actions may be appropriate.

Current rules allow MA organizations to contract with different entities to provide services to beneficiaries. These contracted entities are referred to as first-tier, downstream, and related entities or FDRs, as defined in § 422.500. FDRs must enroll to comply with this rule.

PACE is a Medicare and Medicaid program that helps people meet their health care needs in the community instead of going to a nursing home or other care facility, wherein a team of health care professionals works with participants and their families to make sure participants get the coordinated care they need. A participant enrolled in PACE must receive Medicare and Medicaid benefits solely through the PACE organization. To ensure consistency within our programs, we believe that our provider and supplier enrollment requirements should extend to this program.

Medicare Cost HMOs or CMPs are a type of Medicare health plan available in certain areas of the country. Some Cost HMOs or CMPs only provide coverage for Part B services. Cost HMOs or CMPs do not include Part D. These plans are either sponsored by employer or union group health plans or offered by companies that do not provide Part A services.

Demonstrations and pilot programs, also called research studies, are special projects that test improvements in Medicare coverage, payment, and quality of care. They usually operate only for a limited time for a specific group of people and may only be offered only in specific areas. Providers and suppliers in these programs would not be exempt from the requirements of this final rule.

In §§ 422.224 and 460.86, we are finalizing the prohibition on MA, PACE, the other designated programs and organizations from paying individuals or entities that are excluded by the OIG or revoked from the Medicare program. These provisions also require MA, PACE, the other designated programs and organizations to notify the enrollee and the excluded or revoked provider or supplier that payment shall not be made. We are not, however, finalizing a first time allowance for payment. Based on further analysis, we believe a first time payment allowance would violate existing statute. However, we believe that beneficiaries are adequately protected in these situations based upon regulatory protections afforded at 42 CFR 1001.1901(b) and § 424.555(b) that preclude OIG excluded individuals and entities, as well as revoked, deactivated, or Medicare enrollment denied providers or suppliers from recouping payment from beneficiaries. We continue to believe such excluded or revoked individuals and entities pose a significant risk to enrollees and the Medicare program and should not receive federal dollars, even if payment is made through an intermediary such as an MA organization. Based upon the inclusion of PACE in § 422.222 in the proposed rule, and our relocating the PACE requirement to part 460, the application of the prohibition to pay excluded and revoked providers and suppliers also needs to be separately designated. Therefore, in this final rule, the sections applicable to not paying excluded or revoked providers and suppliers is now designated in § 460.86.

In § 422.501(c)(2), we are finalizing language requiring MA organization applications to include documentation demonstrating that all applicable providers and suppliers are enrolled in Medicare in an approved status. We believe that this will assist CMS in the MA organization application process by requiring MA organizations to provide assurance that the designated providers and suppliers are properly screened and enrolled in Medicare.

In § 422.504(a)(6), we are finalizing language with respect to contract conditions. MA organizations must agree to comply with all applicable provider requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans. In § 422.504(a)(6), we are finalizing the extension of this requirement to suppliers. In this same section, we also are finalizing the requirement for MA organizations to comply with the provider and supplier enrollment requirements referenced in § 422.222. We believe these revisions would help facilitate the MA organizations' compliance with § 422.222. In §§ 422.504(i)(2)(v), 417.484, 460.70, and 460.71, we are finalizing provisions that require MA organizations, Cost plans, and PACE organizations to require all FDRs and contracted entities to agree to comply with the provider and supplier enrollment provision.

Finally, the provisions are effective the first day of the next plan year that begins 2 years from the date of publication of the CY 2017 PFS final rule. For PACE organizations, these requirements will be effective the first day of the calendar year that is 2 years after the publication of this final rule.

We believe this would give all stakeholders sufficient time to prepare for these requirements. We are unable to impose new requirements on MA organizations mid-year, and therefore, must wait to make these rules effective.

The following is a summary of the comments we received on MA provider enrollment.

Enrollment File

Comment: A commenter expressed concern that CMS' requirements for plan validation are overly burdensome. The commenter noted that, as a condition of contracting with CMS, an MA organization would have to agree to provide documentation that all providers and suppliers in the MA or MA–PD plan who could enroll in Medicare were indeed enrolled. Believing that the providers themselves should be involved in this process, the commenter stated that providers should submit the required documentation to CMS (as in the FFS program) and that

CMS should in turn maintain a ''source of truth'' document for audit and compliance purposes. The commenter stated that provider information can change frequently and become outdated; without a ''source of truth'' to confirm a provider's enrollment in Medicare, the commenter said, unintended consequences could arise.

Response: We do not agree that this requirement is overly burdensome. We have made compliance simple by providing a file of enrolled providers and suppliers. We maintain all provider enrollment information in PECOS, our enrollment repository. In an effort to provide MA organization with the necessary information, an online, public file listing enrolled providers and suppliers has already been made available to MA organizations and will continue to be updated at a frequency to be determined and announced through established processes such as a Medicare Learning Network (MLN) article. We believe this approach will provide MA organizations with sufficient access to the necessary provider enrollment information for the relevant requirements under this final rule. In addition, providers and suppliers will be required to submit documentation to a CMS contractor, consistent with current Medicare enrollment processes.

Comment: Several commenters asked how CMS will communicate provider and supplier information to individual MA organizations so that they can remain compliant with our proposed requirement. Another commenter asked how CMS will verify the inclusion or exclusion of enrolled providers and suppliers. Several commenters stated that if CMS finalizes its proposed requirement, it must grant the MA organizations full access to PECOS so they can confirm a provider's or supplier's enrollment status. A commenter recommended that CMS make publicly available a list of all Medicare revocations, including the date and reason for the revocation. Several commenters suggested that MA organizations be given access to PECOS or some other means of verifying an MA provider's or supplier's enrollment in Medicare. This would, they contended, reduce the burden on the plans and help ensure the plans' compliance with the requirements of § 422.222.

Response: We have created a public file that will be regularly updated with provider and supplier enrollment information at a frequency to be determined and announced through established processes such as a MLN article. As mentioned previously, we believe this is an efficient and sufficient approach to providing information to plans, and we do not believe that MA organizations need full access to PECOS to obtain the information necessary to comply with this final rule. Regarding revoked providers, providers or suppliers that are revoked from the program will not be included in the enrollment file because they are not validly enrolled.

Comment: A commenter asked how CMS will communicate with MA organizations if it revokes a provider's or supplier's enrollment and what steps the MA organization would be required to take in response to the revocation.

Response: We will periodically update our enrollment file made available to MA organizations. Providers or suppliers that are revoked from the program will not be included in the enrollment file because they are not validly enrolled. MA organizations will be expected to check the enrollment file to ensure all providers and suppliers are validly enrolled and may not have an unenrolled provider and supplier in their network. As we move toward implementation, we will provide subregulatory guidance with respect to revoked providers and suppliers.

Comment: A commenter asked whether our proposed enrollment requirement represents a mere clarification of § 422.204(b)(2)(i), which outlines the provider credentialing process, or constitutes a new and expanded process that MA organizations must address in their policies and contracting processes. If it is the latter, the commenter requested specific information on the ''source of truth'' and the method for MA organizations to verify this information (for example, whether MA organizations will have to confirm the enrollment statuses of providers and suppliers via a CMS Web site or whether CMS will furnish a list of enrolled providers and suppliers to the MA organizations).

Response: This requirement is not a mere clarification of § 422.204(b)(2)(i) but imposes additional requirements on plans to ensure that their providers and suppliers are screened and enrolled in Medicare. These requirements are an expansion of § 422.204(b)(2)(i). Verification of enrollment can be found by accessing the online enrollment file we have provided to the public, which will be updated to reflect changing enrollment data.

Authority and Burden

Comment: A commenter suggested that CMS estimate the number of providers and suppliers that furnish care to Medicare beneficiaries through an MA organization only and not through the Medicare FFS program and that CMS include this figure and the associated cost in its regulatory burden and Paperwork Reduction Act estimates.

Response: We appreciate the opportunity to clarify that these are the exact figures reflected in the proposed rule and in this final rule in the regulatory burden and Paperwork Reduction Act sections.

Comment: A commenter asked that CMS: (1) Monitor the impact of these requirements on MA organization networks and physician enrollment and, if negative effects are found, to either roll-back the requirement or implement appropriate changes; (2) create realistic implementation timeframes and comprehensive outreach plans; and (3) establish beneficiary financial protections during the transition. Another commenter recommended that CMS improve its enrollment processes so that those affected can enroll in a timely manner.

Response: We appreciate the commenters' suggestions and will take these suggestions into consideration as we move forward with operational plans.

Comment: A commenter asked whether CMS has conducted a preliminary assessment of the potential nationwide impact this requirement.

Response: We have made that assessment, and it is reflected in our Regulatory Impact Analysis.

Comment: A commenter sought clarification on how the provisions of § 422.222 would improve program integrity and quality of care.

Response: This final rule would assist our efforts to prevent fraud, waste, and abuse and to protect Medicare enrollees by carefully screening all providers and suppliers, especially those that potentially pose an elevated risk to Medicare, to ensure that they are qualified to furnish Medicare items and services. These requirements are not a clarification of § 422.204(b)(2)(i), but impose additional requirements on plans to ensure that their providers and suppliers are screened and enrolled in Medicare. Requiring enrollment of those that wish to furnish items or services to MA beneficiaries gives us improved oversight of the providers and suppliers treating beneficiaries and the Medicare Trust Fund dollars spent on their care. Prior to this rule, Medicare did not have direct oversight over all providers and suppliers furnishing items and services to enrollees of MA organizations. Section 422.204 requires MA organizations to conduct screening of their providers. We believe that we can, through our enrollment processes, conduct more robust verification of the

information provided during enrollment so that only qualified providers and suppliers treat Medicare beneficiaries by conducting rigorous screening and rescreening of providers and suppliers, risk-based site visits and fingerprint-based background checks. We also have access to information and data not available to MA organizations, making oversight to ensure compliance with all federal and state requirements more robust. These checks prevent certain providers and suppliers from furnishing items and services to beneficiaries, such as a doctor convicted of a felony for abusing patients. While we are hopeful that licensing boards would take action to prevent providers and suppliers such as this from lawfully providing services to patients in the future, we cannot always rely on the boards to take the action we believe is appropriate when serving beneficiaries. We believe that MA organization enrollees should have the same protections against potentially unqualified or fraudulent providers and suppliers as those afforded to beneficiaries under the FFS and Part D programs. Our program integrity concerns are furthered by having the ability to easily consolidate data across all lines of Medicare to see billing patterns and schemes for a particular provider or supplier. For example, a network provider with a history of performing medically unnecessary tests, treatments, or procedures could threaten enrollees' welfare, as could a physician who routinely overprescribes dangerous drugs. This could also result in improper Medicare payments, harming the Medicare Trust Funds and taxpayers. A benefit of enrolling all providers and suppliers in Medicare is the ability to remove a provider or supplier for failure to meet our requirements or violates federal rules and regulations. Not only is the provider or supplier unable to bill a particular MA organization, but they also may not bill any other plan, bill Medicare, order and certify Medicare items and services, or prescribe Part D drugs.

Comment: A commenter opposed our proposed enrollment requirement, stating that it would be redundant in that all payers have rigorous screening and rescreening processes, as well as programs to ensure quality and cost effectiveness. The commenter also stated that: (1) physician quality data is transparent and made available through payer Web sites and portals to provide members with the opportunity to choose highly rated qualified physicians; and (2) MA plans should be responsible for ensuring that they are enrolling the most qualified physicians into their networks. In addition, the commenter encouraged CMS to ensure that health plans are consulting the OIG exclusion list to guarantee that physicians who have been convicted of crimes are not in the MA networks.

Response: We appreciate the commenter's concerns; however, we respectfully disagree and believe that our enrollment screening processes (for example, risk-based site visits and fingerprint-based background checks) help to ensure that qualified providers and suppliers treat Medicare beneficiaries. We conduct rigorous screening and rescreening of providers and suppliers. We also have access to information and data that is not available to MA organizations, which enhances enrollment screening and helps ensure that providers and suppliers are in compliance with all federal and state requirements. Moreover, we also continually review provider and supplier enrollment information from multiple sources, such as judicial, law enforcement, state licensure, professional credentialing, and other databases for which MA organizations do not have access. In short, we collect and verify information prior to the provider's or supplier's enrollment and, of great importance, continue this monitoring throughout the period of enrollment. Section 422.204, on the other hand, neither requires MA organizations to, for instance, review a provider or supplier's final adverse action history (as defined in § 424.502), nor to verify a provider or supplier's practice location, ownership, or general identifying information.

Comment: A commenter questioned the need for our proposal by stating that CMS did not provide empirical evidence of problems in MA for which our enrollment requirement would be appropriate or fully address the proposal's impact on network adequacy and potential downstream beneficiary access issues. The commenter stated that the requirement is a FFS solution developed for FFS program integrity issues and is improper for the MA program. The commenter urged CMS to withdraw the proposal and work with plans to develop solutions that are better applicable to the MA program. Another commenter suggested that CMS cite the specific OIG or GAO reports that recommend that MA providers and suppliers be enrolled in Medicare FFS and furnish evidence that our proposed requirement would improve care for MA beneficiaries.

Response: We believe that the vulnerabilities identified by the GAO (GAO–15–448) provide sufficient justification to impose this requirement. Based upon our analysis of unenrolled providers and suppliers that only provide services for MA organizations and do not bill Medicare FFS, we do not believe there will be network adequacy issues or beneficiary access issues. Regarding the commenter's concern that Medicare enrollment and screening is a FFS solution and is improper for the MA program, we note that MA organizations' requirements for screening providers and suppliers are similar to Medicare screening and enrollment in that MA organizations have requirements to, for example, perform site visits, check licensure, and to complete background checks. However, MA organizations have discretion in administering their screening and verification procedures. The Medicare enrollment process is much more robust and provides heightened consistency to the MA organizations' screening processes and also allows for screening using databases that are not available to MA organizations.

As discussed in the preamble, a recent GAO study stated that ''as part of an overall effort to enhance program integrity and reduce fraud risk, effective enrollment-screening procedures are essential to ensure that ineligible or potentially fraudulent providers or suppliers do not enroll in the Medicare program.'' (GAO–15–448) This study's recommendations did not specifically recommend MA provider and supplier enrollment; however, these new provisions are part of an overall plan to ensure standard screening for those providers and suppliers treating MA beneficiaries. Evidentiary support for improved care for beneficiaries can be seen by reviewing the Annual Report to Congress on the Medicare and Medicaid Integrity Programs, which gives more information on program integrity efforts and administrative actions. This report demonstrates statistical evidence of the judicial and administrative actions taken against providers and suppliers, such as, licensure suspensions, felony convictions, and Medicare revocations.

Comment: A commenter recommended that CMS identify the types of oversight it currently uses to ensure that MA organizations do not have unlicensed or fraudulent providers and suppliers participating in their network.

Response: These regulatory requirements are specified at § 422.204 and impose obligations on plans.

Comment: A commenter recommended that CMS streamline and improve the enrollment process before implementing its proposed MA enrollment requirements. Another

commenter urged CMS to administer the enrollment requirements in a manner that limits the burden on physician practices as much as possible.

Response: We appreciate the commenters' concerns and have taken steps to make the enrollment process as streamlined as possible, but we do not believe that implementation should be delayed. The application process, especially for physicians and physician practices, requires the provision of basic information that should be easily obtained, such as name, NPI, practice locations, licensure number, criminal history, and education. We do not believe that furnishing this information will be overly burdensome for providers and suppliers. Moreover, this information provides great value in assessing the risk to beneficiaries and the program. Consequently, we decline to delay the requirements in this rule.

Comment: A commenter urged CMS to work with plans so that an informed assessment of the potential impact of our proposed requirements can be developed before the rule is finalized.

Response: We remain committed to working with plans to help them understand and be compliant with these requirements; however, we decline to delay implementation. We have reviewed all public comments and considered the potential impacts provided by commenters and internal stakeholders prior to finalizing this rule.

Comment: Several commenters opposed CMS' proposal. One commenter stated that it represents a regulatory overreach and asked CMS to cite the legal authority for the proposal, explain our justification for the proposal, and identify the specific problem the proposal is intended to resolve. The commenter stated that CMS did not furnish evidence that MA providers are unqualified or fraudulent and suggested that CMS provide examples of where (1) an MA provider or supplier was not licensed to practice medicine and where the MA organization did not take the appropriate action to terminate the provider or supplier; (2) CMS has taken a compliance action against an MA organization for failing to exclude unlicensed or fraudulent providers or suppliers from their network; and (3) CMS imposed civil money penalties or sanctions on an MA organization for its failure to protect its members from unlicensed or fraudulent providers or suppliers. Other commenters stated that the proposed requirement would be overly burdensome on plans and providers.

Response: Our legal authority is based upon section 1856(b) of the Act, which provides that the Secretary shall establish by regulation other standards for Medicare+Choice organizations and plans ''consistent with, and to carry out, this part.'' In addition, section 1856(b) of the Act states that these standards supersede any state law or regulation (other than those related to licensing or plan solvency) for all MA organizations. We have also relied on sections 1102 and 1871 of the Act, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program. Section 1866(j) of the Act gives us specific authority with respect to the enrollment process for providers and suppliers in the Medicare program.

Our justification for broadening our enrollment requirements is based upon a desire for MA organization enrollees to have the same protections against potentially unqualified or fraudulent providers and suppliers as those afforded to beneficiaries under the FFS and Part D programs. We believe that robust screening is fundamentally important to promote quality of care. Medicare beneficiaries and enrollees, the Medicare Trust Funds, and the program at large, are at risk when providers and suppliers that have not been adequately screened furnish, order, certify, or prescribe Medicare services and items and receive Medicare payments. Requiring enrollment allows us to have proper oversight of providers and suppliers, making it more difficult for these types of providers and suppliers to enroll in Medicare and remain enrolled in Medicare. Furthermore, it allows us to remove a provider or supplier that does not comply with our rules across Medicare (Part A, Part B, MA, and Part D).

We believe the GAO report cited herein provides specific examples and evidence of our need to standardize the enrollment process and take advantage of the information available to Medicare that the MA organizations cannot access. We believe the enrollment file provides an efficient way for the plans to ensure that providers and suppliers are enrolled, which will minimize burden on plans.

Comment: A commenter expressed concern that some of the operational challenges encountered in CMS' implementation of the Part D prescriber enrollment requirement could also occur during implementation of a similar requirement in MA. The commenter urged CMS to implement its MA enrollment requirement in a manner that avoids such issues. Specifically, the commenter urged CMS to improve application processing timeframes, test file protocols, and file layouts while developing a mechanism to require providers to update their taxonomy codes.

Response: We appreciate this comment and will continue our ongoing work to minimize burden on MA organizations, as well as providers and suppliers, while ensuring that an effective and efficient enrollment process, as well as outreach and education efforts, exist to operationalize the requirements under this final rule.

Comment: A commenter expressed concern that certain contractual arrangements that are currently required for SNFs under Medicare Parts A and B might be disallowed under the proposed rule. The commenter stated that SNFs are statutorily required under consolidated billing to submit charges for certain ancillary services, such as rehabilitation therapy and portable x-ray services as a part of the nursing facility's institutional claim; that is, Medicare Part B requires that the nursing facility bill Medicare for these services. The commenter sought clarification on the question of contractual disallowance, given the proposed rule's objectives of achieving consistency between MA and Medicare Parts A and B and whether such ancillary service providers must enroll as Medicare providers.

Response: This rule does not address the payment arrangements described by the commenter. We note that Part A and B providers and suppliers are already required to enroll in Medicare. These provisions only provide for requirements for the Medicare enrollment of MA organization providers and suppliers and prohibition of payment in certain circumstances such as an OIG exclusion or Medicare revocation.

Plan Noncompliance

Comment: A commenter contended that sanctioning or terminating plans for non-compliance with our enrollment requirements is too aggressive. The commenter stated that plans will need to ensure that systems are updated with current provider information and that new information can be received and reviewed in a timely manner. The commenter stated that legitimate errors could arise throughout the process, and that rather than immediately sanction or terminate a plan (which would have negative consequences on its members), CMS should instead put into place a process for remediation. Plans that are consistently found to be in non-compliance with the rules, the commenter said, should face enforcement action, but first time ''offenders'' should be given the

opportunity to work through challenges with both CMS and providers.

Response: We will work with MA organizations and all other stakeholders as we move forward with implementation. We have discretion in determining the appropriate action to take for noncompliant plans, such that any remedial actions or penalties imposed on plans that do not comply with the requirements of this rule will be the result of thorough analysis of all relevant factors. Furthermore, we have provided the stakeholders with more than 2 years to make the changes necessary to accommodate this requirement.

Comment: A commenter asked whether beneficiary complaints about the MA organization due to the impact of the enrollment requirement (for example, the beneficiary can no longer receive covered services from a non-enrolled provider) will affect a plan's Star Rating. The commenter believed it would be unfair to penalize plans that are merely attempting to comply with CMS' enrollment requirement.

Response: We do not expect the requirements of this final rule to have a significant impact on Star Ratings, given the relatively few number of providers and suppliers that need to enroll to meet the requirements of this rule. Issues regarding the potential impact that beneficiary complaints have on plans' Star Ratings will be addressed by CMS in future guidance. Furthermore, any remedial actions or penalties imposed on MA organizations that do not comply with the requirements of this rule will be the result of thorough analysis of all relevant factors.

Comment: A commenter sought clarification as to the extent an MA organization may be subject to contract termination, intermediate sanctions, or civil monetary penalties.

Response: It is difficult to predict, prior to our enforcement of these provisions, how and when we will use these sanctions. We cannot yet assess plans' compliance with this requirement and the steps they will take to become compliant. We will consider issuing guidance in the future related to this rule.

Comment: Several commenters expressed concern about the potential penalties for plans that do not adhere to our enrollment requirements. One commenter stated that data or other system issues might prevent plans from having complete and accurate information about a provider's or supplier's status at a certain point in time. The commenter added that it may be critical for beneficiaries to retain access to a provider for continuity of care, that plans should not be sanctioned for ensuring that beneficiaries are protected in these cases, and that appropriate exceptions would need to be developed.

Response: We will work with MA organizations and all other stakeholders as we move forward with implementation. We have discretion in determining the appropriate action to take for noncompliant plans, such that any remedial actions or penalties imposed on plans that do not comply with the requirements of this rule will be the result of a thorough analysis of all relevant factors. Furthermore, we have provided the stakeholders with more than 2 years to make the changes necessary to accommodate this requirement.

Clarification and Exemptions

Comment: A commenter recommended that CMS explain whether a DMEPOS supplier that services Medicare beneficiaries through an MA organization, a cost contract plan under section 1876 of the Act, or a health care pre-payment plan under section 1833 of the Act will be subject to surety bonding, accreditation, and other DMEPOS provisions contained in the Medicare FFS program. The commenter also asked how CMS will address access-to-care issues when such DMEPOS suppliers are unable to comply with § 424.57 and §§ 424.500–424.570. Another commenter recommended that CMS clarify whether Part A providers serving Medicare beneficiaries through an MA organization, a section 1876 cost contract plan, or a section 1833 health care pre-payment plan must obtain a CMS survey or accreditation to enroll in Medicare FFS.

Response: All providers and suppliers that enroll in Medicare are subject to the Medicare enrollment requirements, as assigned by their provider or supplier type. For example, provider and supplier types subject to surety bonding are required to obtain a surety bond to complete the enrollment process. There are no exceptions to the enrollment requirements based on this rule. If a CMS survey or accreditation is required for a particular provider or supplier type, it must comply in order to enroll. We do not anticipate any issues with regard to access to care based on the relatively small number of providers and suppliers that need to enroll to meet the requirements of this rule. If there are access to care issues, the plans will follow established protocols to ensure all beneficiaries have access to needed items and services.

Comment: A commenter requested more explicit definitions of the terms ''provider'' and ''supplier,'' particularly in the context of Medicare-Medicaid plans (MMPs), which the commenter stated would not otherwise qualify for Medicare enrollment but furnish needed services to MMP members; the commenter believed that such providers should be excluded from our proposal.

Response: As stated in the preamble of the rule, those terms are defined in sections 1861(u) and 1861(d) of the Act. We are only requiring enrollment for providers and suppliers that are categorically-eligible to enroll in Medicare. This rule is not requiring MMP plans to enroll.

Comment: A commenter recommended that CMS clarify whether our proposal applies to providers and suppliers furnishing services to a Medicare beneficiary through the Railroad Retirement Board or the Indirect Payment Procedure (IPP) under § 424.66 and, if so, that CMS adjust the regulatory impact analysis accordingly.

Response: This particular rule is not applicable to the Railroad Retirement Board or the IPP.

Comment: A commenter requested clarification as to whether the proposed requirements add MA provider enrollment burdens that extend beyond the current FFS enrollment process requirements.

Response: No, the enrollment requirements do not extend beyond our current requirements. Providers and suppliers that are already enrolled in Medicare for purposes of billing the Medicare program, rather than enrolled to order, refer, certify, or prescribe, have met the enrollment requirements for this rule and are compliant. Part A providers and suppliers that are validly enrolled in the Medicare program do not need to separately enroll to meet the requirements of this rule. In-network providers and suppliers that are not already enrolled in Medicare and that are currently providing services to MA enrollees will need to enroll in Medicare to continue to provide those services to MA enrollees.

Comment: A commenter asked how our proposed requirement applies to providers and suppliers for MMPs. The commenter stated that these plans might have atypical providers and suppliers that would be unable to enroll in Medicare but provide needed care to MMP members. The commenter recommended that such providers be excluded from this requirement.

Response: This rule specifies requirements for providers and suppliers that provide services to beneficiaries enrolled in MA, MA–PD,

PACE, and Cost plans, as well as demonstration and pilot programs. The requirements also apply to FDRs, locum tenens, and incident-to suppliers. To the extent that MMPs are MA or MA–PD plans they would be subject to these requirements. We are not providing any exemptions and are only requiring enrollment in Medicare for providers and suppliers that are categorically-eligible to enroll in Medicare.

Comment: A commenter asked whether providers associated with FDRs would need to be enrolled in Medicare, even if they are not directly engaged in providing services to plan members. The commenter cited the example of dentists and expressed concern that a requirement for dentists to enroll in Medicare to participate in an MA network would threaten beneficiary access to a supplemental dental benefit that many members have as part of their MA benefit package. In general, the commenter urged CMS to clarify which providers are affected by the provision, and how providers associated with FDRs are to be treated in this respect.

Response: FDRs, such as dentists, will need to enroll to meet the requirements of this rule. All providers and suppliers that are categorically-eligible to enroll in Medicare must enroll in Medicare in an approved status in order to meet the requirements of this final rule. A determination as to whether a provider or supplier is eligible to enroll will be based on the type of provider or supplier. For example, if an audiologist works for a PACE organization or an FDR, he or she would need to enroll in Medicare because an audiologist is a type of provider or supplier eligible to enroll. Furthermore, section 1861(ll)(4)(B) of the Act states that a qualified audiologist must have a masters or doctoral degree in audiology, among other requirements. If the audiologist cannot enroll because he or she fails to meet program requirements, such as this educational requirement, he or she may not enroll in the program or provide services to beneficiaries enrolled in programs under this final rule. It does not mean that providers and suppliers, that are of the type of providers or suppliers eligible to enroll in Medicare, are exempt from enrolling because they cannot or do not meet the necessary requirements for their specific provider or supplier type to enroll in Medicare. Providers and suppliers that cannot or do not meet the enrollment requirements may not provide items and services to beneficiaries that receive items and services through FFS, MA, MA–PD, PACE, and Cost plans, as well as demonstration and pilot programs.

Comment: A commenter asked whether there would be a grandfathering provision or grace period for un-enrolled MA providers and suppliers.

Response: We believe that the effective date of the provisions of this rule and length of time we have allowed for plans to comply with these provisions provides enough time for providers and suppliers to enroll. We do not believe that providing a grace period or a grandfathering provision would serve the goals of ensuring consistent screening.

Comment: A commenter recommended that CMS clarify proposed § 422.222 to state that enrollment in Medicare in an ''approved status'' includes providers and suppliers that are deactivated for lack of claims submission.

Response: Providers and suppliers that are deactivated are not considered in an approved status. Deactivated providers and suppliers may reactivate their enrollment by contacting their Medicare Administrative Contractor and following the applicable reactivation procedures which are set forth in our enrollment regulations at § 424.540(b).

Comment: A commenter recommended that the proposed MA enrollment requirement for in-network providers and suppliers extended to out-of-network providers; the commenter believed this would help ensure that all MA beneficiaries have access to fully screened and qualified providers and suppliers.

Response: We appreciate the commenter's support and suggestion. Because we did not propose an expansion to out-of-network providers and suppliers, we are not able to finalize that in this rule. We proposed including only in-network providers and suppliers in this rule to ensure only a minimal impact to beneficiaries. We may consider future rulemaking to address the commenter's concerns.

Comment: A commenter requested clarification as to whether the proposed enrollment requirement extends to employees and contracted services furnished through properly enrolled and approved Medicare providers of services, including SNFs; that is, whether such employees or contractual professionals or agencies of providers meet the definition of FDRs. The commenter stated that, under FFS Medicare, there is no requirement that professional employees or contracted professionals or agencies of a properly enrolled provider of services, such as a SNF, must be independently enrolled in FFS. Another commenter asked whether MA organizations will be responsible for ensuring that the entire staff or all the employees of such organizations (including nurses, medical students, interns and residents of a facility or other ancillary personnel, others in a provider's office, or in an inpatient setting that the MA organization does not directly contract with for the provision of services) are enrolled. Another commenter recommended that these requirements be limited to MA first tier contracted providers and facilities that provide basic Medicare A, B, and D benefits and that the scope of those needed to enroll be scaled back significantly.

Response: We are using the definitions for first-tier, downstream, and related entities in § 422.500. The MA organizations will be responsible for ensuring that the providers and suppliers that are required to enroll, are indeed enrolled.

Comment: A commenter sought clarification as to whether the rule would extend existing requirements for Part A and B providers to MA organization networks, rather than requiring expanded screening for subcontracted providers.

Response: The rule extends Parts A and B enrollment requirements to MA organization networks including other providers and suppliers, such as FDRs.

Comment: A commenter stated that because Medicare FFS does not offer a dental benefit, CMS should not require MA organizations to adhere to the standard of mandating that dentists enroll as MA suppliers in order to provide dental care to MA beneficiaries. Another commenter sought clarification concerning the impact of the enrollment requirement on supplemental providers that are not covered by Medicare Part A or Part B. The commenter cited the example of dental services, which are often included as part of a supplemental services package; the commenter asked whether dentists who are in-network with MA organizations would be required to enroll in Medicare. The commenter urged CMS to consider (1) whether extending its enrollment requirement to dentists and other affected supplemental service providers is in the best interest of beneficiaries and (2) delaying such a requirement for providers of supplemental services until CMS gains experience and understands the effects of the requirement on Part A and Part B providers, and can make any modifications needed to ensure access.

Response: We appreciate the commenter's recommendations; however, we are committed to ensuring that beneficiaries receive items and services from providers and suppliers that are the categorical types of

providers and suppliers eligible to enroll, that are subject to uniform screening processes, including when receiving dental services or other services not covered by Medicare in Part A or Part B.

Comment: A commenter stated that our proposed requirement is too broad, citing as examples its application to locum tenens suppliers and incident-to suppliers. In particular, the commenter stated that MA beneficiaries may receive covered Medicare services from non-contracting and/or out-of-network providers in the case of a local or regional preferred provider organization (PPO), or from hospitals and physicians not under contract with the MA organization for urgent or emergency services; MA organizations, the commenter stated, generally have no relationships to physician staffing organizations for correctional facilities or government and military facilities, yet they are listed as having the MA requirements apply to them. The commenter contended that this is a requirement that appears to be placed on MA organizations, rather than on the traditional Medicare program, but that MA organizations cannot be, and should not be, required to carry out functions that may belong to the Medicare program overall. If Medicare wants to widen its scope of providers enrolled in Medicare for the purpose of expanding its program integrity program, the commenter stated, Medicare's enrollment efforts should be housed in a single source or database, not merely in MA organizations.

Response: The rule specifically applies to network providers and suppliers, including locum tenens and incident-to suppliers. We are unsure of what the commenter means by stating that the MA organizations are required to carry out functions that belong to the Medicare program. Consistent with existing enrollment practices, enrollment will be completed by our MACs, and all enrollment data will be housed in our enrollment repository, PECOS. Information on a provider or supplier's enrollment status will be available on a public file for ease of access to the plans. We do not agree that the application of this rule is too broad. We have limited the provisions to in-network providers and suppliers. Furthermore, we believe it is important that all beneficiaries have the benefits of being treated by providers and suppliers that have been adequately screened by the Medicare program.

Comment: A commenter stated that the proposed rule could be misconstrued as treating all FDRs as Medicare providers and suppliers, thus requiring them to enroll in Medicare; the commenter cited as an example PBMs, which do not provide covered health care services but instead arrange for their provision. The commenter encouraged CMS to make clear that only those entities that meet the definition of a Medicare ''provider'' or ''supplier'' would be required to enroll in Medicare in order to provide services to MA beneficiaries.

Response: This provision does not change enrollment parameters concerning the types of providers and suppliers eligible to enroll in Medicare. The commenter is correct that only providers and suppliers meeting those statutory definitions will be required and allowed to enroll in Medicare.

Comment: Concerning the term ''Medicare-covered services'' as referenced in the rule, a commenter sought clarification as to whether the enrollment requirement only applies to providers and suppliers of Medicare Part A, B, MA, and D covered benefits and not to other services potentially offered by an MA organizations, such as routine eye care services, dental services, wellness programs, and other non-Medicare covered services.

Response: To clarify, we did not use the term ''Medicare-covered services'' in either the preamble or the regulation text with respect to these specific provisions of the rule. However, we expect all providers and suppliers that are categorically-eligible to enroll in Medicare and that fall under the requirements of this rule, to enroll in Medicare if they wish to participate in the MA program. This includes providers and suppliers of dental, eye care, and other supplemental services.

Comment: Several commenters recommended that CMS exclude pharmacies from the MA enrollment requirement, stating that pharmacies are excluded from the Part D prescriber enrollment requirement. Other commenters stated that Part D sponsors and their FDRs are equipped to perform the necessary vetting and credentialing with respect to pharmacy providers, which, one commenter contended, was the rationale for excluding pharmacies from the Part D enrollment requirement. The commenter stated that the same considerations apply in the MA program and added that applying the proposed requirement to pharmacies would create costly, burdensome, and potentially disruptive redundancies without commensurate benefits.

Response: We decline to exempt pharmacies or other individuals or entities that fall within the framework of this rule. We believe that requiring enrollment in Medicare serves a valuable purpose in protecting beneficiaries and safeguarding the Trust Funds and will help reduce the burden on MA organizations as we move forward with operationalizing this policy. However, we note that we currently do not have a process in place to enroll pharmacies for the purpose of dispensing drugs, except in very limited circumstances, such as for Part B drugs. We are working on operationalizing such a process for network pharmacies in MA–PD plans that do not provide only those limited Part B benefits to enroll in Medicare to be able to comply with this rule. We recognize that plans can be compliant only to the extent that our enrollment requirements and processes in place allow at any given time.

Comment: A commenter asked whether our proposed requirement will impact coverage determinations. The comment stated that, with respect to the Part D enrollment requirement, there is uncertainty regarding the actions that Part D sponsors must take upon receiving a coverage determination request from a non-enrolled prescriber or beneficiary regarding a claim that is denied solely because of that enrollment requirement.

Response: This rule establishes requirements that services provided to Medicare beneficiaries by MA organizations must be provided by providers and suppliers that are enrolled in Medicare. This rule does not address any other criteria affecting coverage determinations.

Comment: A commenter requested that CMS exempt emergency medicine physicians from the enrollment requirements. The commenter added that if this were not feasible, CMS at a minimum should: (1) establish a provision similar to § 423.120(c)(6) that would allow CMS to provide reimbursement for covered items, services or drugs ordered, certified, referred or prescribed by emergency medicine physicians on a provisional basis (for example, for a period of 90-days from the date of service); and (2) exclude from the enrollment requirements those providers whose enrollment applications are pending with the Medicare Administrative Contractor (MAC).

Response: We have not provided for any exemptions; however, we have a provision in § 422.224 that provides for allowances for some payments for emergency or urgently needed services, as defined in § 422.113. We also appreciate the suggestion that we exclude providers and suppliers with pending applications from our requirements. We believe that the rule

furnishes sufficient time for providers and suppliers to enroll to meet the requirements of this rule and decline to provide an exemption in these circumstances.

Comment: A commenter asked for more information regarding the providers and suppliers that are covered under this proposal; the commenter specifically sought clarification regarding providers and suppliers that are not currently subject to credentialing (such as hospital-based providers) and only provide supplemental benefits that are not part of the basic benefits under Medicare Parts A and B.

Response: Regarding the commenter's inquiry, neither category of provider would be exempt from the requirements of this provision simply based on those factors. If a provider or supplier falls into the categories articulated in the rule, there will be no exemptions provided.

Concerns for Beneficiaries

Comment: A commenter stated that if CMS terminates a contract with an MA organization for failing to meet provider enrollment requirements or payment prohibitions, CMS should allow impacted patients to continue with their physicians on an in-network basis until the next enrollment period, with the physician's consent. The commenter said that effectively requiring a beneficiary to find a new provider in the middle of an enrollment period with little advanced notice could be extremely disruptive and harmful to the enrollee's health.

Response: We will follow existing protocols and rules regarding beneficiary care if CMS terminates a contract with an MA organization. Beneficiary care and access are always of the highest concern when determining contract action. Furthermore, we have access to tools other than contract termination to ensure MA organizations are compliant with this rule.

Comment: A commenter expressed concern about the potential financial impact on beneficiaries if a provider or supplier requests payment (1) for multiple beneficiaries at once, or (2) for Medicare beneficiaries after notification that the provider or supplier is revoked from Medicare. The commenter recommended that CMS clarify that beneficiaries would not be financially responsible in these cases. Overall, the commenter urged CMS to ensure that beneficiaries are financially protected and do not lose access to care during the transition phase as providers enroll in Medicare.

Response: As we work towards the implementation date, we will continue to monitor beneficiary impact. The public should be aware of the provisions in § 422.224 regarding prohibition of payment for excluded or revoked individuals or entities. This rule also does not change beneficiaries' ability to ask for a coverage determination prior to receiving an item or service if they are unsure of a provider or supplier's enrollment status. The issue of beneficiary liability resulting from an OIG exclusion is addressed in 42 CFR 1001.1901(b). The issue of beneficiary liability resulting from revoked providers and suppliers, deactivated providers and suppliers, or enrollment denials is addressed in § 424.555(b). Any needed additional clarification of this provision will be provided in subregulatory guidance.

Comment: A commenter noted the provision to prohibit MA organizations from paying individuals or entities that are excluded by the OIG or revoked from Medicare. Citing the requirement that the MA organization in such cases must notify the physician and the beneficiary that no future payment will made beyond the first one, the commenter stated that the notification may only reach the beneficiary after numerous services have been provided and billed. The commenter expressed concern that either the beneficiary or the physician would be without reimbursement or payment for the subsequent services provided before notification was received.

Response: We understand the concerns of the commenter and do believe it is important for MA organizations and the other programs and plans that fall within the context of this rule to notify beneficiaries and providers and suppliers that payments will not be made. However, after further analysis, we are not able to finalize the first time payment provision that was proposed because all payments to excluded individuals or entities is prohibited. Beneficiaries have the ability to ask for a coverage determination prior to receiving an item or service if they are unsure of a provider or supplier's enrollment status. The issue of beneficiary liability resulting from an OIG exclusion is addressed in § 1001.1901(b). The issue of beneficiary liability resulting from revoked providers and suppliers, deactivated providers and suppliers, or enrollment denials is addressed in § 424.555(b). All individuals and entities that are excluded or revoked are notified of their exclusion or revocation status, and therefore, should not request or receive payment for items or services that violate federal law.

Comment: A commenter stated that CMS must assess the impact of our proposed requirement on beneficiaries. The commenter specifically asked how the requirement will be explained to beneficiaries and whether beneficiaries themselves will have to pay for services obtained from a non-enrolled provider (for example, an out-of-network PPO provider) if they were unaware of the enrollment requirement.

Response: As we work towards the implementation date, we will continue to assess beneficiary impact, though we believe that based on the low number of providers and suppliers that need to enroll, this impact will be small. This rule applies to in-network providers and suppliers and other providers and suppliers listed herein. This rule does not modify existing rules on out-of-network providers and suppliers; however, the public should be aware of the provisions in § 422.224 regarding prohibition of payment for excluded or revoked individuals or entities. This rule also does not change beneficiaries' ability to ask for a coverage determination prior to receiving an item or service if they are unsure of a provider or supplier's enrollment status.

Operations

Comment: A commenter stated that CMS should engage in robust provider and practice education to ensure that enrollment updates are implemented efficiently and without complication.

Response: We appreciate the suggestion and will incorporate this into our operational plan.

Comment: A commenter asked CMS to address the claims and coding technical components that CMS will implement for our proposed requirement.

Response: We will issue subregulatory guidance that addresses this issue.

Comment: A commenter asked CMS to clarify the components of its provider education campaign.

Response: We will issue subregulatory guidance detailing educational efforts in the future as we move forward in operationalizing this program.

Comment: A commenter suggested that CMS explain how it will communicate provider and supplier information to individual MA organizations so that the latter can remain compliant with our requirements and identify the types of enforcement actions it will take against an MA organization that permits an unenrolled provider or supplier to furnish care in an MA setting. The commenter asked us to list all of the

enforcement actions imposed against MA providers and suppliers based on the provider being unqualified or fraudulent.

Response: We will continue to provide outreach and education to the provider and supplier community about these enrollment requirements and will work with our stakeholders, including MA organizations, to assist them in ensuring compliance. Specific operational plans and guidance are forthcoming as we move towards operationalizing this policy. Regarding enforcement actions, we have provided a number of options and have discretion when determining the appropriate action to take for noncompliant plans. Those specific sanctions and contract actions are in existing policy.

Comment: A commenter supported our proposed requirement to notify the enrollee when the provider's or supplier's enrollment is revoked from Medicare but encouraged CMS to ensure that such notices are consumer-friendly. Another commenter urged CMS to furnish additional details on how plans are to operationalize these new requirements in a format that allows plans to provide feedback on the proposed processes.

Response: We appreciate the commenter's support and will use the suggestion to help operationalize this policy.

Comment: Regarding proposed § 422.224, a commenter asked whether ''first time allowance'' for payment is a requirement or is at the discretion of the MA organization.

Response: After further legal analysis, we have determined that we lack the authority to allow a first time payment granted in the proposed § 422.224. Therefore, MA organizations have no discretion and may not pay an individual or entity that is excluded by the OIG or revoked from the Medicare program.

Comment: Regarding proposed § 422.501, a commenter sought clarification regarding the method of submission and the frequency of checks, and how this process differs from the current standard attestation process.

Response: Further information and direction on this provision will be issued in subregulatory guidance.

Comment: Stating that the proposed requirement contains no specifications for how often plans would be required to confirm the status of a network provider, a commenter sought clarification on the following issues: (1) Whether a plan has met its obligations under the proposed requirements if, for example, the plan confirms the provider's enrollment status before signing the provider to a 5-year contract for network participation; (2) if the provider fails to notify the MA organization of changes to its Medicare enrollment status, whether the plan is responsible for all payments made to the provider beginning as of the date of disenrollment; (3) if a provider's Medicare enrollment status changes and the plan removes the provider from its network, whether and what consequences would ensue if this results in the plan failing network adequacy requirements; and (4) whether there are requirements concerning continuity of care with respect to providers that lose Medicare status.

Response: The requirements of this rule require that after the effective date, MA and MA PD plans must ensure that only enrolled providers and suppliers are providing services to Medicare beneficiaries who are enrolled in their plans. We have developed informational tools—the list of enrolled providers and suppliers referenced in several places throughout this rule—that further support plans' ability to meet these requirements and not rely on notification by providers in ensuring compliance. Based on the small number of providers and suppliers that need to enroll to comply with the provisions of this rule, we do not believe this requirement will cause network adequacy issues. As to the frequency with which the plans will be expected to update their records, further guidance will be provided as we operationalize this requirement; however, it is anticipated that the plans will be expected to update their records with the same frequency that the applicable online files are updated. This rule does not require providers and suppliers to notify the plans, as the enrollment status on the file will change. This rule also does not change any rules regarding continuity of care.

Comment: A commenter sought clarification regarding whether CMS' use of the term ''enrollment'' indicated enrollment in the Medicare program through PECOS or an MA organization's enrollment of health professionals for the purpose of identifying them as legitimate health professionals on claims. The commenter expressed concern that if Medicare enrollment is required without a concomitant requirement that the MA organization enroll the provider or supplier, CMS risks perpetuating the concealment of certain types of health professionals. Citing the example of physician assistants, the commenter stated that when an MA organization requires that a physician's assistant bill under a physician's name, the physician's assistant becomes a ''hidden'' provider, which the commenter stated is contrary to CMS' goal of proper attribution to the health professional who furnished the service. The commenter stated that MA organization should be required to enroll relevant health professionals, including physician's assistants, and mandate the inclusion of the appropriate professional's NPI on a claim.

Response: The term ''enrollment'' is specific to enrollment in Medicare. The enrollment data repository is PECOS. We believe the commenter is referring to incident-to services. Incident-to suppliers and locum tenens suppliers are also required to enroll in Medicare, meaning that the supplier actually furnishing the service, not only the billing supplier, must be enrolled. We believe that this is an important step in addressing the concerns of the commenter and may consider future rulemaking to further prevent the scenario offered by the commenter.

Network Adequacy

Comment: A commenter expressed concern that the enrollment requirement would unduly burden physical therapists, which could harm access to physical therapy services as MA organizations struggle to find physical therapy providers for their networks.

Response: This rule seeks to ensure that beneficiaries receive care from providers and suppliers that have been uniformly screened. We have found relatively few physical therapists that are not already enrolled in Medicare. Therefore, we do not believe this will have an impact on network adequacy.

Comment: A commenter recommended that CMS proceed with its enrollment requirement for only a limited number of providers and suppliers at first, specifically, for those provider types for which MA organizations are required to maintain adequate networks, as specified in the Health Services Delivery Guidance that CMS issues each contract year.

Response: We believe the requirements should be implemented simultaneously and have structured our efforts to accomplish that task. As we have stated throughout this rule, we think the timeframe afforded plans for compliance coupled with the relatively small number of providers and suppliers that are not already enrolled in Medicare will allow plans to ensure that all necessary providers and suppliers can be enrolled and there are no access issues.

Comment: A commenter requested clarification regarding what MA organizations must do if the termination

of providers or suppliers from the plan's network results in network adequacy deficiencies.

Response: Based on the small number of providers and suppliers that need to enroll to comply with the provisions of this rule, we do not believe this requirement will cause network adequacy issues. However, MA organizations should use existing resources and processes to address any network adequacy concerns.

Comment: A commenter stated that the administrative steps involved in enrolling in Medicare will deter some physicians from entering into MA arrangements, thereby potentially impacting the plan's network adequacy and beneficiary access to care.

Response: The vast majority of providers and suppliers providing services in the MA program are already enrolled in Medicare. Based on the number of providers and suppliers needing to enroll to become compliant with this requirement, we do not anticipate this impacting network adequacy and access to care.

PACE

Comment: A commenter asked whether the requirements that are applicable to FDR entities of MA organizations will also apply in the context of PACE organizations.

Response: The requirements for FDR entities also apply to PACE organizations.

Comment: A commenter stated that our proposals should not be applied to the PACE program for several reasons. First, the proposed requirements are duplicative of exclusion screening requirements established by the OIG, which are often reinforced by state screening requirements. Second, PACE organizations are already Medicare-certified provider entities responsible for the comprehensive medical, health and social well-being of their PACE participants; existing regulations under part 460 have requirements in place concerning these policies. The commenter stated that PACE is a different model of care from MA organizations. The latter are insurers while PACE programs are Medicare-certified provider entities that are directly responsible for the care of Medicare and Medicaid beneficiaries. At a minimum, the commenter stated, PACE organization personnel (for example, employees and contractors) should be exempt from the enrollment requirement; the burden of requiring the enrollment of staff members, the commenter contended would be enormous. Another commenter suggested that CMS clarify in the final rule how its MA enrollment policies do not inadvertently exclude long-term services and supports (LTSS) caregivers who cannot presently bill Medicare directly. Another commenter also expressed concern about the rule's effect on LTSS caregivers.

Response: This rule only requires the enrollment of providers and suppliers that are of a type this are eligible to enroll. Staff members that are not of a provider or supplier type that is eligible to enroll, are not subject to this rule. A determination on if a provider or supplier is eligible to enroll will be based on the type of provider or supplier. For example, if a clinical social worker works for a PACE organization, he or she would need to enroll in Medicare because a clinical social worker is a type of provider or supplier eligible to enroll. Furthermore, § 410.73(a) defines clinical social worker and states they must have a masters or doctoral degree in social work, among other requirements. If the clinical social worker cannot enroll because he or she fails to meet program requirements, such as this educational requirement, he or she may not enroll in the program or provide services to beneficiaries enrolled in programs under this final rule, such as the PACE program. It does not mean that providers and suppliers, that are of the type of providers or suppliers eligible to enroll in Medicare, are exempt from enrolling because they cannot or do not meet the necessary requirements for their specific provider or supplier type to enroll in Medicare. Providers and supplier that cannot or do not meet the enrollment requirements may not provide items and services to beneficiaries that receive items and services through FFS, MA, MA–PD, PACE, and Cost plans, as well as demonstration and pilot programs. We have decided to finalize the proposal to include PACE organizations in this rule because we believe it is in the best interest of the beneficiaries to receive items and services from Medicare providers and suppliers that are subject to the same screening requirements. The screening efforts mentioned by the commenter are not duplicative to any other process, specifically OIG and state screening. We have access to information and authority for keeping certain providers and suppliers out of the program that are not available to these entities. Additionally, while it may be true that PACE organizations are Medicare-certified provider entities, the individual providers and suppliers have not been required to enroll. We do not anticipate that this rule will have a significant impact on LTSS caregivers because of the relatively small number of providers and suppliers that need to enroll. Furthermore, some of the LTSS caregivers are not of a provider or supplier type that is eligible to enroll in Medicare.

Comment: A commenter expressed concern about our proposal to amend § 460.32 to require that the PACE program agreement include the name and NPI of providers and suppliers reflecting enrollment in Medicare. The commenter stated that the program agreement is a three-way agreement between CMS, the state, and the PACE organization, and that any change to the agreement would require the three parties to reenter and resign the document. The commenter contended that this would prove burdensome because new agreements would have to be signed each time a provider or supplier enters or departs a contractual relationship with a PACE organization. The commenter recommended that CMS (1) devise an alternative approach, or (2) require PACE organizations to furnish this information only on an annual basis; concerning the latter, the commenter said that this would not absolve PACE organizations from ensuring that all contracted providers and suppliers, but would reduce the reporting burden. Another commenter shared these concerns and added that uninterrupted access to PACE services should be ensured.

Response: We understand the operational concerns and thank the commenters. Based on this concern, we have reduced the burden this requirement would have imposed on PACE organizations by aligning the requirements to the provisions applicable to MA organizations. We have removed the requirement in 42 CFR 460.32 and simply added §§ 460.70 and 460.71. We believe this change will ensure that PACE organizations employ and contract with enrolled providers and suppliers without the additional burden of having the parties update the program agreement.

Comment: A commenter recommended that any enrollment regulatory requirements imposed on PACE organizations be made in part 460 and that such requirements have the same specificity and precision as the regulation changes proposed for part 422.

Response: We believe the appropriate requirements have been reflected in part 460.

Other Comments

Comment: A number of commenters supported our proposal to require

providers or suppliers who furnish health care items or services to an MA beneficiary be enrolled in Medicare in an approved status. A commenter stated that many MA organizations already have this requirement in place, and supported our efforts to standardize this practice across all organizations.

Response: We appreciate the commenters' support.

Comment: A commenter disagreed with the use of the term ''intermediary'' being applied to MA organizations. The commenter stated that MA organizations are state licensed, risk-bearing entities that contract with CMS to provide Medicare Part A, B, and D benefits and services. An intermediary, the commenter stated, is a Medicare Administrative Contractor that bears no risk but is under contract with CMS to pay Medicare covered claims and perform other functions for CMS. The commenter sought greater clarification on this issue.

Response: We used intermediary as a general term to describe an entity that holds a position between CMS and the provider and supplier communities; we did not mean ''intermediary'' as the former contractor entity that paid Medicare claims in the past before there were MACs. As the public is likely aware, we do not pay providers and suppliers directly in the MA program. We appreciate the opportunity to clarify.

Comment: Several commenters requested that CMS delay the implementation of the MA enrollment requirement. They generally stated that a delay would give all stakeholders (for example, MA organizations, providers, suppliers, beneficiaries, and CMS) adequate time to prepare for the requirement. They added that the delay would enable CMS to resolve certain issues encountered in the Part D enrollment process so they are avoided in the MA enrollment process. Some commenters stated that CMS must establish an implementation plan, provide operational and technical guidance (including clarity around FDRs), and develop a comprehensive education and outreach strategy for relevant stakeholders, and that a delay would give CMS time to perform these activities. Several commenters recommended that the requirement be implemented at the same time as the Part D enrollment requirement, with one commenter specifically suggesting an effective date in CY 2020 for both requirements. Other commenters recommended an effective date for the MA enrollment requirement of least 3 years from the date of this final rule; several commenters suggested 4 years from the date of this rule.

Response: We believe that the 2019 implementation date is appropriate and takes into account the concerns raised by the commenters. We thank the comments for the suggestions regarding operational planning and will take them into consideration as we issue future guidance.

Comment: A commenter contended that an increasing number of physician practices may provide most or all of their Medicare services to MA patients. The commenter encouraged CMS to develop means by which such physicians can remain enrolled, for purposes of furnishing MA services, without having to submit Part B claims.

Response: If the commenter is concerned about possible deactivations due to 12 consecutive months of non-billing, we can say that although § 424.540(a)(1) is part of our regulatory authority, its use is limited due to the expansion of our enrollment requirements in Medicare that extend beyond billing Parts A and B. We have thousands of providers and suppliers enrolled in Medicare that do not submit claims for payment, such as providers and suppliers ordering and certifying certain items and services and prescribers of Part D drugs. Thus, systematic deactivations for 12 consecutive months of non-billing would not be appropriate for providers and suppliers that enrolled exclusively for purposes unrelated to billing the Medicare program. We are mindful of the scenario described as we operationalize this rule.

Scope

Comment: A commenter asked CMS to clarify the MA enrollment requirement's relationship to the Part D prescriber enrollment rule and the latter's implementation date.

Response: The Part D prescriber enrollment requirement states that nearly all prescribers of Part D drugs must be enrolled in Medicare or validly opted-out. The requirement in this rule is that providers and suppliers that provide services to Medicare beneficiaries in MA organizations or MA–PD plans, including FDRs, must be enrolled in Medicare. These are separate requirements; therefore, the implementation date for the Part D prescriber rule is outside the scope of this rule.

Comment: A commenter asked CMS to clarify the benefits of increased opportunities for private practice physical therapists to become in-network providers under MA organizations.

Response: We believe this request is outside the scope of the rule.

Comment: A commenter asked whether CMS is collaborating with state Medicaid agencies to discuss implementation issues related to a similar enrollment requirement on the Medicaid side; the commenter indicated that such discussions could assist CMS in effectively implementing the MA enrollment requirement.

Response: On May 6, 2016, we published the ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability'' final rule (81 FR 27498) that includes requirements for providers and suppliers that provide services to Medicaid beneficiaries in a managed care setting to be screened and enrolled in Medicaid. We collaborate regularly with state Medicaid agencies when operationalizing rules and appreciate the commenter's suggestion.

Comment: A commenter asked whether the enrollment requirements apply to providers that are participating in special CMS initiatives, such as Accountable Care Organizations initiatives and, if not, why not, and which entity in these initiatives would be held accountable as to their participating providers and suppliers are enrolled in Medicare. The commenter stated that it would be reasonable to have this requirement extend beyond the MA and Part D programs.

Response: We believe this comment is outside the scope of this rule.

Comment: One commenter expressed support for requiring MA network providers to publicly report quality data in a manner consistent with Part A and B providers, specifically, requiring these providers to submit administrative data sets to CMS such as claims and encounter data in a manner consistent with Medicare Part A and B programs. The commenter stated that there currently is little insight as to the quality, volume, and utilization patterns of beneficiaries who elected MA coverage.

Response: We appreciate this comment but believe it is outside the scope of this rule.

Comment: One commenter, while supporting our proposed requirement, made two recommendations. The first was that CMS should use the MA enrollment requirement as an opportunity to begin deeming providers for general compliance training as well. The second was that CMS should obtain the demographic data for providers at the point of enrollment into Medicare

and require providers to supply CMS with updates; plans would be expected to use the most up-to-date information CMS has on file for providers when updating the directories. This would create a provider demographic repository, which the commenter believed would help ensure consistency between CMS and MA records.

Response: We believe these comments are outside the scope of this rule.

Comment: A commenter recommended that CMS explain whether providers and suppliers participating in a section 1876 cost contract plan, a section 1833 health care prepayment plan, the Railroad Retirement Board, or an Indirect Payment Procedure (IPP) entity that does not treat Medicare FFS beneficiaries, are subject to the $500 application fee.

Response: We believe this comment is outside the scope of this final rule.

J. Expansion of the Diabetes Prevention Program (DPP) Model

1. Summary

This final rule finalizes our proposal to expand the duration and scope of the Diabetes Prevention Program (DPP) model test, which we refer to as the Medicare Diabetes Prevention Program (MDPP) expanded model.[15] The MDPP expanded model aims to prevent the onset of type 2 diabetes among Medicare beneficiaries diagnosed with pre-diabetes. Services available through the MDPP expanded model are MDPP services, which will be furnished in community and health care settings by coaches, such as trained community health workers or health professionals. The MDPP expanded model is a Center for Medicare and Medicaid Innovation (Innovation Center) model that is being expanded in duration and scope under section 1115A(c) of the Act and will be covered as an additional preventive service under Medicare.

We received approximately 700 timely pieces of correspondence containing multiple comments on the MDPP expanded model. We note that some of these public comments were outside of the scope of the proposed rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the corresponding heading.

Commenters ranged from professional organizations, health plans, advocacy groups, individual physicians, and numerous individuals who have direct experience with the National Diabetes Prevention Program (National DPP), and expressed overwhelming support for this model expansion. Commenters raised key considerations as well.

Because the MDPP expanded model will be implemented through at least two rounds of rulemaking, we have chosen in this final rule to finalize aspects of this model expansion that will enable organizations to prepare for enrollment. This includes finalizing the framework for expansion and finalizing details of the MDPP benefit, beneficiary eligibility criteria, and MDPP supplier eligibility criteria and enrollment policies.

We are finalizing our proposal to expand the duration and scope of the DPP model test as proposed. We are also finalizing our proposal to designate MDPP services as ''additional preventive services'' as defined by section 1861(ddd) of the Act. We are finalizing our proposal to use the Secretary's waiver authority under section 1115A(d)(1) of the Act to waive two requirements of the benefit category of additional preventive services: the requirement in section 1861(ddd)(1)(B) of the Act that the services be recommended by a grade of A or B from the United States Preventive Services Task Force (USPSTF) and the requirement of section 1861(ddd)(2) of the Act that the Secretary make the determinations required under section 1861(ddd)(1) of the Act using the National Coverage Determination (NCD) process.

We are finalizing our proposal that the MDPP core benefit is 12 consecutive months and consists of at least 16 weekly core sessions over months 1–6 and at least six monthly core maintenance sessions over months 6–12, furnished regardless of weight loss. Eligible beneficiaries will have access to ongoing maintenance sessions after the MDPP core benefit if they achieve and maintain the required minimum weight loss of five percent. We are adding definitions of ''maintenance session bundle'' and ''maintenance of weight loss'' to help provide clarity. We are revising the definition of ''CDC-approved core curriculum'' to remove specific curriculum topic names. We are also revising the session duration requirement to specify that any session must have a duration of approximately one hour.

We are finalizing the beneficiary eligibility criteria and our referral policy as proposed.

We are finalizing the proposed high screening level for MDPP supplier enrollment, the requirement for coaches to obtain National Provider Identifiers (NPIs), and for DPP organizations to submit a roster of coach NPIs and other coach information upon applying for enrollment. We are modifying our proposal regarding the enrollment of existing Medicare providers or suppliers, and are requiring all DPP organizations, regardless of any existing enrollment in Medicare, to enroll in Medicare as MDPP suppliers in order to furnish and bill for MDPP services.

We are not finalizing our proposal that organizations that deliver DPP virtually or through remote technologies will be eligible to furnish MDPP services to future rulemaking. We intend to address policies related to the delivery of virtual MDPP services in future rulemaking. We are also not finalizing the definition of preliminary recognition. We intend to seek comment on recognition standards in future rulemaking.

We are also deferring certain policies, specifically related to payment, use of coach information during enrollment and monitoring, and other program integrity safeguards to future rulemaking. In particular, specific policies regarding monitoring and enforcement actions for supplier enrollment require future rulemaking. Because we are not implementing such requirements in this rule, we cannot begin any enrollment for organizations seeking to enroll as MDPP suppliers until after the next round of rulemaking is complete in 2017. We intend to begin supplier enrollment before the model expansion becomes effective on January 1, 2018. We intend for organizations to be able to apply to enroll as MDPP suppliers at the conclusion of the next round of rulemaking. We may issue subregulatory guidance to assist in this preparation before subsequent rulemaking is finalized. We will address public comments on sections of the proposed rule we sought comment on, including payment, quality reporting, and program integrity, in future rulemaking.

The MDPP expanded model will become effective nationwide beginning on January 1, 2018. We will continue to evaluate this expanded model test.

2. Background

In January 2015, the Administration announced the vision of ''Better Care, Smarter Spending, Healthier People'' with emphases on improving the way

[15] Centers for Medicare & Medicaid Services, Proposed Rules, ''Proposed Expansion of the Diabetes Prevention Program (DPP) Model,'' **Federal Register** 81, no. 136 (July 15, 2016): 46413–46418, *https://www.federalregister.gov/documents/2016/07/15/2016–16097/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions.*

providers are paid, improving and innovating in care delivery, and sharing information to support better decisions, and that set goals for payments made through alternative payment models and tied to quality or value. In March 2016, the United States Department of Health and Human Services (HHS) announced that an estimated 30 percent of Medicare payments are tied to alternative payment models that reward the quality of care over quantity of services provided to beneficiaries, nearly a year ahead of schedule.

Diabetes affects more than 25 percent of Americans aged 65 or older [16] and its prevalence is projected to increase approximately 2 fold for all U.S. adults (ages 18–79) by 2050 if current trends continue.[17] Additionally, 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.[18] Care for Americans aged 65 and older with diabetes accounts for roughly $104 billion annually, and these costs are growing.[19] In total, we estimate that Medicare will spend $42 billion more in the single year of 2016 on fee-for-service, non-dual eligible, over age 65 beneficiaries with diabetes than it would spend if those beneficiaries did not have diabetes—$20 billion more for Part A, $17 billion more for Part B, and $5 billion more for Part D. On a per-beneficiary basis, this disparity is just as clear. In 2016 alone, Medicare will spend an estimated $1,500 more on Part D prescription drugs, $3,100 more for hospital and facility services, and $2,700 more in physician and other clinical services for those with diabetes than those without diabetes.[20]

Fortunately, type 2 diabetes is typically preventable with appropriate lifestyle changes. The National DPP, administered by the Centers for Disease Control and Prevention (CDC), is an evidence-based intervention targeted to individuals with pre-diabetes, meaning those with blood sugar that is higher than normal but not yet in the diabetes range. The National DPP is a structured health behavior change program delivered in community and health care settings by trained community health workers or health professionals. The National DPP consists of 16 intensive core sessions of a CDC-approved curriculum in a group-based setting that provides practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to sustaining weight loss and a healthy lifestyle. After the 16 core sessions, monthly maintenance sessions help to ensure that the participants maintain healthy behaviors. The primary goal of the intervention is to reduce incidence of type 2 diabetes by achieving at least 5 percent average weight loss among participants. To learn more about the National DPP, please visit *http://www.cdc.gov/diabetes/prevention/lifestyle-program/index.html*.

In 2012, the Innovation Center awarded a Health Care Innovation Award (HCIA) to The Young Men's Christian Association (YMCA) of the USA (Y–USA) to test whether DPP services could be successfully furnished by non-physician, community-based organizations to Medicare beneficiaries diagnosed with pre-diabetes and therefore at high risk for development of type 2 diabetes (referred to hereafter as the DPP model test). The DPP model test has been conducted under the authority of section 1115A of the Act, which authorizes the Innovation Center to test innovative health care payment and service delivery models that have the potential to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of patient care.

Between February 2013 and June 2015, the Y–USA, in partnership with 17 local YMCAs, the Diabetes Prevention and Control Alliance, and seven other non-profit organizations, enrolled a total of 7,804 Medicare beneficiaries into the model. Enrolled beneficiaries represented a diverse demographic across the eight states of Arizona, Delaware, Florida, Indiana, Minnesota, New York, Ohio, and Texas. According to the second year independent evaluation report of the DPP model test, Medicare beneficiaries demonstrated high rates of participation and sustained engagement in the Diabetes Prevention Program. Approximately 83 percent of recruited Medicare beneficiaries attended at least four core sessions and approximately 63 percent completed nine or more core sessions. The first and second independent evaluation reports are available on the Innovation Center's Web site at *https://innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/*.

3. Requirements for Expansion

Section 1115A(c) of the Act provides the Secretary of the U.S. Department of Health and Human Services (the Secretary) with the authority to expand (including implementation on a nationwide basis) through rulemaking the duration and scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the model expansion is expected to either reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net program spending; and (3) The Secretary determines that the expansion would not deny or limit the coverage or provision of benefits.

- *Improved Quality of Care without Increased Spending:* The DPP model test was designed to improve care through diabetes-related preventive services in community- and primary-care based settings. Weight loss is a key indicator of success among persons enrolled in a DPP due to the strong association between weight loss and reduction in the risk of diabetes.[21] According to the second year independent evaluation of the DPP model test, those beneficiaries who attended at least one core session lost an average of 7.6 pounds while beneficiaries who attended at least four core sessions lost an average of 9 pounds. Body Mass Index (BMI) was reduced from 32.9 to 31.5 among Medicare beneficiaries that attended at least four core sessions. The evaluation

[16] 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*.

[17] 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.

[18] X Zhang et al., ''A1C Level and Future Risk of Diabetes: A Systematic Review,'' *Diabetes Care* 33, no. 7 (2010): 1665–1673.

[19] 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.

[20] 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/ReportsTrustFunds/downloads/tr2016.pdf*.; and CMS estimates.

[21] RF Hamman et al., ''Effects of Weight Loss with Lifestyle Intervention on Risk of Diabetes,'' *Diabetes Care* 29, no. 9 (2006): 2102–2107.

also demonstrated a statistically significant reduction in inpatient admissions following the intervention. Based on these findings and results from other DPP evaluations demonstrating the effectiveness of DPP programs in preventing diabetes onset in non-Medicare beneficiaries, some of which were over 65, the Secretary determined that expansion of the DPP model test is expected to improve the quality of patient care for Medicare beneficiaries without increasing spending.

• *Impact on Medicare Spending:* The CMS Chief Actuary (referred to hereafter as the Chief Actuary) has certified that expansion of the DPP model test would not result in an increase in Medicare spending. The Chief Actuary has determined that DPP is likely to reduce Medicare expenditures if made available to eligible Medicare beneficiaries based on historical evidence from evaluations of the DPP model test and other DPPs. In addition, to evaluate the longer-term impact of the expanded model, the Chief Actuary developed a model to estimate lifetime per participant savings of a Medicare beneficiary receiving DPP services.

The full Chief Actuary Certification is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf*.

• *No Alteration in Coverage or Provision of Benefits:* The MDPP model expansion would make MDPP services available to beneficiaries in addition to existing Medicare services, and beneficiaries receiving MDPP services would retain all benefits covered in traditional Medicare. Therefore, the Secretary has determined that expansion of the DPP model test would not deny or limit the coverage or provision of Medicare benefits for Medicare beneficiaries.

The following is a summary of the comments received and our responses.

Comment: Commenters were overwhelmingly in favor of the proposed expansion and Medicare covering the MDPP services as an additional preventive service. Many commenters offered personal stories of their battles with type 2 diabetes, or caring for those with type 2 diabetes, and expressed gratitude toward the agency for proposing to cover the benefit to prevent future beneficiaries from the challenges posed by type 2 diabetes. Commenters encouraged us to consider ways to increase beneficiary awareness and lower barriers to access. Several commenters expressed their desire to assist us in further development of the model expansion. Commenters also encouraged us to continue to align with the CDC Diabetes Prevention Recognition Program Standards and Operating Procedures (CDC DPRP Standards) on various policies such as supplier requirements, recognition status, and required minimum weight loss percentage. Another commenter recommended that we reimburse for technology such as the continuous glucose monitor. Some commenters encouraged us to continue to take steps toward more preventive models. One commenter disagreed altogether with the proposed MDPP model expansion, stating it allows another high risk supplier type into the Medicare program.

Response: We appreciate the commenters' suggestions to increase beneficiary awareness of the benefit, and look forward to exploring ways we can achieve our shared aims through stakeholder engagement and communications efforts, such as updates to the Medicare & You Handbook. We also hope to engage the public and MDPP stakeholders in further developments and any adjustments we make through future rulemaking, subregulatory guidance, or other guidance, as appropriate. We appreciate the comments to test more preventive models and to pay for technology that could be used in connection with the MDPP expanded model, but those are outside the scope of what we proposed to expand, and we decline to include them in the MDPP model expansion. We disagree with the commenter who believed we should not expand the DPP model test. We describe later in this rule some of the enrollment policies that are intended to protect against the risks introduced by the new supplier class. Additionally, we intend to propose specific program integrity policies in future rulemaking.

Comment: A few commenters expressed concerns that the MDPP model expansion will set a flawed precedent for future model expansions. For example, two commenters expressed concerns that the Secretary's determination that the MDPP model expansion would improve the quality of care is not substantiated by the evidence, and asked for more discussion of how the MDPP expansion will improve other elements within quality of care, such as patient experience.

Response: We are undertaking the MDPP model expansion in a manner consistent with the statutory requirements of section 1115A(c) of the Act. Therefore we do not agree that expansion of the DPP model test sets a flawed precedent. We also note that the specific data, analyses, and other factors informing the MDPP expansion are unique to this particular model. For example, different approaches to actuarial modeling may be required for a preventive service payment and service delivery model as compared to a payment model focused on treatment. We expect to take into account the specific aspects of each model when evaluating it for expansion. We found that the DPP model test has been shown to reduce risk of type 2 diabetes through weight loss and behavior change. The second year independent evaluation of the DPP model test also found statistically significant reductions in inpatient and emergency room visits and robust engagement by beneficiaries. Expansion of the DPP model test will give eligible beneficiaries access to MDPP services, which are evidence-based, to improve their health. The Secretary has determined that by improving health outcomes, as measured by participation in the DPP and weight loss, the MDPP expanded model will improve beneficiaries' quality of care. Weight loss is a key indicator of success among persons enrolled in the DPP as it predicts the reduced incidence of type 2 diabetes.[22] According to the second year independent evaluation of the DPP model test, which included 6,874 Medicare beneficiaries, those beneficiaries who attended at least one core session lost an average of 7.6 pounds while beneficiaries who attended at least four core sessions lost an average of nine pounds. BMI was reduced from 32.9 to 31.5 among Medicare beneficiaries that attended at least four core sessions.

Comment: Regarding the Chief Actuary's certification, some commenters expressed appreciation that the determination was made available to the public several months before the proposed rule. One commenter also asked us to clarify if, and how, stakeholders can engage with the certification process in the event that there are outstanding questions of methodology and model assumptions. Two commenters criticized the Chief Actuary's consideration of findings in addition to the DPP model test, such as other DPPs in the National DPP, in making the certification. A commenter stated that the Chief Actuary certified the expansion of a model that is different than the tested model, which the commenter viewed as contrary to the statute. MedPAC expressed concern that the MDPP expanded model would

[22] RF Hamman et al., ''Effects of Weight Loss with Lifestyle Intervention on Risk of Diabetes,'' *Diabetes Care* 29, no. 9 (2006): 2102–2107.

expand far beyond the structure of the initial model test. One commenter expressed concern that this determination was made based on a preliminary, 2-year evaluation.

Response: We appreciate commenters' interest in the certification process. The CMS Office of the Actuary, led by the Chief Actuary, functions in accordance with professional standards of actuarial independence. The statute does not require that in certifying an expansion the Chief Actuary may consider data only from the model evaluation; rather, the statute requires only that the evaluation be taken into consideration.

The Chief Actuary also reviewed data from other sources besides the model evaluations in certifying the Pioneer Accountable Care Organization (ACO) Model, the first Innovation Center model determined eligible for expansion. In April 2015, the Chief Actuary certified that expansion of the Pioneer ACO Model, as it was tested in the model's first 2 years, would reduce net program spending. The Chief Actuary used historical evidence from the formal evaluation of the Pioneer ACO Model as well as the Chief Actuary's independent internal analysis of financial impacts. The Chief Actuary's certification of the Pioneer ACO Model is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Pioneer-Certification-2015-04-10.pdf*. The Secretary also determined that expansion would not limit coverage or benefits, and that expansion would maintain or improve patient care without increasing spending. While the Pioneer ACO Model has not been expanded through section 1115A(c) of the Act, CMS has incorporated successful design elements of the Pioneer ACO Model into the Medicare Shared Savings Program.

The statute does not require that an expanded model test be identical to the initial model test. Indeed, section 1115A(c) of the Act authorizes the Secretary to expand (including implementation on a nationwide basis) the duration and the scope of a model being tested under subsection (b) or a demonstration project under section 1866C of the Act through rulemaking. The rulemaking requirement indicates that the expansion is to be subject to public comment, which, in turn, indicates that the expansion can and should be modified as appropriate to reflect the outcome of the rulemaking process. In addition, we expect that we will need to modify some design features in nearly all cases of expanded model tests, by virtue of the shift in duration or scope. For example, a nationwide expansion may require different policies and operations to manage large-scale provider enrollment or payment than does the initial model test. The Chief Actuary certified expansion of the DPP model test understanding that the expansion would include specific changes driven by policies and operations necessary in bringing the model to a national scale. As the expansion's full design is implemented in future rulemaking, the Chief Actuary will assess whether such expansion will reduce or not increase net program spending, and will update the certification as appropriate.

Comment: Some commenters supported the determination that the DPP model expansion would not deny or limit the coverage or provision of Medicare benefits for Medicare beneficiaries as the MDPP expanded model makes additional services available to eligible beneficiaries. Two commenters asked that in future model expansions we assess the impact of a model on patient access to covered items and services based on a broad evaluation of the direct and indirect barriers to care that may result from a model's expansion.

Response: We appreciate the commenters' support regarding the determination that the expansion of the DPP model test would not deny or limit the coverage or provision of Medicare benefits. We will apply the statutory criteria for expanding a model on an individual basis and will take the particular features of each model into account when making any determinations.

Comment: Several commenters encouraged us to continue to collect data and evaluate the impact of the expanded model test.

Response: We will continue to evaluate this expanded model test as indicated in the proposed rule. Using an evaluation design that could include a before and after assessment and or matched comparison groups, we will examine the impact of the model on utilization of services and cost of care, particularly whether the model has had an impact on the development of diabetes, and other health consequences of diabetes. We will also examine the expanded model's impact on changes in health metrics, such as weight loss.

In general, evaluations of Innovation Center models address the impact of the models on use of services and the quality of care provided, relative to a comparison group, using CMS administrative data and relevant beneficiary experience data when available. Utilization measures can be used to monitor whether beneficiaries are receiving the services that would be expected given beneficiaries' health status. The comparison group generally consists of beneficiaries who are similar to the beneficiaries receiving services under the model, and are often matched on underlying health status and other important characteristics, including whether the beneficiary is part of another model test. We intend to apply additional information on the evaluation in the future. 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.

4. Expansion of the Diabetes Prevention Program Model

We proposed to expand the duration and scope of the DPP model test under section 1115A(c) of the Act, and we proposed to refer to this expanded model as the MDPP. In this section of this final rule, we are finalizing a framework for the MDPP expanded model. We intend to engage in additional rulemaking in 2017, to establish additional requirements of the MDPP expanded model. We solicited comment on all of the proposals below and on other policy or operational issues that need to be considered in implementing this expansion.

a. Designation of MDPP Services as Additional Preventive Services Under Section 1861(ddd) of the Act

We proposed to designate MDPP services as ''additional preventive services'' available under Medicare Part B. Section 1861(ddd) of the Act defines ''additional preventive services'' as services (other than screening or other preventive services or personalized prevention plan services described in other sections of the Act) that identify medical conditions or risk factors, and that the Secretary determines, using the National Coverage Determination (NCD) process, are (A) reasonable and necessary for the prevention or early detection of an illness or disability; (B) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and (C) appropriate for individuals entitled to benefits under Part A or enrolled in Part B.

We believe that MDPP services are consistent with the types of additional preventive services that are appropriate

for Medicare beneficiaries. In particular, we believe that MDPP services meet the requirements of section 1861(ddd)(1)(A) of the Act (that is, that they are reasonable and necessary for the prevention or early detection of an illness or disability) because they are specifically designed to prevent pre-diabetes from advancing into type 2 diabetes and their effectiveness is supported by the evaluations of the DPP model test.

We proposed to use the Secretary's waiver authority under section 1115A(d)(1) of the Act to waive two requirements of the benefit category of additional preventive services. MDPP services do not meet the requirement in section 1861(ddd)(1)(B) of the Act in that MDPP services have not been recommended with a grade of A or B by the USPSTF, and thus a waiver of that requirement is necessary. We proposed to use the Secretary's waiver authority to waive this requirement with respect to MDPP services.

We proposed to waive the requirement of section 1861(ddd)(2) of the Act that the Secretary make the determinations required under section 1861(ddd)(1) of the Act using the NCD process. We proposed to waive this requirement because applying the NCD process to the MDPP model expansion is inappropriate, and thus the waiver is necessary. The creation of a new supplier class is necessary for coaches to furnish MDPP services, which the NCD process was not designed to address.

Since Medicare cost-sharing does not apply to additional preventive services, MDPP services would not be subject to Medicare cost-sharing.

We solicited comment on these proposals.

The following is a summary of the comments we received on designating MDPP services as additional preventive services and our responses.

Comment: While some commenters supported the Secretary's use of the waiver authority provided by section 1115A(d)(1) of the Act in expansion of the DPP model test, a few commenters stated that the statute does not permit the Secretary to waive statutory or regulatory requirements when a model is expanded under section 1115A(c) of the Act. These commenters stated that any use of waiver authority in an expanded model is not made ''with respect to testing models described in subsection (b).'' As a consequence, these commenters stated, the Secretary lacks the authority to waive the provisions of section 1861(ddd) of the Act proposed in the proposed rule.

Response: We disagree with the commenters. Section 1115A(d)(1) of the Act authorizes the Secretary to waive certain requirements as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b). We believe that the phrase ''described in subsection (b)'' is simply a reference that describes the models that are authorized under subsection (b), and that the waiver authority extends to expanded models because they continue to be models described in subsection (b). The language of section 1115A(c) of the Act itself supports this view because it gives the Secretary authority to expand the duration and scope of a model that is being tested under subsection (b).

Therefore, in our view, the Secretary is authorized to waive requirements of Title XI, Title XVIII, and sections 1902(a)(1), 1902(a)(13), 1902(m)(2)(A)(iii), and 1934 of the Act (other than subsections (b)(1)(A) and (c)(5) of such section) in connection with expanded model tests. As the MDPP model expansion is an expansion of the duration and scope of a model described in and tested under subsection (b), the Secretary may waive Medicare requirements as necessary for the purposes of the expanded model.

Comment: Many commenters believed that the Secretary's waiver of section 1861(ddd)(1)(B) of the Act, which requires that a benefit must be recommended with a grade of A or B by the USPSTF, is unnecessary. These commenters stated that the USPSTF issued guidance in October 2015 entitled *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening,* which provided a B rating for intensive behavioral counseling interventions for patients with abnormal blood glucose based on National DPP clinical trial evidence. This recommendation is available at *https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/screening-for-abnormal-blood-glucose-and-type-2-diabetes.* Because of this recommendation, these commenters suggested, the Secretary does not need to waive the requirement in section 1861(ddd)(1)(B) of the Act.

Response: While the interventions mentioned in the USPSTF's recommendation bears some similarity to the expanded DPP model test, and provides evidence to support DPPs generally, there are differences between the USPSTF's recommendation and the design of the MDPP expanded model, both as initially tested and as we have proposed to expand it. We believe these differences make USPSTF's recommendation inapplicable to MDPP, and therefore the waiver is necessary.

In particular, the specific USPSTF recommendation cited by commenters is for ''adults aged 40 to 70 years who are overweight or obese who are seen in primary care settings,'' which does not include Medicare beneficiaries over 70 who would be eligible for MDPP services or the furnishing of MDPP services by a community service organization.

While the USPSTF recommendation discussed by the commenters does not match with the elements of the MDPP model expansion, we do note that the recommendation supports the principle of the MDPP expanded model. In addition, we have spoken to the USPSTF about its recommendation and shared the findings of the evaluation of the model in case the USPSTF would like to reconsider its recommendation.

Similarly, we note that in 2014, the Community Preventive Services Task Force (CPSTF), a ''sister entity'' to the USPSTF that is focused on population-based interventions, issued a recommendation for *Diabetes: Combined Diet and Physical Activity Promotion Programs to Prevent Type 2 Diabetes Among People at Increased Risk,* specifically recommending ''combined diet and physical activity promotion programs for people at increased risk of type 2 diabetes based on strong evidence of effectiveness in reducing new-onset diabetes.'' The CPSTF recommendation is available at *https://www.thecommunityguide.org/findings/diabetes-combined-diet-and-physical-activity-promotion-programs-prevent-type-2-diabetes.* We believe that the MDPP expanded model is consistent with the CPSTF recommendation.

Comment: One commenter suggested that the Secretary should not waive the National Coverage Determination (NCD) process required by section 1861(ddd)(2) of the Act. One commenter suggested that it is irrelevant that the NCD process does not address the creation of a new supplier class. This commenter also suggested that the statute does not require CMS to implement an additional preventive service via the NCD process; all it requires is that CMS make the three determinations that are prerequisites for additional preventive service status using the NCD process. This commenter also stated that the timing of the NCD process will not hinder this expansion, suggesting that we have the discretion to expedite the NCD process. Another commenter suggested that waiving the NCD process is unnecessary because the

creation of a supplier class is not hindered by the NCD process.

Response: We disagree that waiving requirements of section 1861(ddd)(2) of the Act is unnecessary. In particular, we disagree with the commenters who believe that using the NCD process would not create timing challenges for the MDPP expanded model. To the contrary, we believe that the use of the NCD process is inappropriate for the MDPP expanded model.

The MDPP expanded model necessitates the creation of a new supplier class that must be able to enroll in Medicare so that it may furnish MDPP services as of the effective date of the expanded model. We are establishing the new supplier class through rulemaking, in conjunction with the model expansion. Contrary to commenters' assertions, using the NCD process to designate MDPP services as additional preventive services would create significant timing challenges, given that we need to expand the model and establish the MDPP supplier class through rulemaking. If we were to use the NCD process to determine that MDPP services are additional preventive services, we would not be able to begin covering MDPP services on the date the NCD was issued, even if it were issued simultaneously with the effective date of a final rule establishing the supplier class. This is because in order to align the effective dates, we would have had to issue a final rule establishing the MDPP supplier class 60 days before we determined that MDPP services were covered by Medicare. Were we to instead issue an NCD simultaneously with the release of a final rule establishing a new supplier class, the benefit would be unavailable for a period of time after the NCD's effective date because of the 60-day delay in effectiveness of the final rule plus time needed thereafter to process MDPP supplier enrollment applications. Because we cannot allow MDPP suppliers to enroll specifically to provide a service that is not yet a Medicare service, we find that it is necessary for purposes of expanding the MDPP model to waive the requirements of section 1861(ddd)(2) of the Act. This rulemaking establishes MDPP services as additional preventive services that will become available after there is sufficient time to enroll MDPP suppliers to furnish those services, which allows us to avoid timing and logistics problems while also providing the public with the opportunity to comment in a manner similar to the NCD process.

Comment: Commenters overwhelmingly supported the proposal to not hold beneficiaries responsible for cost sharing for MDPP services. A few commenters asked us to clarify that beneficiaries would not have to pay cost-sharing, particularly because they were concerned that cost sharing would restrict beneficiary access.

Response: 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.

Final Decision: We finalize our proposal to expand the duration and scope of the DPP model test as proposed. We finalize our proposal to designate this benefit as an additional preventive service according to section 1861(ddd) of the Act as proposed, and we also finalize our proposals to waive the requirements of sections 1861(ddd)(1)(B) and (ddd)(2) of the Act as proposed.

b. Timing of the Expansion of the Medicare Diabetes Prevention Program Model

We proposed that the expansion of the duration and scope of the DPP model test would become effective on a nationwide basis beginning on January 1, 2018. Expanding the DPP model test is a complex undertaking, which could be approached in different ways, such as expanding the scope of the DPP model test nationally in its first year of implementation or expanding the duration and scope using a phase-in approach. The phase-in approach could expand MDPP initially for a period of time in certain geographic markets or regions or among a subpopulation of MDPP suppliers, with the goal of addressing technical issues prior to broader expansion. We solicited comment on whether to expand the scope of the DPP model test nationally or use a phase-in approach, and if phased-in, what factors we should consider in the possible selection of initial phased-in MDPP suppliers.

Comment: We received many comments related to the timing of the MDPP expansion. Commenters overwhelmingly supported nationwide expansion of the DPP model test on January 1, 2018, over a phase-in approach. Several commenters, including MedPAC, supported a phase-in approach, to allow CMS to address program integrity issues before nationwide expansion. Some commenters made suggestions for where and with which providers to phase the benefit in if CMS were to adopt the phase-in approach. Others asked for clarification on what criteria would be used to determine the details of a phased-in approach.

Response: We believe that nationwide expansion of the scope of the model would allow the greatest access to the MDPP services for beneficiaries. We also acknowledge the concerns that the MDPP expanded model introduces a new service and a new supplier type to the Medicare program, and we will prioritize beneficiary safety and the need to consider program integrity concerns in our implementation of this expansion.

MDPP services will be available to eligible beneficiaries beginning on January 1, 2018, subject to additional rulemaking on issues such as payment for the service. However, as a factual matter, eligible beneficiaries' access to MDPP services will increase over time as more organizations seek and receive CDC DPRP recognition, enroll in Medicare as MDPP suppliers, and therefore furnish MDPP services. As of October 2016, more than 1,000 organizations have pending or full recognition from the CDC DPRP to provide DPP services. As described in section III.J.7.a. of this final rule, these organizations will have to meet certain standards before becoming eligible to enroll as a Medicare supplier. This will provide a de facto phase in that will allow us to gain experience with the MDPP expanded model with fewer organizations initially who meet the supplier eligibility criteria, and more over time as supplier enrollment increases.

c. Other Comments on the Expansion of the Medicare Diabetes Prevention Program Model

Comment: A few commenters expressed concern that MDPP suppliers should be coordinating with primary care providers or other physicians, and a few commenters did not support the MDPP expanded model because they believed it would further fragment the health care system.

Response: We appreciate and respect the concern regarding coordination with the clinical care system, and we encourage MDPP suppliers to promptly communicate with the beneficiary's health care providers as appropriate with the beneficiary's consent to promote care coordination. We also expect that some clinicians will furnish MDPP services on behalf of organizations that have or will obtain CDC DPRP recognition and enroll in Medicare as MDPP suppliers. However, we did not propose specific rules or requirements around coordination with primary care providers or other health care entities for the purposes of this

MDPP expanded model because the DPP model test did not require this level of coordination. We also want to provide organizations with the flexibility they need to effectively coordinate care with physicians while decreasing the administrative burden of offering the services. We will take these comments into consideration as we finalize various aspects of MDPP in future rulemaking.

Comment: One commenter suggested the use of mobile application-based technology with built in incentives for beneficiaries.

Response: We appreciate the suggestion and we will consider it as we engage in future rulemaking.

Comment: A few commenters recommended they be allowed to apply Diabetes Self-Management Training (DSMT) to beneficiaries with pre-diabetes. One commenter suggested that CMS merge DSMT and MDPP because core training elements are identical.

Response: While we acknowledge that there may be similarities between the two benefits, DSMT and MDPP have different eligibility criteria and goals. Beneficiaries with a type 2 diabetes diagnosis have different needs than those with pre-diabetes. We therefore do not believe we should merge these benefits.

Comment: Several commenters recommended that we add MDPP services to the personalized prevention plan offered as part of the Medicare Annual Wellness Visit (AWV). A few commenters expressed disagreement with the focus on weight loss, citing fitness and physical activity, metabolic and behavioral markers, and other alternatives that CMS should consider as outcomes for value-based payments.

Response: We did not test the other indicators that commenters recommended such as fitness, metabolic activity and behavioral markers. We will make adjustments through rulemaking, as necessary, if through our continuing evaluation we find that such adjustments are warranted. One of the elements of the AWV is for the health professional to furnish personalized health advice to the beneficiary, and a referral, as appropriate, to health education or preventive counseling services or programs. An eligible beneficiary can be referred for MDPP services as part of a personalized prevention plan. We reiterate, however, that we did not propose to require that beneficiaries obtain a referral for MDPP services, though as discussed in section III.J.7.c. of this final rule, referrals are permitted.

Comment: Some commenters suggested using the term ''delay'' rather than ''prevent'' diabetes, and others suggested using the name National Diabetes Prevention Program (National DPP), rather than MDPP, citing confusion in the market of payers that currently cover DPP for their members.

Response: We believe prevention of type 2 diabetes is the goal of the MDPP expanded model even though some beneficiaries may still be diagnosed with type 2 diabetes, so we decline to change the name to reference a ''delay'' in diabetes onset. We also believe MDPP is the appropriate name for this expanded model because there are differences between MDPP and the National DPP, such as the age of the beneficiaries served, beneficiary eligibility criteria, and the DPP organization or MDPP supplier eligibility criteria.

5. MDPP Benefit Description

We proposed the MDPP core benefit to be 12-months of sessions using a CDC-approved DPP curriculum, consisting of at least 16 core sessions furnished over a range of 16 to 26 weeks (that is, the first 6 months) and at least 6 monthly core maintenance sessions over weeks 27–52 (second 6 months). We proposed that beneficiaries who complete the 12-month core benefit, and achieve and maintain a required minimum weight loss of 5 percent from the first core session, in accordance with the CDC Diabetes Prevention Recognition Program Standards and Operating Procedures (CDC DPRP Standards), would be eligible for monthly ongoing maintenance sessions for as long as the weight loss is maintained. The CDC DPRP Standards are available at *http://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf*. We proposed to require each MDPP core and maintenance session (both core and ongoing) be at least one hour in duration. We proposed that the MDPP expanded model will use the CDC-approved curriculum. Details pertaining to the content of both the core sessions and maintenance sessions, as set by the CDC, are available at *http://www.cdc.gov/diabetes/prevention/pdf/curriculum_toc.pdf*.

We proposed that during the first 6 months (weeks 1–26) of the MDPP core benefit, each of the 16 core sessions must address a different curriculum topic included on the list of 16 curriculum topics, ensuring all topics are addressed by the end of the 16 sessions. We proposed that the second 6 months (weeks 27–52) of the MDPP core benefit must include at least one core maintenance session furnished in each of the 6 months (for a minimum of six sessions), and all core maintenance sessions must address different topics. We proposed that ongoing maintenance sessions adhere to the same curriculum requirements as the core maintenance sessions.

We solicited comment on these proposals.

The following is a summary of the comments received and our responses.

Comment: Several commenters suggested that we clarify whether MDPP suppliers must furnish MDPP services in the second 6 months of the core benefit (the core maintenance sessions) or Medicare payment for services furnished in the second 6 months of the core benefit without achievement of the required 5 percent weight loss. The commenters recommended that we allow MDPP suppliers to document and bill for achievement of beneficiary weight loss at any time during the first year, rather than during only the first 6 months. One commenter suggested that CMS clarify if there is a minimum or maximum number of beneficiaries that an MDPP supplier must/may serve.

Response: We clarify that core maintenance sessions in the second 6 months are furnished as part of the 12-month core benefit, regardless of weight loss. We refer readers to section III.J.7.b. of this final rule for discussion of the requirement that organizations maintain CDC DPRP recognition to enroll in Medicare to bill for furnishing MDPP services. The CDC DPRP Standards require that DPP-eligible individuals be able to access the core maintenance sessions, regardless of weight loss, in order for an organization to maintain CDC DPRP recognition. Therefore, we are finalizing our proposal that the MDPP core benefit is a 12-month program that consists of at least 16 weekly core sessions, over months 1–6, and at least 6 monthly core maintenance sessions over months 6–12, furnished regardless of weight loss. We are making corresponding changes to the regulations text to address when the MDPP core benefit will be available. We intend to address payment for MDPP services in future rulemaking. We will not require a minimum or maximum number of beneficiaries at this time, recognizing that MDPP suppliers will vary in capacity and mode of delivery. However, we will monitor for signs of adverse selection of beneficiaries and propose specific program integrity requirements in future rulemaking, as appropriate.

Comment: Numerous commenters expressed general support for ongoing maintenance sessions after the 12-month core benefit and recommended that CMS allow beneficiaries access to ongoing maintenance sessions if they achieve the required 5 percent weight

loss any time during the 12-month core benefit. A few commenters recommended that CMS clarify the definition of maintenance of weight loss, noting that it is common for individuals to lose, regain, and lose weight again. One commenter recommended that beneficiaries whose weight increases during the maintenance period should have up to 3 months to bring their weight back to the maintenance level. Another commenter requested clarification on when and how MDPP suppliers should track weight on an ongoing basis to ensure a beneficiary qualifies for maintenance sessions, and whether beneficiaries should be weighed every month to qualify.

Several commenters recommended allowing beneficiaries who did not achieve and maintain the required 5 percent weight loss to still be able to access the ongoing maintenance sessions. The commenters stated various reasons, including that weight loss of less than 5 percent is clinically relevant and also reduces type 2 diabetes risk; the evidence base suggests greater impact on onset of diabetes through re-enrolling beneficiaries who are regaining weight than through continuing the service for those who can maintain weight loss; weight regain is common due to metabolic adaptation or receding behavior changes; discontinuing the service for beneficiaries who do not lose weight will discourage them and increase their risk for diabetes; the opportunity to provide a safe environment of recovery for individuals who have a binge-eating disorder; and that the intervention will still reduce diabetes among beneficiaries who are unable to achieve or maintain weight loss. Additionally, commenters stated that exclusion from maintenance sessions for beneficiaries who do not achieve the required weight loss would be punitive, particularly for beneficiaries who need the additional support to achieve the desired weight loss goal. Some commenters suggested that MDPP expanded model risks perpetuating health inequities because low-income beneficiaries who need MDPP services the most struggle disproportionately to achieve the required weight loss and will not be able to access ongoing maintenance sessions.

One commenter suggested that CMS use an aggregate, not individual, 5 percent weight loss across a supplier's beneficiaries to align with the CDC DPRP Standards and promote ongoing maintenance session eligibility for populations that experience difficulty achieving the 5 percent weight loss due to socioeconomic or demographic factors. Another recommendation was to allow participants within 2 percentage points of the minimum weight loss to have their maintenance sessions covered to account for weight gain during extenuating circumstances (for example, falling ill or other circumstances that interfere with weight loss).

Several commenters recommended that access to ongoing maintenance sessions, and payments for maintenance session attendance, depend not on the 5 percent weight loss, but instead on attendance of monthly maintenance sessions. Other commenters suggested that payment should be linked to alternative measures rather than weight loss, such as A1C, waist measurement, and knowledge tests.

Response: As noted previously, MDPP eligible beneficiaries are eligible to access core maintenance sessions in the second 6 months of the 12-month core benefit regardless of weight loss. MDPP eligible beneficiaries are eligible to access ongoing maintenance sessions after the 12 month core benefit if the beneficiary achieves and maintains the required minimum weight loss percentage. We understand that beneficiaries' weight may fluctuate after meeting the 5 percent required weight loss. We are defining maintenance of weight loss, which allows a beneficiary to access ongoing maintenance sessions, as achieving the required minimum weight loss from baseline weight at any point during each 3 months of core maintenance or ongoing maintenance sessions. In other words, a beneficiary can access the next three months of ongoing maintenance sessions if the beneficiary achieved maintenance of weight loss at any point during the previous three months of maintenance sessions. As mentioned in comments, 3 months is the appropriate interval because it aligns with the proposed payment structure that pays for each three maintenance sessions attended with maintenance of weight loss. A beneficiary's weight must be measured and recorded during every core session and maintenance session the beneficiary attends. In response to comments, we are also adding a definition for maintenance session bundle to refer to each 3-month interval of core maintenance or ongoing maintenance sessions. Each bundle must include at least one maintenance session per month, for a minimum of three sessions in each bundle.

We acknowledge some commenters' desire for CMS to cover ongoing maintenance sessions for beneficiaries who do not achieve and maintain the required 5 percent weight loss. The requirement that eligible beneficiaries must maintain 5 percent weight loss is consistent with the weight loss goal tested in the DPP model test, and was factored into the Secretary's determination to expand the model and the Chief Actuary's certification that MDPP expansion would not result in an increase of Medicare spending. We are not changing the requirement that beneficiaries must maintain the 5 percent minimum weight loss in order to receive ongoing maintenance sessions. We acknowledge commenters' concerns regarding potential unintended consequences if the MDPP expanded model results in low-income or other disadvantaged populations having less access to ongoing maintenance sessions. We may consider making adjustments as appropriate if, through our monitoring and evaluation and through tribal consultation, we find that such adjustments are warranted to address disparities in access.

We disagree with a commenter's suggestion that we use an aggregate, not individual, 5 percent weight loss for ongoing maintenance session eligibility. We do not believe aggregate weight loss is an appropriate application for individuals' eligibility for ongoing maintenance sessions. We believe it is unfair to deny a beneficiary access to ongoing maintenance sessions if the beneficiary achieves 5 percent or more weight loss but happens to attend MDPP sessions with other beneficiaries who gain or do not lose the minimum weight. Aggregate weight loss can be arbitrary because there is no minimum or maximum number of beneficiaries per MDPP supplier, and there is no way to ensure equal access to the benefit. It decreases a beneficiary's incentive to meet the weight loss goal in order to access ongoing maintenance sessions and a suppliers' incentive to actively help each beneficiary to meet that weight loss goal, particularly if a few people lost a large percent of their weight. The goal of the DPP model test is at least 5 percent weight loss for each individual, which is expected to lead to a reduction in the incidence of diabetes. We do not have data to support an expanded model that does not require the achievement and maintenance of the minimum weight loss. We clarify that beneficiaries have access to the MDPP core benefit regardless of weight loss. This provides all eligible beneficiaries with access to 12 months of MDPP services, without cost-sharing, to achieve the target weight loss. We believe the incentive to achieve the target weight loss would be diluted for

beneficiaries if they could access the ongoing maintenance sessions regardless of weight loss.

Comment: Commenters recommended limiting the number of years of payment for ongoing maintenance sessions due to the limited administrative and operational capability of many MDPP suppliers to provide ongoing maintenance sessions in perpetuity. A few commenters opposed payment for ongoing maintenance sessions at all, stating that indefinite monthly maintenance sessions extend beyond what is supported by scientific research. The commenters recommended additional review of clinical effectiveness and cost implications of payment for ongoing maintenance sessions, suggesting that we study the optimal number of maintenance sessions for beneficiaries who achieve and maintain the required weight loss. One commenter recommended that we eliminate ongoing maintenance sessions or make them voluntary for MDPP suppliers to furnish. The commenter noted the potential difficulty of assembling enough ongoing maintenance session attendees to cover a supplier's costs due to factors such as beneficiary attrition or schedule variation and administrative burdens associated with documenting beneficiary eligibility. The commenter also suggested that we clarify whether MDPP suppliers can offer and charge beneficiaries directly for additional services, such as health coaching beyond MDPP services or counseling to beneficiaries who regain weight and are no longer receiving MDPP services.

One commenter recommended that we clarify whether beneficiaries must participate with the same coach or group of beneficiaries upon the transition from the core benefit to ongoing maintenance sessions. Another commenter recommended that CMS use different terminology for the ongoing maintenance sessions after the 12-month core benefit because it is confusing that the core maintenance sessions in the second 6 months are also called maintenance sessions.

Response: We believe it is important for CMS to cover ongoing maintenance sessions after the 12-month core benefit to better equip beneficiaries to maintain healthy lifestyle changes and prevent type 2 diabetes. As part of the expanded model, MDPP suppliers are required to provide eligible beneficiaries access to ongoing maintenance sessions. We acknowledge commenters' concern regarding the sustainability of ongoing maintenance sessions in perpetuity, and we intend to propose a limit to the duration of ongoing maintenance sessions in future rulemaking. As acknowledged by several commenters, continued participation by an individual in a DPP after year 3 has been generally untested, and we intend to take this into consideration when we address a limit in future rulemaking.

In response to comments on the provision of services outside of MDPP, the MDPP model expansion only includes MDPP services. We note the distinction between core maintenance sessions and ongoing maintenance sessions is important in that core maintenance sessions are a part of the core benefit and are accessible to all eligible beneficiaries, while ongoing maintenance sessions require beneficiaries to maintain weight loss after the 12 month core benefit. As mentioned in section III.J.6. of this final rule, we defer questions of beneficiary attribution, such as how to address beneficiaries who switch suppliers upon the transition from the core benefit to ongoing maintenance sessions, to future rulemaking.

Comment: Numerous commenters supported the use of CDC's DPRP Standards for the MDPP curriculum. Several commenters suggested that we permit MDPP suppliers to furnish any CDC-approved curriculum, rather than requiring the use of a particular curriculum. Commenters stated that CDC regularly updates its suggested curriculum, as well as reviews and approves alternative curricula that are submitted with an organization's application for CDC DPRP recognition. Commenters requested clarification on whether suppliers may use the 2016 CDC Prevent T2 Curriculum or the 2012 CDC-developed curriculum, both of which are permitted by the CDC DPRP Standards. Commenters recommended that CMS clarify whether CMS would need to undergo a rule change if CDC makes changes to the curriculum.

Commenters also suggested clarification on the curriculum topics that MDPP suppliers should follow for ongoing maintenance sessions, as the National DPP curriculum only specifies content for what is analogous to the MDPP core benefit. Other commenters recommended allowing MDPP suppliers to use the CDC-approved DPP curriculum in another language or making the curriculum more culturally sensitive. Commenters suggested changes to the curriculum, such as shifting the focus away from calorie counting, emphasizing physical activity and exercise goals, training coaches to handle emotional issues and offering oral hygiene sessions.

One commenter suggested we consider ways to embed the curriculum into the Diabetes Self-Management Training (DSMT) benefit.

Response: We agree with commenters that MDPP suppliers should be permitted to, consistent with their CDC DPRP recognition, use any curriculum approved by the CDC. The CDC-preferred curriculum is available at *http://www.cdc.gov/diabetes/prevention/lifestyle-program/curriculum.html*. We note that if a DPP organization chooses to use a different curriculum, it must send the curriculum to the CDC DPRP so it can be evaluated to ensure that it covers similar content and is consistent with the current evidence base. To mitigate confusion surrounding the use of specific topic names, we will remove specific curriculum topics from the regulations text and instead specify that the sessions must be furnished consistent with any CDC-approved curriculum. We believe this change also will make it unnecessary for us to undertake rulemaking to address regular CDC curriculum updates. This will reduce the risk that MDPP suppliers would need to have two separate curricula, one for their Medicare beneficiaries and one for the rest of their enrollees, which could be unnecessarily burdensome.

For the ongoing maintenance session curriculum, we are requiring that MDPP suppliers use a CDC-approved curriculum. The purpose of ongoing maintenance sessions is to reinforce and revisit what was learned and practiced in the core benefit, so beneficiaries can maintain healthy behavioral changes and weight loss. Coaches can offer any of the curriculum topics except for the introductory sessions. We support the use of culturally sensitive curricula based on the MDPP supplier's population and furnishing MDPP services in languages other than English. If the CDC approves a curriculum that has adjustments to address language barriers or cultural differences, the MDPP supplier can use the curriculum. We remind organizations that the policies and procedures of approved curricula must ensure accessibility to persons with disabilities, persons with limited English proficiency, and other populations in compliance with HHS civil rights non-discrimination regulations, including those implementing section 504 of the Rehabilitation Act of 1973, Title VI of the Civil Rights Act, section 1557 of the Patient Protection and Affordable Care Act, and Title IX of the Education Amendments of 1972, as amended. More information is available at *http://www.hhs.gov/civil-rights*. With respect to embedding the DPP curriculum into DSMT, we decline to adopt this

recommendation. As noted previously, DSMT and MDPP services, though similar, serve different purposes and are for individuals with different needs.

Comment: Some commenters recommended that CMS modify the session duration requirement from ''at least one hour'' to align with the CDC DPRP Standards of ''each session must be of sufficient duration to convey the session content—or approximately one hour in length.'' Commenters stated that the time it takes to complete a curriculum topic depends on the number of attendees, how the services are furnished, beneficiaries' assessed need, the curriculum topic, and the approach to the curriculum, and the one-hour requirement would be too rigid and too long for many CDC-recognized organizations. Other commenters recommended we focus on completion of modules in the required curriculum, not session-based time standards, since module completion requires active participation and the ability to turn learning into action, while a time-based standard does not correlate with impact on outcomes. Some commenters stated that value-based care de-emphasizes the amount of time involved with furnishing a given service and focuses on the results achieved.

Response: We agree with commenters that the one-hour requirement may be too rigid when compared against CDC-approved DPP curricula that vary in approach and mode of delivery. We agree that ''approximately one-hour in duration'' is an appropriate requirement for in-person sessions because completion of a curriculum topic may vary depending on factors such as number of attendees, how the program is delivered, beneficiaries' assessed need, the curriculum topic, and the approach to the curriculum. We do not believe the CDC DPRP Standard that ''each session must be of sufficient duration to convey the session content'' is an auditable requirement, and therefore, we decline to adopt it for MDPP because, as noted in the proposed rule, having auditable requirements is a critical component of our program integrity efforts. For these reasons, we are amending our regulations to specify that sessions must be ''approximately one-hour in duration.''

Final Decision: After consideration of the public comments received, we are finalizing the proposal that the MDPP core benefit is a 12 consecutive month program that consists of at least 16 weekly core sessions over months 1–6 and at least six monthly core maintenance sessions over months 6–12, furnished regardless of weight loss. We are also finalizing the proposal that beneficiaries have access to ongoing maintenance sessions after the 12-month core benefit if they achieve and maintain the required minimum weight loss of 5 percent. We are modifying the regulations in § 410.79 to add the definition of ''maintenance session bundle'' to refer to each 3-month interval of core maintenance or ongoing maintenance sessions, with at least one maintenance session delivered in each of the 3 months. We are also adding the definition of ''maintenance of weight loss'' to clarify that maintenance of weight loss is achieving the required minimum weight loss from baseline weight at any point during each 3-month core maintenance or ongoing maintenance session bundle. We are revising the definitions of the CDC-approved core curriculum to remove specific curriculum topic names and to indicate MDPP suppliers must use any CDC-approved curriculum. We are revising the session duration to specify that sessions must have a duration of approximately one hour. We are also making minor technical changes to the proposed definitions to improve clarity.

6. Beneficiary Eligibility

a. MDPP Eligible Beneficiaries

We proposed that coverage of MDPP services would be available for beneficiaries who meet all of the following criteria: (1) Are enrolled in Medicare Part B; (2) 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. The CDC DPRP Standards have defined a lower BMI for self-identified Asian individuals based on data that show Asians develop abnormal glucose levels at a lower BMI; (3) have, within the 12 months prior to attending the first core session, a hemoglobin A1c (HgA1c) test with a value between 5.7 and 6.4 percent, or a fasting plasma glucose of 110–125 mg/dL, or a 2-hour post-glucose challenge of 140–199 mg/dL (oral glucose tolerance test); (4) have no previous diagnosis of type 1 or type 2 diabetes with the exception of a previous diagnosis of gestational diabetes; and (5) does not have end-stage renal disease (ESRD).

Comment: MedPAC commented that the proposed eligibility requirements may be too broad and could result in the inclusion of beneficiaries who meet the stated eligibility criteria but have other conditions such as dementia or frailty that could render a weight loss program inappropriate.

Response: We appreciate the views of commenters, including MedPAC. We are considering ways to monitor for MDPP suppliers who consistently bill for session attendance and not weight loss, and intend to address this in our program integrity and payment proposals in future rulemaking. We recognize that performing mental capacity assessment prior to enrollment would be difficult and create an additional burden for MDPP suppliers. We will consider how to address the issue of beneficiaries who are eligible to receive MDPP services, but for whom MDPP may not be clinically appropriate, in future rulemaking, as necessary.

Comment: Many commenters stated that differences between the MDPP expanded model's proposed eligibility criteria and the National DPP eligibility criteria will cause confusion for providers and beneficiaries. Commenters specifically noted that the BMI cut off for National DPP eligibility is 24 kg/m^2 and 22 kg/m^2 for those self-identified as Asian, whereas the proposed BMI cut offs for the MDPP expanded model are 25 kg/m^2 and 23 kgm^2 for those self-identified as Asian. Commenters also noted the differences in the blood test criteria for the fasting plasma glucose test between the National DPP (range is 100–125 mg/dL) and MDPP expanded model (range is 110–125 mg/dL). Commenters who pointed out these differences recommended that CMS align its eligibility criteria with CDC's eligibility criteria.

Several commenters also supported the lower BMI threshold for self-identified Asians.

Response: We agree with commenters that there are differences between the MDPP beneficiary eligibility criteria and National DPP eligibility criteria, which may be a source of confusion for suppliers, providers and beneficiaries. However, we proposed a BMI cut off for non-Asians of 25 kg/m^2 because this was the cut off used in the DPP model test. In addition, the generally accepted clinical definition of overweight is a BMI of 25.0—29.9 in adults over age 20.[23] We proposed a lower BMI cut off for self-identified Asians of 23 kg/m^2 which is endorsed by the American Diabetes Association and aligns with the CDC DPRP Standards which allow for a lower BMI in self-identified Asians

[23] Centers for Disease Control and Prevention, ''Healthy Weight,'' *Centers for Disease Control and Prevention,* 2015, *https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html.*

consistent with the latest research.[24] In summary, the evidence used to make the certification determination indicated that individuals who fall into the 100–110mg/dL range for fasting plasma glucose and those with BMIs of 24 kg/m^2 (22 kg/m^2 for Asians) or less have lower risk for developing type 2 diabetes. We have chosen to focus on the highest risk population, and therefore the Chief Actuary's analysis for certification focused on this population.[25] [26]

Comment: Several commenters stated that Medicare currently does not cover the HgA1c test for people without diabetes. These commenters recommended that the HgA1c test be covered with no cost-sharing under Medicare for those seeking to receive MDPP services. Commenters suggested the precedent of Diabetes Self-Management Training (DSMT) requiring HgA1c as a diagnostic test for DSMT eligibility, and that the test is covered for this purpose. Commenters recommended a parallel coverage determination should be made for the MDPP expanded model. One commenter stated that the oral glucose tolerance test should be covered if it is being considered as one of the eligibility tests.

Response: CDC standards for eligibility, which align with the American Diabetes Association definition for pre-diabetes, include an option for demonstrating eligibility using an HgA1c test and we proposed to adopt these eligibility standards for the MDPP expanded model. However, the blood tests that are permitted to be used to demonstrate MDPP eligibility are not covered as part of the MDPP services and occur before the start of the beneficiary's participation in MDPP. We did not propose to cover HgA1C tests for purposes of screening for pre-diabetes, but we note that the other blood tests that can be used to demonstrate eligibility for MDPP services, the oral glucose tolerance test and fasting plasma glucose test, are covered for pre-diabetes screening under Medicare. To cover HgA1C tests for purposes of screening for pre-diabetes, we would first need to make a separate coverage determination.

Comment: Commenters requested clarity on how suppliers would verify that beneficiaries meet certain eligibility criteria. Specifically, commenters asked how suppliers would determine whether a Medicare beneficiary has had a prior diagnosis of type 1 or type 2 diabetes, or whether they have already used the benefit. Commenters requested clarity that beneficiaries would be able to self-report their history of gestational diabetes to become eligible for MDPP. Commenters also encouraged us to explain what documentation MDPP suppliers will be required to collect from participants who are presenting MDPP-qualifying blood test results to confirm eligibility. Commenters also suggested allowing beneficiaries to complete an eligible risk questionnaire in lieu of the qualifying lab tests for up to 50 percent of their participants as this would align with the current CDC DPRP Standards for eligibility. Commenters suggested using other types of criteria such as family history, hypertension, high cholesterol, and high triglycerides, to determine eligibility among patients for whom abnormal blood glucose values are not available. One commenter requested that we clarify the timeframe in which the BMI and blood tests must occur to qualify for participation, such as whether the beneficiary has to have a qualifying BMI either when the blood tests were completed or upon enrollment. Other commenters requested guidance on whether the blood tests have to come from a lab or primary care physician or if the supplier can provide HgA1c finger pricks to determine eligibility. Commenters also asked if proof of lab work is required or if documentation of the values is sufficient. MedPAC commented that beneficiaries should receive blood tests by a provider other than the MDPP supplier as a safeguard to prevent fraud.

Response: The following eligibility criteria can be self-reported: Asian ethnicity; no history of type 1 or type 2 diabetes; and no previous receipt of MDPP services. We cannot verify self-reported eligibility criteria when beneficiaries begin receiving MDPP services. We will know which beneficiaries are participating in MDPP when the MDPP supplier submits claims with beneficiary identifiers. In our next round of rulemaking we intend to propose specific policies and requirements to protect MDPP suppliers from furnishing services that may not be covered by Medicare in cases where the beneficiary's eligibility for MDPP services is assessed based on self-reported eligibility criteria that cannot be verified prospectively. We clarify that beneficiaries can participate in MDPP regardless of a history of gestational diabetes (so long as they do not have a history of type 1 or type 2 diabetes), but must also meet the other criteria such as qualifying BMI and blood test results.

We believe the requirement to obtain blood test results is important for maintaining program integrity, and use of risk questionnaires presents opportunities for invalid and unreliable data reporting. The DPP model test required blood test results as part of its eligibility criteria to show a beneficiary has pre-diabetes, and therefore we are requiring blood tests for MDPP eligibility. In considering how to expand the DPP model test, we relied on eligibility criteria that was either tested in the initial DPP model test and/or set forth by the American Diabetes Association or World Health Organization, and we do not intend to include additional eligibility criteria at this time.

Regarding comments about the timeframe of eligibility tests and required documentation: We did not propose specific requirements for how or where blood test results may be obtained as we do not want to create unnecessary obstacles for beneficiaries and MDPP suppliers. An MDPP supplier may administer an HgA1c finger prick to determine eligibility. We note that Medicare only covers the fasting plasma glucose test and the oral glucose tolerance test when the beneficiary has a referral from his or her primary care physician or qualifying provider. Similarly, we did not propose specific documentation methods beyond our proposal that MDPP suppliers maintain records that document each beneficiary's eligibility status. We will consider whether it is necessary or appropriate to establish specific documentation standards in future rulemaking.

Comment: Commenters requested guidance on how to handle beneficiaries who are diagnosed with diabetes during the screening process or while receiving MDPP services. Commenters recommended we work with CDC to develop a protocol of how to address beneficiaries who receive a diagnosis of diabetes while being screened for or while receiving MDPP services. Several commenters stated that this protocol should ensure participants receive proper care and a referral into a DSMT program.

Response: We reiterate that beneficiaries who are diagnosed with diabetes before they begin receiving MDPP services, such as during the enrollment process, based on their lab

[24] William Hsu et al., ''BMI Cut Points to Identify At-Risk Asian Americans for Type 2 Diabetes Screening,'' *Diabetes Care* 38, no. 1 (2015): 150–158.

[25] Gregory Nichols et al., ''Trends in Diabetes Incidence Among 7 Million Insured Adults, 2006–2011: the SUPREME–DM Project,'' *American Journal of Epidemiology* 181, no. 1 (2015): 32–39.

[26] DH Morris et al., ''Progression Rates from HbA1c 6.0–6.4% and Other Prediabetes Definitions to Type 2 Diabetes: a Meta-Analysis,'' *Diabetologia* 56, no. 7 (2013): 1489–1493.

results or history of type 1 or type 2 diabetes are not eligible beneficiaries. These beneficiaries may be eligible for other types of diabetes-related care under Medicare, such as DSMT.

We did not propose an eligibility policy for beneficiaries who receive a diagnosis of diabetes while receiving MDPP services. However, we agree with commenters that a protocol needs to be developed to ensure beneficiaries who are diagnosed with diabetes while receiving MDPP services are receiving the proper care for their condition. We intend to address this issue in future rulemaking.

Comment: A number of commenters requested that we include populations beyond those that meet the eligibility criteria, such as all Medicare beneficiaries, Medicaid beneficiaries, those with ESRD and those who have been diagnosed with type 1 or type 2 diabetes. Additionally, one commenter suggested that beneficiaries who do not meet the BMI criteria, but have a family history of diabetes and motivation to receive MDPP services, should be able to do so.

Response: We believe that beneficiaries who meet the eligibility criteria that we proposed are the most appropriate population to access MDPP services because these beneficiaries are among the highest risk within the pre-diabetic population for developing diabetes. Targeting lower risk beneficiaries is not consistent with the model that we are expanding. Beneficiaries with type 1 or type 2 diabetes do not meet the eligibility criteria for MDPP but may be eligible for services such as Medicare's obesity counseling benefit and DSMT. We do not believe MDPP is appropriate for those with ESRD because beneficiaries with ESRD have more complex dietary requirements that are better addressed by dieticians and other health care professionals.

We appreciate the commenters' interest in Medicaid coverage. However, this model expansion pertains only to Medicare beneficiaries, though we note that Medicaid beneficiaries who are also Medicare beneficiaries are eligible if they meet the MDPP beneficiary eligibility requirements. We encourage states to work with the Center for Medicaid & CHIP Services (CMCS) to discuss options to cover diabetes preventive services within the Medicaid program.

Final Decisions: We are finalizing the beneficiary eligibility criteria as proposed. These criteria are set forth in § 410.79.

b. Limitations on Coverage

We proposed that beneficiaries who meet the beneficiary eligibility criteria would be able to receive MDPP services only once in their lifetime.

Comment: Many commenters asked CMS to allow exceptions to the once per lifetime restriction based on significant life events. Commenters recommended that CMS allow beneficiaries to access the benefit again after a certain period of time (for example, 6 months or 1 year) and to allow beneficiaries to access MDPP services at least two times in their lifetime. Several commenters suggested the lifetime benefit policy may be unfair due to extenuating circumstances that may arise throughout the core benefit, such as hospitalization or death of a loved one.

Commenters also requested clarity on how we may handle attribution if beneficiaries switch suppliers. One commenter believed there may be operational implications of managing this benefit across hundreds of suppliers should participants change suppliers or elect to withdraw from MDPP while it is underway and re-enroll at a later date. The commenter recommended that we issue guidelines on how MDPP suppliers should address changes, particularly with respect to beneficiary eligibility and billing and reimbursement.

Response: We understand concerns regarding the potential for life events to disrupt the beneficiary's receipt of MDPP services. However, the MDPP expansion is designed to generate savings for the Medicare program by preventing individuals with pre-diabetes from developing type 2 diabetes. We believe the once per lifetime restriction is necessary in order to generate enough savings to offset the cost of delivering MDPP services.

We are finalizing the policy that eligible beneficiaries can participate in MDPP only once in their lifetimes. However, we acknowledge the commenters' concerns, and plan to address any exceptions to the once per lifetime restriction in future rulemaking as appropriate. As we did not propose to restrict eligible beneficiaries' choice of MDPP suppliers, we are confirming that they will be able to change suppliers at any time; however, because beneficiary attribution directly relates to payment, we will consider the comments on how to address attribution and its attendant effect on payment in developing proposals for future rulemaking.

Final Decision: We will finalize limitations on coverage of MDPP as proposed. The MDPP core benefit is available only once per lifetime per MDPP eligible beneficiary, and ongoing maintenance sessions are available only if the MDPP eligible beneficiary has achieved maintenance of weight loss. These limitations are specified in § 410.79.

c. Referrals

The DPP currently allows community-referral such as by Y–USA and self-referral of patients, in addition to referral by physicians and other health care practitioners, if the patient presents DPP-qualifying blood test results that the DPP organization keeps on record. We proposed to similarly permit beneficiaries who meet our eligibility criteria to obtain MDPP services by self-referral, community-referral, or health care practitioner-referral.

The following is a summary of the comments received and our responses.

Comment: Commenters generally supported our proposal allowing for self-referral, community-referral, or health care practitioner referral to obtain MDPP services, although MedPAC expressed concern that MDPP services could be inappropriately used and suppliers could initiate services without a referral. Commenters suggested that we broaden the types of providers eligible to make referrals to MDPP suppliers. For example, a commenter recommended clarification of what types of provider referrals would be permitted for MDPP and recommended that such providers include nurse practitioners to broaden program access; another commenter suggested that we will be able to increase access to and streamline beneficiary access to MDPP services by allowing community-based organizations to refer beneficiaries. Many commenters recommended that we promote referrals from MDPP suppliers to psychologists to help address psychosocial components of their care. Other commenters opposed a physician referral requirement. One commenter opposed the requirement of blood tests as part of referral pathway. Some commenters recommended that we explicitly state that MDPP services will be paid for when ordered/referred by non-physician practitioners. A commenter recommended that we require non-clinician health care MDPP suppliers to ask beneficiaries about their usual source of care and mandate that MDPP suppliers share results with the beneficiary's self-identified primary care physician.

Response: We agree with commenters that there should be broad program access, which is why we are not requiring any specific type of referral for this expanded model test. With respect

to the comments on program integrity, we will take these comments into consideration in future rulemaking, as discussed in section III.J.8.b. of this final rule. We agree with commenters and clarify that non-physician practitioners can order or refer eligible beneficiaries for MDPP services. We understand the value of coordinating results from the MDPP with a beneficiary's primary care provider, however, we will not require this type of coordination because we believe it creates an additional burden for this new supplier type that will discourage DPP organizations from enrolling in Medicare as MDPP suppliers. Additionally, the MDPP suppliers have no reimbursement mechanism for coordinating services with primary care physicians, specialists or other providers. The value-based payment proposed for the MDPP expanded model affords no compensation for coordination among providers. We are concerned that holding MDPP suppliers to a higher service coordination standard than other Medicare suppliers and providers may negatively impact MDPP supplier capacity. We do not believe it is appropriate to address referrals from MDPP suppliers to other providers in this expansion because suppliers may or may not employ providers with the credentials to make referrals to other providers, and we believe this is beyond the parameters of the MDPP expanded model.

Final Decision: We are finalizing the procedure for referrals to MDPP as proposed.

7. Enrollment of MDPP Suppliers

a. MDPP Supplier Enrollment Requirements

We proposed that any organization with preliminary or full CDC DPRP recognition would be eligible to apply for enrollment in Medicare as an MDPP supplier beginning on or after January 1, 2017. This proposal would promote timely enrollment of CDC-recognized organizations before the MDPP expanded model becomes effective on January 1, 2018. We proposed that MDPP suppliers would be subject to the enrollment regulations set forth in 42 CFR part 424, subpart P.

Organizations seeking to enroll in Medicare to become MDPP suppliers would be subject to screening under § 424.518. We proposed that potential MDPP suppliers be screened according to the high categorical risk category defined in § 424.518(c) because the MDPP expanded model allows organization types that are new to Medicare to enroll. We also believe that MDPP suppliers have some similarities to home health agencies, a provider screened according to the high categorical risk category, because non-licensed personnel may furnish MDPP services in a non-clinical setting, such as at Y–USA.

We proposed that existing Medicare providers and suppliers that wish to bill for MDPP services would have to inform us of that intention and satisfy all other requirements, such as preliminary or full CDC DPRP recognition, but would not need to enroll a second time. These existing Medicare providers and suppliers would be eligible to bill for MDPP services furnished on or after January 1, 2018. We also considered an alternative approach where existing Medicare providers and suppliers would have to submit a separate enrollment application (including any applicable enrollment application fee) and be separately screened to be eligible to bill for MDPP services. This alternative would enable all organizations furnishing MDPP services to have the same classification as MDPP suppliers and undergo the same application requirements. Under this option, should an entity have an issue related to their MDPP enrollment, for example, falsely attesting to beneficiary weight loss, CMS would have discretion to apply revocation to its MDPP enrollment, rather than affecting their broader enrollment in Medicare.

We proposed to require that all MDPP suppliers comply with applicable Medicare supplier enrollment, program integrity, and payment rules. These regulations include, but are not limited to, time limits for filing claims (§ 424.44), requirements to report and return overpayments (§ 401.305), and procedures for suspending, offsetting or recouping Medicare payments in certain situations (§ 405.371).

The following is a summary of the comments we received regarding supplier enrollment.

Comment: Several commenters supported the proposal to allow organizations that previously would not be eligible to enroll in Medicare to enroll as MDPP suppliers. One commenter stated that enabling organizations with either preliminary or full CDC DPRP recognition to furnish MDPP services as officially enrolled suppliers is an important step in validating community health workers' place in the health care system. Other commenters stated that these organizations should be able to enroll and furnish MDPP services, but that they should do so with a clinical affiliate to serve as a resource to provide medical insight or oversight as necessary.

Many commenters who supported allowing these organizations to enroll in Medicare as MDPP suppliers recommended that the enrollment policies should be aligned as closely to CDC DPRP Standards as possible to avoid additional burden to organizations that are less familiar with Medicare rules and regulations.

Response: We appreciate the commenters' support for allowing organizations that meet the MDPP supplier eligibility criteria to enroll in Medicare, even for those that in other circumstances would be ineligible to enroll in Medicare. As described in detail in section III.J.7.c. of this final rule, the literature does not support the need for coaches to have clinical credentials to successfully achieve the behavior change MDPP seeks to encourage. Therefore, we disagree with commenters who suggested requiring that these new suppliers enroll with a clinical affiliate, that is, a provider or supplier that is currently enrolled in Medicare and currently furnishes services.

For those who requested that we closely align MDPP supplier eligibility requirements to the DPP organization recognition requirements in the CDC DPRP Standards, an organization that obtains CDC DPRP recognition can become an MDPP supplier if they meet a few additional Medicare requirements.

Comment: Some commenters disagreed with requiring community-based organizations to enroll as an MDPP supplier in order to furnish MDPP services, stating that the enrollment process would be too burdensome. Others recommended that due to the burden that enrolling as a Medicare supplier could place on smaller, community-based organizations that wish to furnish MDPP services, we should offer them an easier, expedited enrollment process that is less complex and burdensome. Other commenters noted that given the burden that enrolling, recordkeeping, and billing could impose on these organizations, particularly smaller community-based organizations, many such organizations utilize third party administrators to assume these roles on their behalf. Commenters recommended that we consider the role that third party administrators, which are not CDC-recognized to deliver DPP, could play in MDPP, particularly providing administrative services to new Medicare suppliers to lighten their burden.

Response: We acknowledge that smaller, community-based organizations without experience in the traditional

health care system may not be familiar with Medicare's enrollment requirements, and may find Medicare enrollment burdensome. Medicare enrollment is the process through which suppliers acquire eligibility to submit claims to Medicare to bill for services furnished. (In other contexts enrollment can also be the process used to establish eligibility to order or certify Medicare covered items and services.) Furthermore, enrolling into Medicare also enables us to maintain program integrity through screening, monitoring and revocation. Thus, we believe the benefits of enrollment, even for smaller community-based organizations, outweigh the costs of the associated administrative burden. We note that organizations that face financial difficulty related to the enrollment application fee may apply for a hardship exception. For more information on the hardship exemption, please visit: *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7350.pdf*.

We recognize the role that third party administrators may play in facilitating the enrollment process for DPP organizations. We intend to allow MDPP suppliers to utilize third-party administrators for the purposes of enrollment but will further consider how these entities may fit into the MDPP enrollment and policy framework in future rulemaking, as appropriate.

Comment: A few commenters questioned whether new suppliers could obtain a National Provider Identifier (NPI) to become eligible to enroll in Medicare. Some commenters believed that many DPP organizations with CDC DPRP recognition do not meet the requirements to obtain an NPI given the definition of health care provider under 45 CFR 160.103, and requested that we explain how unlicensed organizations and individuals with no health care experience qualify for an NPI.

Commenters requested clarity regarding what supplier type an MDPP supplier would indicate on the Medicare enrollment application. Other commenters requested clarity on what taxonomy code suppliers would use when applying for their NPI.

Response: We disagree with commenters who stated that some organizations that meet the MDPP supplier requirements would be unable to obtain an NPI. Under 45 CFR part 162, subpart D, health care providers, as defined in 45 CFR 160.103, may obtain NPIs. The definition of health care provider at 45 CFR 160.103 specifies, in part, that any person or organization who furnishes health care in the normal course of business is a health care provider. Section 45 CFR 160.103 defines ''health care'' to include, among other things, preventive services. Because MDPP services are considered additional preventive services, we believe MDPP suppliers and coaches who furnish MDPP in the normal course of business are furnishing health care and therefore qualify as health care providers that are eligible for NPIs under 45 CFR part 162, subpart D.

We acknowledge commenters' questions regarding which provider taxonomy to include when applying for an NPI, as well as which supplier type MDPP organizations would denote when enrolling. We plan to issue additional details through guidance or future rulemaking as appropriate to help guide organizations in applying for an NPI. For the purposes of providing guidance in this final rule, we would like to note for DPP organizations that we believe the taxonomy code of Health Educator (174H00000X) could be appropriate for MDPP suppliers when applying for an NPI. As for supplier type to denote upon applying to enroll in Medicare, we intend to create a new supplier type, specific to MDPP suppliers, and may release an appropriate application form accordingly.

Comment: Many commenters sought clarity regarding enrolling suppliers new to Medicare. One commenter asked whether these suppliers could furnish MDPP services at community locations such as faith-based organizations and community centers, as was permitted in the DPP model test. One commenter stated that DSMT and MDPP should be subject to consistent rules, but noted that current rules for DSMT do not permit hospital-based programs to be offered at community locations. Another commenter noted that while we do not define ''qualified physical practice location,'' the Medicare Program Integrity Manual suggests that in order to enroll in Medicare, organizations must have a physical location where a Medicare beneficiary could visit in person. This commenter recommended that CMS clarify how suppliers furnishing virtual DPP services would meet this physical location requirement, whether it would be waived, or whether their company headquarters would serve as the ''qualified physical practice location.''

Response: Consistent with the DPP model test, MDPP suppliers will be able to provide the service at community-locations such as faith-based organizations and community centers. Given that MDPP services can be furnished in community-based settings, the physical location associated with the MDPP supplier's base of operations in each state, as indicated on their enrollment application, would meet the requirements for the qualified physical practice location, provided that the location was open and operational as described in Chapter 15 of Medicare's Program Integrity Manual, Section 19.2.2. As described in III.J.7.e. of this final rule, we will address policies related to virtual DPP organizations in future rulemaking.

Comment: Several commenters agreed with our proposal that we would screen MDPP suppliers as high categorical risk. Many other commenters disagreed and stated that MDPP, like Diabetes Self-Management Training (DSMT), is educational by teaching beneficiaries about eating healthy and being active, which makes MDPP suppliers more analogous to DSMT organizations than Home Health Agencies (HHAs). Both the MDPP expanded model and DSMT are educational in nature, and both MDPP and DSMT organizations require recognition or accreditation by a third party organization or agency to be eligible to furnish services. Given these similarities, commenters noted that organizations that enroll as DSMT providers are screened according to the limited categorical risk, and therefore MDPP suppliers should similarly be screened at the limited categorical risk. Some commenters stated that MDPP suppliers should face less scrutiny and screening than that of medical professionals because of the fundamental difference between the educational MDPP and the medical services furnished by traditional Medicare providers.

Other commenters disagreed with CMS' parallel between HHAs and MDPP, noting that the requirement to obtain CDC DPRP recognition establishes a higher level of program integrity than that faced by HHAs. One commenter noted that Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) suppliers and HHAs became classified as high categorical risk in response to reports issued by the HHS Office of Inspector General (HHS–OIG) and the Government Accountability Office (GAO).

Response: We understand that MDPP bears similarities to an educational service like DSMT, but do not agree with commenters who stated MDPP suppliers should face less scrutiny or screening than that of medical professionals. CMS assigns risk level based not on the nature of the benefit that the supplier furnishes, but on the

level of risk that the supplier type may pose to the Medicare program. Therefore, we disagree with commenters who sought a limited screening level for MDPP suppliers on the basis that DSMT suppliers face limited screening. Fewer organizations are eligible to furnish DSMT than MDPP because DSMT organizations must already be enrolled in Medicare to furnish services other than DSMT. Due to their existing enrollments, all DSMT providers are affiliated with medical professionals enrolled in Medicare. Medical professionals face many additional regulations outside of those set by Medicare, including state licensure requirements that help to protect against fraud or abuse by these individuals. This is not comparable to MDPP suppliers that are not required to have an existing enrollment in Medicare. Given the requirements that credentialing and licensure place on these providers, the DSMT supplier type poses less risk to Medicare than suppliers like HHAs and DMEPOS suppliers that do not have the same credentialing and licensure requirements to serve as an additional check on fraud or abuse in addition to Medicare efforts. Similar to home health aides, individuals who furnish MDPP services are not required to have medical credentials or state licensure. Given the similarities between MDPP suppliers and HHAs, we believe the concerns HHS–OIG and GAO have regarding HHAs' vulnerability for fraud and abuse could also apply to MDPP. We believe our policy to require high-risk screening during enrollment will safeguard against potential fraud and abuse associated with this new supplier type.

Comment: Some commenters stated that the high categorical risk screening requirement would carry a substantial financial burden that may discourage MDPP supplier enrollment. One commenter noted that the on-site visits required in moderate and high categorical risk screenings would be redundant to the CDC DPRP Standards that already subject recognized organizations to random audits and site visits. These commenters noted that financial burdens may disproportionally affect community-based organizations that are well-suited to furnish a behavioral change program like the DPP. Commenters highlighted that the burden of collecting fingerprints would disproportionately affect independently run community-based organizations more so than corporate entities that typically only have one central board.

Commenters also requested additional information on the requirements for high categorical risk screening. One commenter stated that for entities that are corporately owned or traded, requirements for regional, privately owned suppliers may not be appropriate given the different ownership structures that are not well captured by CMS's enrollment applications. A few commenters also noted that suppliers newly enrolled into Medicare for MDPP, and providers or suppliers with existing enrollment in Medicare who wish to furnish MDPP, should be screened at the same level.

Response: While we agree that CDC ensures the quality of DPP programs using performance data, which will help ensure the quality of MDPP suppliers, CDC is not a regulatory body responsible for the integrity of Medicare payments. We therefore disagree that program integrity policies in Medicare would duplicate CDC's random site visits and audits of DPP organizations because the agencies play different roles. CMS's program integrity and audits focus on payments, whereas CDC focuses on monitoring whether organizations are meeting the CDC DPRP standards.

We agree with commenters who noted that suppliers newly enrolling into Medicare for MDPP should be screened at the same level as those with existing enrollment in Medicare who wish to furnish MDPP services. We acknowledge the financial burden that enrolling may place on some community-based DPP organizations. It is not our intent to hinder smaller organizations' ability to enroll in Medicare. We do not, however, believe that a high screening level as opposed to limited or moderate would greatly affect participation given the minimal additional requirements the higher screening levels entail. The difference between limited and high categorical risk screening includes a site visit for each base of operations and fingerprinting of certain individuals within the organization. This site visit poses no cost to the supplier, and should not delay the enrollment process beyond the 45 to 60 day window. Fingerprints are required of all individuals with 5 percent or more ownership interest in the entity. Organizations would not be required to submit fingerprints from managing members, coaches, or other employees. The enrollment application fee a supplier pays to Medicare is the same regardless of screening level, therefore the only difference in cost to the supplier amounts to the cost of obtaining fingerprints of those with 5 percent or more direct or indirect ownership interest in the entity. We do not believe this additional cost of high screening is cost prohibitive for enrollment, even for smaller community-based organizations. We understand the commenter's concern that for entities that are corporately owned or traded, screening requirements and CMS's enrollment applications may be difficult or may not be applicable given the different ownership structures. We will not change our requirement to collect fingerprints from all individuals with a direct or indirect ownership interest, though we recognize that not all suppliers under this requirement will have individual owners who meet this criterion. However, when an individual has 5 percent or more direct or indirect ownership in a prospective MDPP supplier, whether private or publically traded, submitting a set of fingerprints would be required for enrollment into Medicare.

We refer those interested in learning more about the requirements associated with a high screening level to § 424.518. Given the nominal financial difference of obtaining fingerprints from 5 percent or more owners, we do not believe that application of the high screening level will be a barrier to organizations to enroll in Medicare as an MDPP supplier. Additionally, we expect that MDPP suppliers will revalidate at a moderate risk level, consistent with the revalidation policy of other high risk suppliers. We will address the screening level of MDPP suppliers seeking to revalidate in future rulemaking.

Comment: Various commenters recommended that we clarify whether the MDPP supplier eligibility criteria would apply to existing providers and suppliers in Medicare. Specifically, commenters asked whether certified diabetes educators, pharmacies, pharmacists, physical therapists, registered dietitians, licensed clinical social workers, and licensed naturopathic physicians who graduated from accredited medical schools would have the ability to bill Medicare for MDPP services. Other commenters highlighted that certain types of medical professionals that are not currently eligible to enroll in Medicare, like RNs, have the capabilities to furnish MDPP services as a coach, and requested the ability to enroll in Medicare to furnish and bill for MDPP services.

Some commenters noted that many existing health care providers are well suited to furnish MDPP services, but may lack familiarity with the CDC National DPP and the process to obtain CDC DPRP recognition. These commenters recommended that CMS provide education and outreach to these

providers to ensure that they have the opportunity to obtain CDC DPRP recognition in a timely manner and eligible to furnish MDPP services.

Response: We appreciate interest from existing Medicare providers and suppliers in furnishing MDPP services. Any organization that obtains CDC DPRP recognition would be eligible to enroll in Medicare as an MDPP supplier. The CDC recognizes organizations, not individuals. As such, only organizations, not individuals, would be able to enroll as an MDPP supplier. Any claims submitted for MDPP services would therefore be billed by the MDPP supplier, and not by an individual or any other enrollment type a supplier may have.

Although many individual clinicians could serve as MDPP coaches, we note that entities, not individuals, receive CDC DPRP recognition. Furthermore, we would like to reiterate that entities enrolled in Medicare for the sole purpose of furnishing MDPP services would be eligible to submit claims only for MDPP services.

We agree that many health care entities may be well suited to furnish MDPP services but may lack familiarity with the CDC DPRP recognition process. We will further consider the recommendations to undertake targeted education and outreach efforts to build supplier capacity.

Comment: Some commenters noted that rural health clinics (RHCs) and federally qualified health centers (FQHCs) serve beneficiaries who could benefit from MDPP services, and sought clarification and/or recommended that RHCs and FQHCs be eligible to furnish MDPP services. One of these commenters also recommended that we allow RHCs to bill for MDPP services using the UB–04 form so that RHCs would not have to remove the cost of furnishing MDPP services from their cost report, which they said would make the benefit too administratively difficult to implement.

Response: RHC and FQHC services are defined in section 1861(aa) of the Act as services furnished by a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or clinical social worker. Under certain conditions, an FQHC visit may be furnished by a qualified practitioner of outpatient DSMT and medical nutrition therapy (MNT) when the FQHC meets the relevant program requirements for provision of these services. RHC and FQHC visits are medically-necessary primary health services, and qualified preventive health services, that are furnished face-to-face to a patient by a RHC or FQHC practitioner.

RHCs and FQHCs can enroll as MDPP suppliers if they otherwise meet the enrollment eligibility criteria, but we clarify that MDPP is not a RHC/FQHC service. However, a clinic that chooses to furnish MDPP services could exclude all costs related to furnishing MDPP services from its cost report and instead submit claims for MDPP services under its separate MDPP supplier enrollment. RHCs and FQHCs must ensure that there is no commingling of RHC or FQHC resources in the cost report used to furnish MDPP services. We understand that some clinics believe this will be burdensome, but only RHC or FQHC services can be billed on a UB–04 form.

Comment: Commenters generally supported the proposal that providers and suppliers with existing enrollment in Medicare only be required to inform us of their intent to furnish MDPP services. A few commenters explicitly stated that providers and suppliers with existing enrollment should not have to create a separate enrollment as an MDPP supplier to bill for MDPP services because the burden of doing so would unnecessarily discourage enrollment. In support of this assertion, commenters stated that providers and suppliers with existing enrollment face stringent regulations both from and outside of Medicare requirements, and therefore requiring an additional enrollment process for MDPP would only add redundancy, rather than support program integrity concerns. One commenter highlighted that under current CMS requirements, retail pharmacies must already undergo two enrollment processes and pay two application fees to serve dual roles as durable medical equipment suppliers and mass immunizers. The commenter stated that an additional enrollment process and fee would not further protect against fraud and abuse, but would simply add redundancy and inefficiency that could deter supplier uptake and limit beneficiary access.

For providers and suppliers with existing enrollment in Medicare, some commenters noted that they should not have to be held to the CDC DPRP Standards, but instead meet other requirements, as noted above. Other commenters expressed support for specific health care provider types that are well suited to furnish MDPP services.

A few commenters supported our alternative proposal that existing Medicare providers and suppliers separately enroll as MDPP suppliers and be separately screened to be eligible to bill for MDPP services. One commenter noted that consistency of procedures and guidelines among organizations furnishing MDPP services, regardless of whether they were new entrants to Medicare, would benefit the program to ensure the same requirements applied across all entities furnishing MDPP services.

Response: We agree with commenters who support the alternative approach we proposed that suppliers and providers with existing Medicare enrollment enroll separately as an MDPP supplier. We believe existing providers and suppliers will benefit from a standardized procedure that all MDPP suppliers follow.

Though requiring existing Medicare providers and suppliers to separately enroll as MDPP suppliers initially imposes an additional requirement, this is a standard procedure for current suppliers. Other types of Medicare providers, such as hospitals or clinics who wish to provide home health services, would similarly need to enroll as HHA suppliers and undergo screening requirements associated with HHAs. We also believe this requirement would ultimately protect existing Medicare providers from revocation action against their enrollment and ability to furnish services outside of MDPP. For example, should an existing provider furnishing MDPP services lose CDC DPRP recognition, the provider would be subject to revocation. If the provider were not enrolled separately as a MDPP supplier, the provider's Medicare enrollment would be subject to revocation action, not just the billing privileges associated with MDPP services. As discussed in section III.J.7.d. of this final rule, many commenters agreed with the proposal that loss of CDC DPRP recognition should result in revocation only of MDPP billing authorities, and not necessarily affect the existing provider or supplier's eligibility to furnish and bill for non-MDPP services. By requiring all prospective MDPP suppliers—regardless of whether they have existing enrollment in Medicare—to enroll as an MDPP supplier, CMS has the discretion to target any revocation action against the MDPP supplier enrollment alone, rather than affect the existing provider or supplier's other enrollment. It is important to note that revocation removes a provider or supplier's enrollment in Medicare, not just its billing privileges for a particular Medicare service. For example, if a hospital had an additional enrollment as an MDPP supplier and one of their coaches was fraudulently reporting weight loss that beneficiaries did not achieve, CMS would have the discretion

to revoke the hospital's MDPP supplier enrollment, but could withhold revocation of the hospital's Part A Medicare enrollment. Alternatively, if CMS pursued the original proposal and the hospital did not reenroll as an MDPP supplier, under the same scenario, the hospital's entire enrollment could be revoked for up to three years, which could have deleterious effects on the provision of care well beyond MDPP. For this reason, we are adopting our alternative proposal.

We acknowledge the concerns that requiring enrolled providers and suppliers to separately enroll as an MDPP suppler imposes a burden. However, we disagree that enrollment screening for the purposes of one supplier type would satisfy program integrity concerns for a different supplier type. Many program integrity checks specifically target the licensure and credentials of a particular supplier type that would not necessarily transfer to other suppliers. Similarly, we disagree with commenters who stated that the program integrity efforts and regulations on providers or suppliers with an existing, non-MDPP enrollment in Medicare would sufficiently address any program integrity related concerns with regards to MDPP services. MDPP services and the manner in which those services will be provided differ from other Medicare benefits and therefore require separate monitoring and regulation to ensure the program integrity.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal to permit organizations that meet the supplier enrollment eligibility criteria to enroll in Medicare as MDPP suppliers. We are modifying our proposal with respect to existing Medicare providers or suppliers and requiring them to adhere to the same enrollment requirements as MDPP suppliers if they wish to furnish and bill for MDPP services and otherwise meet the MDPP supplier enrollment eligibility criteria.

We are finalizing the high screening level as proposed. We will continue to monitor enrollment efforts and program integrity, and should our policy merit adjustment, we may amend this decision in future rulemaking as necessary.

We are finalizing that MDPP suppliers are obligated to comply with all statutes and regulations that establish generally applicable requirements for Medicare suppliers. These regulations include, but are not limited to, time limits for filing claims (§ 424.44), requirements to report and return overpayments (§ 401.305), and procedures for suspending, offsetting or recouping Medicare payments in certain situations (§ 405.371). As explained in more detail in section III.J.7.c. of this final rule, we will not be able to begin supplier enrollment until enforcement activities are finalized during subsequent rulemaking in 2017, but we encourage DPP organizations to use this final rule to prepare for enrollment. This may include working towards CDC recognition, as detailed in III.J.7.b. of this final rule, obtaining NPIs, or obtaining claims processing software.

The final policies for MDPP supplier enrollment are set forth in § 424.59.

b. CDC DPRP Recognition

CDC grants pending recognition to an organization upon its approval of the organization's application and the organization's agreement to comply with requirements for use of a CDC-approved curriculum and for duration and frequency of sessions. CDC also establishes an effective date for each approved organization which is the first day of the month following their approval date. Organization must submit data every 12 months from their effective date. CDC grants full recognition after an organization with pending recognition has consistently furnished sessions with a CDC-approved curriculum, met CDC performance standards, and met CDC reporting requirements. CDC makes the first determination for full recognition 24 months after their effective date. Organizations not meeting full recognition at that time are reassessed at 36 months. Organizations that do not achieve full recognition within 36 months after their effective date will lose any recognition and must wait 12 months before reapplying.

In our proposal regarding eligibility of DPP organizations to enroll in Medicare, we proposed the use of an additional CDC recognition status: preliminary recognition.

We proposed that DPP organizations must have either preliminary or full CDC DPRP recognition in order to be eligible to enroll in Medicare as MDPP suppliers. We proposed that DPP organizations can attain preliminary CDC DPRP recognition upon meeting CDC DPRP performance standards and reporting requirements for 12 months after applying for recognition, and full recognition upon demonstrating program effectiveness for 24–36 months after applying for CDC DPRP recognition. We proposed that if an organization loses its CDC DPRP recognition status at any point, for example for not meeting CDC standards or failing to move from preliminary to full recognition within 36 months of their effective date, or withdraws from the CDC DPRP at any point, the organization would be subject to revocation of its Medicare billing privileges for MDPP services as provided by 42 CFR part 424, subpart P. Under the CDC DPRP Standards, an organization that loses its CDC DPRP recognition (and thus, under our proposal, would no longer be able to bill Medicare for MDPP services) must wait 12 months before reapplying for recognition. We proposed that DPP organizations would be eligible to re-enroll in Medicare as an MDPP supplier if, after reapplying for CDC DPRP recognition, the organization again achieves preliminary recognition.

The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported requiring DPP organizations to obtain CDC DPRP recognition in order to be eligible for enrollment in Medicare as an MDPP supplier. Some commenters recommended we take into account the socioeconomic status of participants when considering CDC's recognition, and work with CDC to account for the risk of inadvertently precluding suppliers serving vulnerable populations who have fewer resources to achieve healthy eating and fitness goals. Some commenters requested that CMS allow MDPP supplier eligibility to be based on alternative accreditations and standards focused on diabetes education.

A few commenters noted that CDC DPRP recognition is difficult to attain because it relies on average weight loss of 5 percent across the population of participants an organization serves, and if organizations fall a few decimal points short of that threshold, they can lose their recognition. Some commenters expressed the concern that beneficiary access may be disrupted if a supplier falls short of CDC DPRP Standards, therefore losing recognition and Medicare eligibility. Furthermore, commenters were concerned with the timelines the CDC DPRP Standards require for reapplication. Tribal organizations collectively requested CDC DPRP recognition be automatically granted to providers of the Special Diabetes Program for Indians.

Response: In response to comments regarding CDC recognition (socioeconomic status of participants, average weight loss requirement, timelines with reapplication) we note that CDC is responsible for developing standards related to CDC recognition,

and we are not. We are coordinating with CDC to promote alignment between the CDC DPRP and MDPP expanded model requirements, to the extent possible. We are not considering other accrediting bodies or at this time. We expect that the updated CDC DPRP Standards will be published for public comment in 2017 and go into effect in 2018.

We welcome consultation with tribes and tribal organizations as required by the CMS Tribal Consultation Policy,[27] and will address this and other concerns that have tribal implications, as appropriate, in future rulemaking.

Comment: Several commenters expressed support for the proposal that organizations must obtain preliminary or full CDC DPRP recognition in order to become eligible to enroll in Medicare as an MDPP supplier. Other commenters recommended that we clarify the requirements for preliminary recognition and how preliminary recognition differs from the CDC DPRP Standards' definition of pending recognition. The commenters noted that the CDC DPRP Standards currently do not have a preliminary recognition definition. A commenter recommended that CDC be the entity responsible for recognizing organizations with preliminary recognition, just as CDC is responsible for recognizing organizations with pending recognition and full recognition.

Several commenters recommended that CMS clarify which performance standards and reporting requirements need to be met for 12 consecutive months to qualify for preliminary recognition. The commenters noted that they assume that an MDPP supplier would comply with the first year of CDC DPRP Standards for pending recognition status, starting at the effective date of the DPP organization's pending recognition. The commenters also noted that this means submitting data at 12 months from the effective date, but not achieving any particular outcomes at 12 months because current CDC DPRP Standards do not consider outcomes for achieving recognition until 24 months from the effective date. Several commenters recommended that we clarify whether an organization must submit 6 months or one year of data to obtain preliminary recognition. The commenters expressed their support that an organization offer DPP services for at least a year before qualifying for recognition as an MDPP supplier. A separate commenter suggested that CMS clarify that to obtain preliminary recognition, an organization must offer the CDC-approved curriculum within 6 months of the effective date of the organization's CDC DPRP application and submit at least 6 months of participant data at 12 months post-effective date of the application. Several commenters recommended removing the requirement to submit one year's worth of data before obtaining preliminary recognition.

One commenter noted that given the work and time required for DPP organizations to start providing DPP services, it may be difficult to obtain 12 months of reporting data immediately after the effective date of the DPP organization's pending recognition status. The commenter expressed concern that an organization that has met the standards and reporting requirements for 11 of the 12 months immediately following its application to participate in the DPRP should not have to reapply for preliminary recognition and start the 12-month process over again. Another commenter recommended that preliminary recognition performance standards focus on percent of weight loss achieved, as opposed to average weight loss, and maintenance of weight loss among participants.

Some commenters recommended that we allow organizations that have either pending recognition or full recognition from CDC to enroll as MDPP suppliers. The commenters noted that organizations obtain pending recognition from CDC after they agree to curriculum, duration, and intensity requirements. One commenter noted that the additional status of preliminary recognition adds a complicated layer of bureaucracy to the existing CDC DPRP, adds little value, and will likely delay enrollment of organizations in Medicare as MDPP suppliers due to lack of defined requirements for preliminary recognition. Several commenters suggested that we allow participation of DPP organizations with pending recognition until CDC standards for preliminary recognition status are established. One commenter requested that we explain why we proposed an additional recognition status, whether we can create new CDC DPRP recognition standards, and if so, how the new recognition standards will be incorporated into the CDC DPRP Standards.

One commenter recommended that only organizations with full CDC DPRP recognition may serve as MDPP suppliers in order to eliminate potential confusion caused by the preliminary recognition standard and preserve program integrity. The commenter suggested that we should only pay suppliers that have demonstrated their effectiveness as MDPP suppliers or their ability to establish and maintain the necessary infrastructure. Another commenter suggested that organizations with full recognition be paid at a higher rate than organizations with preliminary recognition.

Several commenters recommended that CMS adopt a grandfathering policy where organizations with 12 months of data may obtain preliminary recognition. A few commenters noted that the creation of the preliminary recognition definition risks having few or no MDPP suppliers with preliminary recognition by MDPP's scheduled effective date of January 1, 2018, thus delaying the implementation of MDPP. One commenter noted that the preliminary recognition status does not exist in CDC DPRP Standards, and that the preliminary recognition definition would be published in CDC DPRP Standards too late for MDPP suppliers to begin enrolling into Medicare in time to begin furnishing MDPP services on January 1, 2018. The commenter recommended that we require CDC to identify organizations with pending recognition that qualify for preliminary recognition no later than December 31, 2016 and require that CDC release interim guidance on standards or requirements for preliminary recognition no later than March or April 2017. The commenter notes that additional, minor clarifications may also be needed when the CDC issues updated CDC DPRP Standards in January 2018 to reflect early experience with the new preliminary recognition definition. One commenter believed it should be permitted to enroll as an MDPP supplier because it has one year of data, even though it lacks CDC DPRP recognition. Another commenter urged that we review its organization's data before 2018, and if it meets the standards for MDPP suppliers in 2017, that CMS reimburse the organization in 2017.

Response: We appreciate the support for our proposal to allow DPP organizations with full CDC recognition, as well as certain DPP organizations that do not yet have full CDC recognition, to enroll as MDPP suppliers. We received many comments that raised questions and concerns about preliminary CDC recognition status or offer suggestions about how preliminary CDC recognition status should be determined. Because the CDC has not adopted standards for preliminary recognition, however, we are not finalizing any of our proposals

[27] Centers for Medicare & Medicaid Services, ''CMS Tribal Consultation Policy,'' *Centers for Medicare & Medicaid Services,* 2015, *https://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Downloads/CMSTribalConsultationPolicy2015.pdf.*

with respect to preliminary recognition status at this time. Although we anticipate that CDC will address standards for preliminary recognition when it publishes updated DPRP Standards for public comment next year, because any such standards for CDC preliminary recognition would not take effect until 2018, it will not be possible to permit DPP organizations to enroll in Medicare based on achievement of CDC preliminary recognition before then.

For this reason, we intend to use future rulemaking to propose interim standards for preliminary recognition, under CMS authority, that would bridge the gap until CDC preliminary recognition standards are established. We anticipate that our proposed interim preliminary recognition standards would be consistent with the principles described in the proposed rule. We intend to align our MDPP supplier enrollment policies with CDC recognition standards, as appropriate, as they are established. We will take the commenters' comments on preliminary recognition into account as we develop our proposal for interim CMS recognition standards. We do not intend to delay implementation of the MDPP expansion.

We proposed that certain DPP organizations that had not yet achieved full recognition could enroll in Medicare in acknowledgement that full recognition might take 36 months and require achievement of certain performance standards. We proposed this eligibility requirement for Medicare enrollment to allow an increased number of organizations that have demonstrated a capacity to provide DPP services to enroll in Medicare, thereby allowing access to MDPP services in a timely manner as of January 1, 2018. We continue to believe that it is appropriate to permit enrollment in Medicare prior to achievement of full CDC recognition in cases where there is demonstrated capacity to furnish DPP services, and as noted above, we intend to address this issue in future rulemaking. Therefore, we decline to permit DPP organizations that have only pending recognition to enroll in Medicare because such organizations may not have any demonstrated capacity to furnish DPP services. We are aware that most DPP organizations are currently in pending recognition status, and that CDC's definition for pending recognition currently includes a 6-month grace period before organizations are required to start offering DPP sessions. We are also aware that the current definition of full recognition requires organizations to meet certain standards for average weight loss and participation, and relative to those in pending status, few organizations have obtained full recognition. However, we believe it is important to ensure that prospective MDPP suppliers have demonstrated experience in actually furnishing DPP services, and therefore we do not believe it is appropriate to permit organizations to enroll in Medicare before they have submitted any performance data to CDC that allows CDC to assess their capacity to deliver DPP services.

We recognize the timing and nature of our proposal has caused some confusion, particularly because we intend to use CDC recognition status as a Medicare enrollment standard. We also agree with commenters that in general CDC should be responsible for recognizing DPP organizations, consistent with its recognition standards. However, as noted above, we intend to propose in future rulemaking interim CMS recognition standards that would permit DPP organizations that are seeking full CDC recognition and have demonstrated capacity to furnish DPP services to enroll in Medicare prior to January 1, 2018. We are considering performance criteria that we could propose as part of any interim CMS standards that we would use to permit DPP organizations that have not yet achieved full CDC recognition to enroll as MDPP suppliers before the CDC standards are updated. For example, we are considering proposing that DPP organizations with pending CDC recognition would be required to meet a performance standard threshold of 60 percent participant attendance in at least 9 core sessions in months 1–6 and 60 percent participant attendance in at least 3 core maintenance sessions in months 7–12. In addition, we intend to consider options to ensure program integrity and mitigate fraud and abuse during the preliminary recognition stage. We encourage interested parties to submit comments on any updates to CDC's DPRP Standards when CDC publishes them for public comment.

Finally, in response to commenters, we do not intend to propose differential payments based on whether the supplier has full recognition. We also do not intend to make payments for MDPP services prior to January 1, 2018. We will also propose details on the payment structure in future rulemaking.

Final Decision: We finalize our proposal that an entity must have full CDC DPRP recognition as a requirement to enroll in Medicare as an MDPP supplier. Due to timing issues with CDC standards updates, we are not finalizing any proposals for preliminary recognition at this time. We intend to address this issue in future rulemaking.

c. Coach Requirements

We proposed to require personnel who would furnish MDPP services, referred to hereafter as ''coaches,'' to obtain a National Provider Identifier (NPI) to help ensure the coaches meet CMS program integrity standards. We also considered requiring that coaches enroll in the Medicare program in addition to obtaining an NPI, and we solicited comment on this approach. Another alternative policy we considered was to require DPP organizations to collect and submit information on the coaches who would furnish MDPP services, which could include identifying information such as first and last name and social security number (SSN). We proposed to require MDPP suppliers to submit the active and valid NPIs of all coaches who would furnish MDPP services on behalf of the MDPP supplier through a roster of coach identifying information. We proposed that if MDPP suppliers fail to provide active and valid NPIs of their coaches, or if the coaches fail to obtain or lose their active and valid NPIs, the MDPP supplier may be subject to compliance action or revocation of MDPP supplier status.

The following is a summary of the comments we received and our responses.

Comment: We received comments regarding coach enrollment into Medicare. Commenters overwhelmingly stated objections to coach enrollment, citing reasons including high turnover and the reality that many coaches work part time or as volunteers. Commenters also highlighted that since claims and payment are handled directly by the supplier, coaches have limited reasons to enroll. Other commenters noted that coaches lack medical licensure, indicating that only medical providers should enroll. And several commenters cited the burden that enrollment would impose on coaches, and that requiring this approach could limit coach participation and ultimately reduce beneficiary access to services.

The majority of commenters indicated that organizations alone should enroll in Medicare as MDPP suppliers, though one commenter proposed that diabetes prevention coordinators, who oversee the coaches as outlined in the CDC DPRP Standards, should enroll. A few commenters recommended that coaches enroll, stating that this would ensure our ability to protect the integrity of the Medicare program and have direct oversight over coaches furnishing the benefit. Other commenters cited

consistent use of CMS processes such as enrollment for program integrity efforts rather than creating new processes. Several commenters highlighted the opportunity for coaches to be directly paid for the services furnished.

Response: We agree with the commenters who stated that coaches should not enroll in Medicare and should not be submitting MDPP claims. Though we understand there may be program integrity advantages if coaches were to enroll, we do not believe the existing enrollment process is appropriate for coaches. Most notably, enrollment is for the purpose of permitting Medicare billing, and we have proposed that only MDPP suppliers, not coaches, would submit claims for MDPP services. We do not believe coaches should have the ability to submit claims for MDPP or be directly paid for the services furnished because CDC DPRP recognition is obtained at the organization level, not for the individual coach furnishing MDPP services. Additionally, we believe that the burden of enrolling and submitting claims, as well as the medical record retention requirements associated with claim submissions, would be too burdensome to place on individual coaches, and that suppliers are more appropriate and suitable to assume this responsibility. We did not propose enrolling diabetes prevention coordinators, but we believe the same rationale against requiring coaches to enroll would apply to these individuals as we did not propose that diabetes prevention coordinators would be able to bill for MDPP services.

Comment: We received many comments regarding whether coaches should obtain NPIs, with commenters split on whether CMS should require only suppliers, or both suppliers and coaches, to obtain NPIs. A few commenters alternatively suggested that diabetes prevention coordinators, not coaches, would be more appropriately suited to obtain NPIs. Most commenters did not provide a reason for supporting the proposal that coaches obtain an NPI, but those that did stated that having coaches obtain an NPI would serve to validate community health workers' role in health care. Many commenters expressed their support for coaches obtaining an NPI as an alternative to enrolling in Medicare. One commenter indicated that given that MDPP services will be additional preventive services, the processes that would apply to other additional preventive services should also apply, and coaches who furnish these services should therefore obtain NPIs.

Commenters who opposed the requirement for coaches to obtain NPIs largely expressed that only health care providers should obtain NPIs. Some commenters believed that MDPP coaches do not meet the definition of health care provider under 45 CFR 160.103, and therefore coaches should not be allowed to obtain an NPI. Other commenters questioned how coaches could obtain NPIs, particularly when registered nurses (RNs) and other credentialed professionals can neither obtain NPIs nor enroll as Medicare suppliers. Several commenters recommended that CMS extend those same proposals for coaches to RNs and other medical professionals who currently lack the ability to obtain an NPI. As an alternative to obtaining NPIs, a number of commenters proposed that coaches should have specialized training.

Response: We did not propose any requirements for diabetes prevention coordinators, but we may consider this possibility for future rulemaking as appropriate. Given that coaches directly furnish MDPP services, we believe that for any process aiming to track and screen professionals working with an MDPP supplier, the coach will likely stand as the most appropriate individual to track and screen, as opposed to the coordinators who do not directly furnish MDPP services.

To commenters who did not believe that coaches would be eligible for an NPI, we note that 45 CFR part 162, subpart D specifies that health care providers, as defined in 45 CFR 160.103, may obtain NPIs. Among other things, a health care provider under 45 CFR 160.103 is a person or organization who furnishes health care in the normal course of business. Because 45 CFR 160.103 specifies that health care includes preventive services, we believe MDPP coaches provide health care and are therefore health care providers under 45 CFR 160.103 and eligible to obtain NPIs. We disagree that requiring coaches to obtain NPIs would impose an undue burden on coaches, even those who work as coaches part-time or as volunteers. Obtaining an NPI takes approximately 20 minutes and can be done easily online. We will further consider the impact of coach requirements for rural and tribal areas that lack reliable access to the internet and will consider adjusting policies in future rulemaking as appropriate.

Requests for CMS to address NPI issues and enrollment for other health care providers such as RNs are outside of the scope of this rulemaking for MDPP. Should RNs or other providers who currently lack an NPI decide to work as a coach, these individuals would be able to obtain an NPI on that basis for purposes of furnishing MDPP services.

Given the relatively low burden that obtaining NPIs places on coaches and important considerations for monitoring, evaluation, and program integrity, we will require every coach furnishing MDPP services on behalf of an MDPP supplier to obtain an active and valid NPI that will be submitted to Medicare on the supplier's updated roster of coaches. This roster of coach identifying information would be submitted alongside the MDPP supplier's enrollment application to be used for vetting and program integrity purposes. However, we did not propose specific standards for how we would use roster information in connection with MDPP supplier enrollment. We intend to propose such standards in future rulemaking, and will begin enrollment of MDPP suppliers once appropriate standards are in place.

Comment: We received general support from commenters for the proposal to track coaches using some form of identifiable information to help ensure the coaches meet CMS program integrity standards. Few commenters detailed in their response the type of information that should be collected. While some commenters preferred using coach names and NPIs for tracking purposes, slightly more commenters preferred using identifiable information such as social security numbers (SSNs).

Response: We appreciate the support from commenters. Use of NPIs and SSNs would serve different purposes in vetting coaches against program integrity risks upon the supplier's enrollment in Medicare, as well as evaluation and monitoring purposes for performance and continuing program integrity efforts. In existing areas of Medicare's enrollment process where both NPIs and SSNs are used for individual providers who enroll into Medicare, SSNs serve the purposes of completing background checks, while NPIs serve an identifying and tracking purposes with regards to Medicare claims and actions. These two identifiers play distinct and important roles in ensuring the integrity of Medicare's programs and the safety of the beneficiaries served. Given commenters' openness to using both pieces of identifying information, we will finalize a requirement that MDPP suppliers submit the names, NPIs and SSNs of their coaches.

Upon enrollment, MDPP suppliers must submit, and update within 30 days of any changes, a roster of coaches, including individuals' first and last

name, SSN and NPI to CMS along with its enrollment application to help ensure the coaches meet CMS program integrity standards. Changes that must be reported to us include adding identifying information for any coach beginning to furnish MDPP services on behalf of the supplier or removing a coach who ceases furnishing MDPP services on behalf of the supplier. We intend to address how this coach information might affect MDPP supplier enrollment and be used in enforcement actions in future rulemaking as appropriate. As noted previously, enrollment of MDPP suppliers will not begin until such standards are in place.

Comment: We received a number of comments on coach requirements under the MDPP expanded model. The majority of commenters stated that training should be required, some stipulating that specific trainers should be utilized. Within the discussion of training, some commenters stipulated that medical professionals should be exempt from any additional training imposed on coaches, while others stipulated that everyone—including medical professionals—should undergo training to become a coach. One commenter recommended that CMS create an audit process to ensure that training occurred. Several commenters urged us to consider creating a certification program for coaches. Commenters also referred to the CDC DPRP Standards for coach requirements and requested that CMS clarify whether formal lifestyle coaching is a requirement and specifically what constitutes the definition of trained coach to furnish the required curriculum. Other commenters asked whether we will require additional training sources or continuing education requirements above the CDC DPRP Standards in order to qualify as a coach.

Many commenters supported specific practitioners to serve as coaches, such as Certified Diabetes Educators (CDEs). Other commenters recommended that coaches should have clinician oversight. Similarly, other commenters suggested that we require for coaches to have clinicians as affiliates who can serve as a medical resource. A few commenters stated that coaches should have some form of credentials, particularly given that participants may have medical questions about weight loss that extend beyond a CDC-approved curriculum, which credentialed professionals are better equipped to handle. A number of commenters specifically requested that we recognize the value that CDEs can have in the MDPP expanded model and specify the role that they play in the management of lifestyle changes.

While we received many comments suggesting additional requirements for coaches, a number of commenters also urged against adding additional requirements on coaches beyond CDC DPRP Standards.

Response: We do not, at this time, see any need to require additional training, certification, or clinician oversight or affiliation beyond the CDC DPRP Standards, particularly given that the initial DPP model test met the criteria for expansion without these requirements.

Though we agree that CDEs, RNs, and other credentialed professions can be effective MDPP coaches, the DPP model test showed that trained, non-credentialed coaches can effectively deliver the program. Additionally, we do not believe that the literature supports this claim that coaches with credentials would result in better participant performance than non-credentialed individuals trained to be coaches.[28] [29] [30] [31] Therefore, we do not believe credentials are necessary at this time, but may evaluate and revisit this proposal as necessary. Therefore, any individuals—with or without credentials—can become a coach provided that they meet CDC DPRP Standards and work for a MDPP supplier.

We will further consider commenters' suggestions regarding mechanisms to ensure that coaches have received high quality training, whether we will require coach certification, the impact credentials may have on coaches, and the possibility of clinician affiliation or oversight as we monitor and evaluate the expanded model.

Final Decision: We are finalizing the proposal that DPP organizations must enroll in Medicare to become MDPP suppliers, and that coaches will not enroll in Medicare for purposes of furnishing MDPP services. We are finalizing the proposal that coaches must obtain NPIs. We are requiring MDPP suppliers to submit the active and valid NPIs of all affiliated coaches and to update CMS within 30 days of a coach beginning to or ceasing to furnish MDPP services. We finalize that this roster of coaches submitted will include the first and last name, SSN, and NPI. We intend to propose policies specific to enrollment standards and enforcement actions, as they relate to the roster, in future rulemaking.

The final policies for coach requirements are set forth in § 424.59.

d. Revocation of MDPP Supplier Enrollment

We proposed that all MDPP suppliers would be required to comply with the requirements of 42 CFR part 424. If an MDPP supplier has its Medicare enrollment revoked or deactivated for reasons unrelated to its loss of CDC DPRP recognition, that MDPP supplier would lose its ability to bill Medicare for MDPP services but would not automatically lose its CDC DPRP recognition. We proposed that existing Medicare providers and suppliers who lose CDC DPRP recognition would lose their Medicare billing privileges with respect to MDPP services, but may continue to bill for other non-MDPP Medicare services for which they are eligible to bill. We proposed that MDPP suppliers that have their Medicare billing privileges revoked or that lose billing privileges for MDPP may appeal these decisions in accordance with the procedures specified in 42 CFR part 405, subpart H, 42 CFR part 424, and 42 CFR part 498. We proposed to add a new § 424.59 to our regulations to specify the suppliers who would be eligible for Medicare enrollment and billing for MDPP services. We solicited comment on these proposals.

The following is a summary of the comments we received regarding these proposals and our responses.

Comment: A few commenters agreed with the proposal that loss of CDC DPRP recognition should lead to loss of MDPP billing privileges. Some commenters specifically agreed that revocation should be limited to MDPP privileges. Commenters also stated that the ability to appeal a revocation decision was important. One commenter expressed concerns that losing Medicare billing privileges would affect MDPP suppliers less than medical professionals, presenting a potential vulnerability to fraud. For medical professionals, Medicare provides a key source of income and livelihood, whereas non-traditional Medicare providers who primarily deliver non-health care related services like those in a community center would not necessarily be as affected by a

[28] D Vojta et al., ''A Coordinated National Model for Diabetes Prevention: Linking Health Systems to an Evidence-Based Community Program,'' *American Journal of Preventive Medicine* 44, no. 4 Suppl 4 (2013): S301–S306.

[29] Mohammed K. Ali et al., ''How Effective were Lifestyle Interventions in Real-World Settings that were Modeled on the Diabetes Prevention Program?,'' *Health Affairs* 31, no.1 (2012): 67–75.

[30] L Ruggiero et al., ''Community-Based Translation of the Diabetes Prevention Program's Lifestyle Intervention in an Underserved Latino Population,'' *The Diabetes EDUCATOR* 37, no. 4 (2011); 564–572.

[31] JA Katula et al., ''The Healthy Living Partnerships to Prevent Diabetes Study 2-Year Outcomes of a Randomized Controlled Trial,'' *American Journal of Preventive Medicine* 44, no. 4S4 (2013): S324 –S332.

revocation than a health clinic. The commenter did not suggest an alternative approach that could make losing Medicare billing more impactful for these organizations.

Response: We appreciate the support from commenters on our proposed revocation policies, including the right to appeal a revocation. Should we deny a prospective MDPP supplier's enrollment, we expect that appeal rights set forth in 42 CFR part 424 would apply, however we will address any provisions related to Medicare enrollment denial appeal rights in future rulemaking. We agree with commenters that should a supplier lose CDC DPRP recognition, the supplier's revocation would be only of the supplier's MDPP enrollment. We disagree that revocation of MDPP enrollment would affect existing providers and suppliers less than new MDPP suppliers. In both cases, the supplier would lose its ability to bill for MDPP services. We reiterate that all MDPP suppliers—whether a new Medicare supplier or a currently enrolled provider and supplier—must comply with the requirements of 42 CFR part 424, subpart P, including, but not limited to, enrollment bars. CMS notes that we did not propose a policy regarding the effective date of the revocation, and will do so in future rulemaking. We retain the authority to revoke any Medicare enrollment—MDPP supplier or otherwise—if a supplier does not comply with Medicare requirements.

Final Decision: We are finalizing our proposals that all MDPP suppliers must comply with the requirements of 42 CFR part 424, will have their MDPP supplier enrollment revoked upon loss of CDC DPRP recognition or noncompliance with Medicare requirements, and may appeal these decisions in accordance with the procedures specified in 42 CFR part 405, subpart H, 42 CFR part 424, and 42 CFR part 498.

The final revocation and appeal policies are set forth in § 424.59.

e. Virtual MDPP Services

Currently, CDC-recognized DPP organizations deliver DPP services in-person or virtually via a telecommunications system or other remote technology. The majority of current DPP organizations furnish DPP services in-person, but an emerging body of literature [32] [33] [34] [35] supports the effectiveness of virtual sessions furnished remotely. We proposed to allow MDPP suppliers to furnish MDPP services through remote technologies. As part of our evaluation of the MDPP expansion, to the extent feasible, we planned to evaluate the effectiveness of MDPP services, particularly in relation to virtual versus in-person services, and, using the evaluation data, modify or terminate this component of the expansion as appropriate. To permit such evaluation, we are considering specifying the nature of the virtual service and the site of the service in codes included on claims submitted for payment, as well as collecting information on the nature of the virtual service and the site of service at the beneficiary level from MDPP suppliers.

We planned to monitor administrative claims for virtual services to identify any unusual and/or adverse utilization of the MDPP services. We solicited comment on specific monitoring activities or program integrity safeguards with respect to virtual services, in addition to the time period in which such enhanced monitoring activities should occur.

We noted that MDPP services provided via a telecommunications system or other remote technology will not be part of current Medicare telehealth benefits and have no impact on how telehealth services are defined by Medicare. We recognize that the provision of MDPP services by such virtual methods may introduce additional risks for fraud and abuse, and we plan to address specific policies in future rulemaking to mitigate these risks. We thus solicited comment on whether there are quality or program integrity concerns regarding the use of virtual sessions, or whether they offer comparable or higher quality MDPP services when compared to in-person services. We solicited comment on strategies to strengthen program integrity and minimize the potential for fraud and abuse in virtual sessions.

The following is a summary of the comments we received regarding these proposals and our responses.

Comment: In response to our proposals for virtual MDPP services, we received many insightful and informative public comments suggesting matters related to furnishing virtual services, various modes of furnishing virtual services, how effective these services are, and that the standards that apply to in-person sessions may not be applicable to virtual sessions. Commenters were overwhelmingly supportive of the proposal to allow virtual providers to participate, particularly to ensure adequate access to the benefit in underserved areas. Only one commenter noted that in-person services should be prioritized over virtual services. Commenters provided specific suggestions on how to mitigate fraud and abuse and evaluate these services by using site of service codes on claims, and requiring technology based methods for weight loss reporting (for example, digital scales) versus self-reported methods.

Response: We appreciate the comments on the virtual furnishing of MDPP services. We noticed many differences between the way a virtual MDPP supplier and in-person supplier may operate, in addition to hybrid virtual and in-person programs. We do not have enough information to finalize this proposal at this time, but expect to continue gathering more information on the virtual delivery of DPP services. We appreciate the many insights and comments we received, particularly suggestions of strategies to maintain program integrity. We remain committed to including virtual providers and services in MDPP as soon as possible, but we intend to use future rulemaking to address detailed policies on virtual providers' eligibility to enroll, furnish and bill for MDPP services.

f. Information Technology (IT) Infrastructure and Capabilities

We proposed that in order to receive payment, MDPP suppliers would be required to submit claims to Medicare using standard claims forms and procedures. Claims would be submitted in batches that contain beneficiary Protected Health Information (PHI) and Personally Identifiable Information (PII), including the Health Insurance Claim Number (HICN). Most Medicare claims are submitted electronically except in limited situations. We provide a free software package called PC–ACE Pro32 that creates a patient database and allows organizations to electronically submit claims to Medicare Part A and B. We understand there are several other electronic claims submissions software packages available in the market for purchase. We encouraged current and prospective DPP organizations to investigate adopting these systems to enhance the efficiency of claims

[32] W Su et al., ''Return on Investment for Digital Behavioral Counseling in Patients With Prediabetes and Cardiovascular Disease,'' *Preventive Chronic Disease* 13, no. E13 (2016).

[33] J Ma et al., ''Translating the Diabetes Prevention Program Lifestyle Intervention for Weight Loss into Primary Care: a Randomized Trial,'' *JAMA Internal Medicine* 173, no. 2 (2013): 113–121.

[34] CS Sepah et al., ''Translating the Diabetes Prevention Program into an Online Social Network: Validation Against CDC Standards,'' *The Diabetes Educator* 40, no. 4 (2014): 435–443.

[35] Y Fukuoka et al., ''A Novel Diabetes Prevention Intervention Using a Mobile App: A Randomized Controlled Trial with Overweight Adults at Risk,'' *American Journal of Preventive Medicine* [serial online] 49, no. 2 (2015): 223–237.

submission, and we sought comment on the capacity of DPP organizations to integrate these systems into their workflows. We indicated that we would provide guidance to MDPP suppliers regarding the Medicare claims submission standards.

We proposed to require MDPP suppliers to maintain a crosswalk between the beneficiary identifiers they submit to CMS for billing purposes and the beneficiary identifiers they provide CDC for beneficiary level-clinical data. We proposed that MDPP suppliers provide this crosswalk to the CMS evaluator on a regular basis.

We proposed that MDPP suppliers maintain records that contain detailed documentation of the services furnished to beneficiaries, including but not limited to the beneficiary's eligibility status, sessions attended, the coach furnishing the session attended, the date and place of service of sessions attended, and weight. We proposed that MDPP suppliers maintain these records within a larger medical record, or within a medical record that an MDPP supplier establishes for the purposes of administering MDPP. Consistent with the requirement in § 424.516(f) we proposed that these records be retained for 7 years from the date of service and that MDPP suppliers would provide CMS or a Medicare contractor access to these records upon request. We proposed to require MDPP suppliers to accurately track payments and resolve any discrepancies between claims and the beneficiary record within their medical record. We also proposed that MDPP suppliers would be required to maintain and handle any beneficiary PII and PHI in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), other applicable privacy laws, and CMS standards. We indicated that we would provide education and guidance to MDPP suppliers to mitigate the risk of data discrepancies and audits. We stated that we would address specific recordkeeping requirements and standards in future rulemaking as appropriate.

The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended CMS clarify what the medical record should include, whether the medical record should be paper or electronic, and whether suppliers should retain records of any referrals and diagnostic tests demonstrating beneficiary eligibility or simply document that one was presented at the time of enrollment. Commenters requested guidance on whether the medical record would require proof of lab work or if documentation of the values would suffice. One commenter noted that while beneficiaries' data should be held in an EHR, suppliers should be able to transfer this information in electronic, paper, or fax format to beneficiaries' other providers. Though commenters generally agreed with the recordkeeping requirements, including the duration of recordkeeping, many of these same commenters and others noted the burden that recordkeeping requirements might impose on community-based organizations. These commenters urged us to consider the implications that a high cost, HIPAA-compliant recordkeeping system might impose on such organizations, as well as the subsequent strain it would place on beneficiary access should the requirement be cost prohibitive. Additionally, a number of commenters urged that when making IT-related policy decisions, that we consider the lack of internet and issues with electricity in rural and tribal areas.

These commenters suggested clarifying the medical record requirement in such a way that would be economically feasible for community-based programs. Due to these concerns, a number of commenters suggested that we work with CDC or other entities to identify a low cost data and billing system. Other commenters went further to suggest that CMS work with CDC to streamline the two data reporting systems such that when coaches or suppliers input performance data on beneficiary sessions to CDC, the Medicare claim would automatically be generated. Others appreciated the reliance on existing claim forms and software and applauded CMS for not creating a new data submission system. A few commenters noted that given the cost burdens of adequate IT, data, and recordkeeping systems, many community-based programs are likely to use third party integrators. These commenters did not advocate for a specific role for these integrators. One commenter, however, requested that MDPP suppliers be permitted to partner with and use the IT system of a healthcare entity to maintain records and submit claims for Medicare payment. Lastly, one commenter suggested that MDPP suppliers be required to take HIPAA-compliant training due to concerns about non-medical professionals housing HIPAA-compliant information.

Response: We wish to clarify that for purposes of MDPP, the medical record would need to contain information related to the MDPP services furnished to the beneficiary, in compliance with HIPAA and other applicable privacy laws, and CMS standards, such as documentation of the beneficiary's eligibility, including blood test results, sessions attended, the coach furnishing the session(s) attended, the date and location of service(s), and weight. We understand various forms of documentation exist depending on the type of blood test administered, and we will provide additional details on what specific records are required to demonstrate eligibility in future guidance and/or future rulemaking as appropriate. In response to commenters' questions on the format of these records, we encourage the use of electronic records, but do not require it for purposes of this expanded model. Further details on specific information that would qualify as auditable documentation of the supplier's record will be provided in guidance and/or future rulemaking as appropriate. Although we require entities to maintain these records for the purposes of auditing, medical reviews, or other CMS requests, we do not intend to require that suppliers submit additional data, outside what is on the claim, to CMS for the purpose of payment.

Although we understand it might be easier for suppliers to submit claims and performance data to one joint CMS–CDC data system, we believe that maintaining MDPP claims independent from CDC performance data would allow us to compare information submitted to CMS with those submitted to CDC to identify inconsistencies, as supported by certain commenters. Additionally, it is important to note that while all MDPP suppliers will be organizations that have CDC recognition, it is likely that not all organizations with CDC recognition will enroll in Medicare. Similarly, not all participants in the National DPP are Medicare beneficiaries. Thus, Medicare claims information will not be relevant to CDC's assessment of performance data. For the aforementioned reasons, we do not agree with commenters that a joint CDC–CMS data system would be appropriate. We appreciate that these recordkeeping requirements can impose burdens on MDPP suppliers, particularly those who have not previously had to comply with these types of recordkeeping requirements. While MDPP suppliers are responsible for complying with these requirements, MDPP suppliers can decide which resources to utilize in order to do so, including the use of a third party administrator or other entity.

Comment: Several commenters noted the current proposed requirements for recordkeeping do not apply to the nature of sessions furnished virtually. One commenter proposed alternative record keeping requirements that were consistent with the proposal, but would allow flexibility for suppliers who furnish MDPP services through virtual technologies.

Response: We are deferring all decisions regarding virtual providers to future rulemaking as discussed in section III.J.7.e. of this final rule.

Comment: Numerous commenters agreed with the proposal that MDPP suppliers maintain a crosswalk between beneficiary identifiers submitted to CMS for billing and beneficiary identifiers submitted to CDC for beneficiary-level clinical data. A few commenters disagreed, stating CMS and CDC should not impose this requirement on suppliers and should instead coordinate directly to alleviate further reporting requirements for MDPP suppliers. Regarding monitoring and program integrity comments, we received general support for this approach to compare CMS claims with CDC performance data. Several commenters requested further clarity on the crosswalk, its format, whether or not CMS would provide a template, the frequency with which suppliers would be required to submit the same data to CMS, and the need for the crosswalk to CDC data given that CMS is requiring all suppliers to retain records for auditing purposes, medical reviews, or other requests.

Response: We understand the desire to avoid undue burdens on MDPP suppliers. We intend for the crosswalk to alleviate the redundancy for suppliers submitting performance data to CMS that is already being sent to CDC. Since MDPP is an expanded model test, we are required to evaluate the effectiveness of the MDPP expansion, and this crosswalk will facilitate this evaluation. While we understand the recommendation to create the crosswalk directly with CDC, the CDC does not receive any personal identifying information (PII) on beneficiaries who participate in the National DPP that would enable CMS and CDC to directly create the beneficiary crosswalk. While we are requiring organizations to retain records for CMS-directed audits, a crosswalk between CMS and CDC data will enable CMS to conduct an evaluation on the effectiveness of MDPP, as well as provide any necessary documents during an audit, medical review, or other CMS request. The crosswalk therefore has a role both with program integrity purposes as well as for evaluating the expanded model's effectiveness, as required of any Innovation Center model. We intend to provide guidance to suppliers on how to set up the crosswalk, and make any further adjustments or clarifications (for example, frequency of submissions) in future rulemaking, as appropriate.

Final Decision: We are finalizing as proposed the documentation retention requirements and requirements for suppliers to provide documents in the case of an audit, medical review, or other CMS request. The final policies are set forth in § 424.59.

8. Policies for Future Rulemaking

a. MDPP Reimbursement Structure

We proposed to reimburse for MDPP services at the times and in the amounts set forth in the Table 41, with payment tied to the number of sessions attended and achievement of a minimum weight loss of 5 percent of baseline weight (body weight recorded during the beneficiary's first core session).

TABLE 41—MDPP EXPANSION PAYMENT MODEL

	Payment per beneficiary (non-cumulative)
Core Sessions	
1 Session attended	$25
4 Sessions attended	$50
9 Sessions attended	$100
Achievement of minimum weight loss of 5% from baseline weight	$160
Achievement of advanced weight loss of 9% from baseline weight	$25 (in addition to $160 above)
Maximum Total for Core Sessions	$360
Core Maintenance Sessions (Maximum of 6 monthly sessions over 6 months in Year 1)	
3 Core Maintenance Sessions attended (with maintenance of minimum required weight loss from baseline)	$45
6 Core Maintenance Sessions attended (with maintenance of minimum required weight loss from baseline)	$45
Maximum Total for Maintenance Sessions	$90
Maximum Total for First Year	$450
Ongoing Maintenance Sessions After Year 1 (Minimum of 3 sessions attended per quarter/no maximum)	
3 Ongoing Maintenance Sessions attended plus maintenance of minimum required weight loss from baseline	$45
6 Ongoing Maintenance Sessions attended plus maintenance of minimum required weight loss from baseline	$45
9 Ongoing Maintenance Sessions attended plus maintenance of minimum required weight loss from baseline	$45
12 Ongoing Maintenance Sessions attended plus maintenance of minimum required weight loss from baseline	$45
Maximum Total After First Year	$180

As proposed, Table 41 illustrates that payments would be heavily weighted toward achievement of weight loss over the 12-month core benefit, and no payments would be available after the first 6 months without achievement of

the minimum weight loss. In the payment structure we proposed, claims for payment would be submitted following the achievement of core session attendance, minimum weight loss, maintenance (both core and ongoing) session attendance, and maintenance of minimum weight loss. For example, MDPP suppliers would not be able to submit another claim after core session one until the beneficiary has completed four sessions, and maintenance sessions (both core and ongoing) would not qualify for payment unless minimum weight loss was achieved and maintained. Similar value-based payments are being offered by commercial insurers and accepted by DPP organizations. We sought comment on this payment structure. Additionally, we sought comment on whether to update payment rates annually through an existing fee schedule, such as the PFS, or establish a new fee schedule for MDPP suppliers.

We are deferring finalizing the proposed reimbursement structure to future rulemaking. In response to our solicitation, we received many comments. We intend to address these comments in future rulemaking.

b. Program Integrity

We recognize the potential for fraud and abuse by suppliers filing inaccurate claims and/or duplicative claims on the number of sessions attended or amount of weight loss achieved. We also recognize beneficiaries may move between MDPP suppliers, and we intend to address in future rulemaking as appropriate any requirements necessary to prevent duplication claims for MDPP services furnished by more than one MDPP supplier to the same beneficiary. We are also concerned about the potential for beneficiary inducement or coercion and the potential program risks posed by permitting a new type of organization to receive payment from Medicare for furnishing MDPP services. We also realize that there may be other risks to program integrity. We intend to develop policies to mitigate these risks and monitor the MDPP expansion, to ensure MDPP suppliers meet all applicable CMS program integrity and supplier enrollment standards, and will address them in future rulemaking, as necessary. We intend to develop system checks to identify when CMS may need to audit an MDPP supplier's records. We are considering ways to cross reference the data DPP organizations are currently required to report to the CDC to identify potential discrepancies with data submitted to CMS. We sought comment on such approaches. Finally, MDPP suppliers would be subject to audits and reviews performed by CMS program integrity and/or review or audit contractors in addition to program-specific audits. We sought comment on these approaches and others to mitigate these risks and strategies to ensure program integrity.

In response to our solicitation, we received many comments. We intend to address these comments in future rulemaking.

c. Learning Activities

The CDC provides technical assistance to DPP organizations with CDC DPRP recognition to improve performance. We solicited comment on what additional technical assistance would be needed for providers and other organizations in order to expand the MDPP model.

In response to our solicitation, we received many insightful and informative public comments and will consider the input when developing our strategy for ensuring that organizations seeking to enroll in Medicare and furnish and bill for MDPP services have the information and guidance they need to do so.

d. Quality Monitoring and Reporting

We solicited comment on the quality metrics that should be reported by MDPP suppliers in addition to the reporting elements required on Medicare claims submissions outlined above (attendance and weight loss) or by the CDC DPRP. We solicited comment specifically on what quality metrics should be considered for public reporting (not for payment) to guide beneficiary choice of MDPP suppliers.

In response to our solicitation, we received many comments. We intend to address these comments in future rulemaking.

K. Medicare Shared Savings Program

Under section 1899 of the Act, we established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in health care costs. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802) (November 2011 final rule)). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Shared Savings Program; Accountable Care Organizations Final Rule (80 FR 32692) (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) (June 2016 final rule)). As noted below, we have also made use of the annual PFS rules to address quality reporting and certain other issues.

Additionally, on April 27, 2016, the Department of Health and Human Services (HHS) issued a proposed rule to implement key provisions of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and establish a new Quality Payment Program (QPP) (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 28162) (QPP proposed rule)). On October 14, 2016, HHS issued a final rule to implement key provisions of the MACRA and establish a new QPP (QPP final rule with comment period). (The rule will appear in the November 4, 2016 **Federal Register**, and can be accessed at *https://qpp.cms.gov/education*.) The QPP final rule with comment period establishes a new program under which Medicare will reward physicians for providing high-quality care, instead of paying them only for the number of tests or procedures provided. The QPP final rule with comment period addresses issues related to APMs, such as Tracks 1, 2, and 3 of the Medicare Shared Savings Program, and issues related to reporting for purposes of MIPS by eligible clinicians (ECs) that are participating in APMs.

Our intent in the CY 2017 PFS proposed rule was to propose further refinements to the Shared Savings Program rules, and we identified several policies that we proposed to update or revise. First, we discussed and proposed policies related to ACO quality reporting including proposed changes to the quality measures used to assess ACO quality performance, changes in the methodology used in our quality

validation audits and the way in which the results of these audits may affect an ACO's sharing rate, various issues related to alignment with policies proposed in the QPP proposed rule, and revisions related to the terminology used in quality assessment such as ''quality performance standard'' and ''minimum attainment level.'' We also proposed conforming changes to our regulatory text. Next, we addressed several issues unrelated to quality reporting and assessment. Specifically, we proposed to implement a process by which beneficiaries may voluntarily align with an ACO by designating an ACO professional as responsible for their overall care. We also proposed to introduce beneficiary protections related to use of the SNF 3-day rule waiver. Finally, we proposed to make technical changes and updates to certain rules related to merged and acquired TINs and the minimum savings rate (MSR) and minimum loss rate (MLR) that would be used during financial reconciliation for ACOs that fall below 5,000 assigned beneficiaries.

1. ACO Quality Reporting

Section 1899(b)(3)(A) of the Act requires the Secretary to determine appropriate measures to assess the quality of care furnished by ACOs, such as measures of clinical processes and outcomes; patient, and, wherever practicable, caregiver experience of care; and utilization such as rates of hospital admission for ambulatory sensitive conditions. Section 1899(b)(3)(B) of the Act requires ACOs to submit data in a form and manner specified by the Secretary on measures that the Secretary determines necessary for ACOs to report to evaluate the quality of care furnished by ACOs. Section 1899(b)(3)(C) of the Act requires the Secretary to establish quality performance standards to assess the quality of care furnished by ACOs, and to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for the purposes of assessing the quality of care. Additionally, section 1899(b)(3)(D) of the Act gives the Secretary authority to incorporate reporting requirements and incentive payments related to the PQRS, EHR Incentive Program and other similar initiatives under section 1848 of the Act. Finally, section 1899(d)(1)(A) of the Act states that an ACO is eligible to receive payment for shared savings, if they are generated, only after meeting the quality performance standards established by the Secretary.

In the November 2011 final rule and recent CY PFS final rules with comment period (77 FR 69301 through 69304; 78 FR 74757 through 74764; 79 FR 67907 through 67931; and 80 FR 71263 through 712710), we have established the quality performance standard that ACOs must meet to be eligible to share in savings that are generated. Through these previous rulemakings, we have worked to improve the alignment of quality performance measures, submission methods, and incentives under the Shared Savings Program and PQRS.

In the CY 2017 PFS proposed rule, we proposed several changes and other revisions to our policies related to the quality measures and the quality performance standard, including the following:

- Changes to the measure set used in establishing the quality performance standard;
- Changes to the methodology used to validate quality data submitted by the ACO along with penalties that may apply if the audit match rate is less than 90 percent;
- Revisions to the use of the terms ''quality performance standard'' and ''minimum attainment level'' in the regulation text;
- Revisions related to use of flat percentages to establish quality benchmarks; and
- Alignment with policies proposed in the QPP proposed rule.

a. Changes to the Quality Measure Set Used in Establishing the Quality Performance Standard

(1) Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. In the November 2011 final rule, we established a quality performance standard consisting of 33 measures across four domains, including patient experience of care, care coordination/patient safety, preventive health, and at-risk population. In subsequent PFS final rules with comment period, we have made a number of updates to the set of measures that make up the quality performance standard. The quality measure set currently includes 34 quality measures.

Quality measures are submitted by the ACO through the CMS web interface, calculated by CMS from administrative and claims data, and collected via a patient experience of care survey based on the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) survey. The measures collected through the CMS web interface are also used to determine whether eligible professionals participating in an ACO avoid the PQRS and automatic Physician Value Modifier (VM) payment adjustments for 2015 and subsequent years. Currently, eligible professionals billing through the TIN of an ACO participant may avoid the downward PQRS payment adjustment when the ACO satisfactorily reports all of the ACO GPRO measures on their behalf using the CMS web interface. Beginning with the 2017 VM, ACO performance on the CMS web interface measures and all cause readmission measure will be used in calculating the quality component of the VM for groups and solo practitioners participating within an ACO (79 FR 67941 through 67947).

In the CY 2017 PFS proposed rule, we explained that our principal goal and rationale for selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels with a focus on outcomes and a preference for NQF-endorsed measures. We noted, however, that the statute does not limit us to using endorsed measures in the Shared Savings Program. As a result, we have also exercised our discretion to include certain measures that we believe to be high impact but that are not currently endorsed, including for example, ACO#11, which is currently titled Percent of PCPs Who Successfully Meet Meaningful Use Requirements.

Further, we described our continuing work with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date and reduce reporting burden. Importantly, we noted that the Core Quality Measures Collaborative was formed in 2014, as a collaboration between CMS, providers, and other stakeholders, with the goal of aligning quality measures for reporting across public and private stakeholders in order to reduce provider reporting burden. On February 16, 2016, the Core Quality Measures Collaborative recommended a core quality measure set that aligns and simplifies quality reporting across multiple payers (*https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-02-16.html*) and made specific recommendations for ACOs (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/ACO-and-PCMH-Primary-Care-Measures.pdf*). We proposed to

integrate several recommendations made by the Core Quality Measures Collaborative into the CMS web interface as part of the QPP proposed rule (81 FR 28399). These recommendations were subsequently adopted in full in the QPP final rule with comment period. Groups that are eligible to report using the CMS web interface for purposes of reporting quality measures to CMS for various quality reporting initiatives such as PQRS and the Shared Savings Program are required to report on all measures included in the CMS web interface. In addition, for purposes of the QPP, we proposed and finalized a policy requiring that groups using the CMS web interface must report on all measures in the CMS web interface.

(2) Proposals

In efforts to continue to align with other CMS initiatives and reduce provider confusion and the burden of reporting, we proposed modifications to the quality measure set that an ACO is required to report. Specifically, to align the Shared Savings Program quality measure set with the measures recommended by the Core Quality Measures Collaborative and proposed for reporting through the CMS web interface under the QPP proposed rule, we proposed to add, and in some cases to replace, existing quality measures with the following:

• *ACO–12 Medication Reconciliation Post-Discharge (NQF #0097).* This measure addresses adverse drug events (ADEs) through medication reconciliation, which is an important aspect of care coordination. According to HHS' Agency for Healthcare Research and Quality (AHRQ), ADEs account for nearly 700,000 emergency department visits and 100,000 hospitalizations each year.[36] The ACO–12 Medication Reconciliation measure was previously in the Shared Savings Program measure set, however, it was replaced with ACO–39, Documentation of Current Medications in the Medical Record (79 FR 67912 through 67914). The Core Quality Measures Collaborative, in coordination with providers and stakeholders, determined the original Medication Reconciliation measure would be more appropriate for alignment across quality reporting initiatives. Based on this recommendation, we proposed to require reporting of the measure through the CMS web interface in the QPP proposed rule (81 FR 28403). In an effort to align with the QPP proposals, we therefore proposed to replace the Documentation of Current Medications in the Medical Record measure (ACO–39) by reintroducing Medication Reconciliation (ACO–12) in the Care Coordination/Patient Safety domain. We noted that in accordance with our policy for newly introduced measures, this measure would be pay for reporting for 2 years and proposed that it would phase into pay for performance in accordance with the schedule indicated in Table 36 of the proposed rule (81 FR 46421–46422).

• *ACO–44 Use of Imaging Studies for Low Back Pain (NQF #0052).* Imaging utilization is an important area for quality measurement, because of the wide use of imaging services. This measure reports the percentage of patients with a primary diagnosis of low back pain that did not have an imaging study (for example, MRI, CT scan) within 28 days of the diagnosis. (A higher score indicates higher performance). The Use of Imaging Studies for Low Back Pain quality measure is specified for patients 18–50 years of age. We proposed adding this measure in the Care Coordination/Patient Safety domain to address a gap in measures related to resource utilization and align with the ACO measures recommended by the Core Quality Measures Collaborative core measure set (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/ACO-and-PCMH-Primary-Care-Measures.pdf*). We noted that the measure was also proposed in the QPP proposed rule for measuring the quality of care furnished by individual and specialty ECs (81 FR 28399 and 28460 Tables A and E). In the QPP final rule with comment period, we adopted the low back pain measure for EHR reporting. Under the Shared Savings Program, we proposed that this measure would be calculated using Medicare claims data without any additional provider reporting requirement. We noted that in accordance with our policy for newly introduced measures, this measure would be designated as pay for reporting in 2017 and 2018. We proposed to phase it into pay for performance in accordance with the schedule indicated in Table 36 of the proposed rule (81 FR 46421–46422). However, given the possible small case sizes due to the measure specifications, we specifically solicited comment on whether this measure should be phased in to pay for performance or whether it should remain pay for reporting for all 3 performance years.

As we stated in the CY 2017 PFS proposed rule, by aligning the Shared Savings Program measures with the Core Quality Measures Collaborative recommendations and proposals under the QPP proposed rule, we hope to reduce the burden of provider data collection and reporting of measures that do not align across public and private quality reporting initiatives. Therefore, we proposed to retire or replace the following measures in order to reduce provider reporting burden by reducing the number of measures that must be reported and because these measures do not align with the core measure set recommendations from the Core Quality Measures Collaborative and the measures that we proposed for reporting through the CMS web interface in the QPP proposed rule:

• ACO–39 Documentation of Current Medications in the Medical Record.

• ACO–21 Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented.

• ACO–31 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).

• ACO–33 Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy—for patients with CAD and Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%).

In addition to our proposals above to modify the quality measure set to align with the Core Quality Measures Collaborative and the proposed modifications to the measures reported through the CMS web interface under the QPP proposed rule, we proposed a few additional modifications as follows:

First, we proposed to retire the two AHRQ Ambulatory Sensitive Conditions Admission measures (ACO–9 and ACO–10). Although ACO–9 and ACO–10 address admissions for patients with heart failure, chronic obstructive pulmonary disease (COPD), and asthma, we introduced two all-cause, unplanned admission measures for heart failure and multiple chronic conditions (ACO–37 and ACO–38, respectively) in the 2015 PFS final rule (79 FR 67911–67912). We believe ACO–37 and ACO–38 report on a similar population with similar conditions as ACO–9 and ACO–10. Therefore, in order to continue our efforts to reduce redundancies within the Shared Savings Program measure set, we proposed to remove ACO–9 and ACO–10 from the measure set.

Second, although we proposed to remove ACO–9 and ACO–10, we stated that we continue to believe AHRQ's Prevention Quality Indicator (PQI)

[36] "Medication Errors." AHRQ. *https://psnet.ahrq.gov/primers/primer/23/medication-errors.*

measures are important because they report on inpatient hospital admissions of patients with clinical conditions (such as dehydration, bacterial pneumonia, and urinary tract infections) that could potentially be prevented with high-quality outpatient care. We therefore proposed adding *ACO–43 Ambulatory Sensitive Condition Acute Composite (AHRQ PQI #91)* to the Care Coordination/Patient Safety domain. We noted that this measure is a composite measure, currently used in the Physician Value-Based Payment Modifier, which includes PQIs reporting on admissions related to dehydration, bacterial pneumonia, and urinary tract infections (PQIs #10, 11, and 12). We noted the measure would be risk-adjusted for demographic variables and comorbidities. In accordance with our policy for newly introduced measures, we proposed that this measure would be pay for reporting for 2 years, and then phase into pay for performance in accordance with the schedule indicated in Table 36 of the proposed rule (81 FR 46421–46422).

Comment: Commenters were generally supportive of the proposed changes to the Shared Savings Program quality measure set. Most commenters supported alignment of quality measures with Core Quality Measures Collaborative recommendations.

Response: We appreciate the support for proposed changes to the Shared Savings Program quality measure set and for aligning with the recommendations of the Core Quality Measures Collaborative.

The following is a summary of the comments we received on specific proposed changes to the quality measure set:

Comment: Regarding our proposal to reinstate use of ACO–12 Medication Reconciliation and remove ACO–39 Documentation of Current Medications in the Medical Record, one commenter suggested that using ACO–12 Medication Reconciliation would be a better means to improve population health. One commenter expressed concern over reintroducing ACO–12 since it counts a readmission within 30 days as a new index discharge for the measure and suggested using NQF #0554 Medication Reconciliation Post-Discharge instead.

Response: We appreciate the comments submitted on our proposal to reinstate ACO–12 Medication Reconciliation, including the comment suggesting the measure would be a better means to improve population health. While one commenter suggested using NQF #0554 Medication Reconciliation Post-Discharge, as NQF notes on its Web site, NQF #0554 measure is no longer endorsed, because the measure developer, NCQA, determined the measure is outdated and withdrew the measure from endorsement. Although readmissions could be counted as a new index discharge based on the measure specifications, it is important that providers coordinate care and engage in medication reconciliation following each hospital discharge, whether it be an initial admission or subsequent readmission. ACO–12 also maintains alignment with quality reporting under the QPP. Given that ACO–12 aligns with the QPP and is an NQF endorsed measure that is recommended by the Core Quality Measures Collaborative, we are finalizing our proposal to replace ACO–39 with ACO–12. In accordance with our policy for newly introduced measures, we are also finalizing our proposal that this measure will be pay for reporting for 2 years, and then phase into pay for performance in accordance with the schedule as proposed in Table 36 of the proposed rule (81 FR 46421–46422).

Comment: Several commenters specifically supported the removal of ACO–21 Screening for High Blood Pressure and Follow-up Documented, ACO–31 Beta-Blocker Therapy for LVSD, and ACO–33 ACE Inhibitor or ARB Therapy—for patients with CAD and Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%) in the interest of harmonization, even though the measures do include an important follow-up component. One commenter raised concerns about removing ACO–21 because it has a follow-up component they believe is particularly important for women with heart disease.

Response: We appreciate the commenter support we received for removing these measures. To the extent that commenters noted the importance of certain aspects of these measures, we acknowledge that these measures address important health issues. Many quality measures that are not part of the ACO quality measure set address various important health issues for patients. However, it is not feasible for us to include all measures that address important health issues in the quality measure set for the Shared Savings Program. Rather, we must choose measures based upon a consideration of the importance of the measures for the patient population served by ACOs, the reporting burden placed on ACOs and their participants, and the extent to which measures align with other quality reporting initiatives. Accordingly, we are finalizing our proposal to retire ACO–21, ACO–31, and ACO–33 in order to reduce provider reporting burden and align with the Core Quality Measures Collaborative recommended core set and the measures that will be reported for purposes of the QPP.

Comment: Most commenters agreed that ACO–44 Use of Imaging Studies for Low Back Pain is an important quality measure and supported addition of this measure. However, concerns were raised regarding the measure specifications. Some commenters were concerned about the narrow age range of this measure and potentially small case sizes that could result from the age range being limited to adults aged 18–50. These commenters made various suggestions for modification of our proposal such as using a broader age range or making the measure pay for reporting for all years. While some commenters appreciated that the use of claims data to calculate this measure would avoid unnecessary administrative burden on providers, one commenter was concerned about relying solely on claims data without incorporating clinical data from the medical record and suggested that the measure be pay for reporting until CMS has the capacity to incorporate robust clinical data. A few commenters opposed the addition of ACO–44, stating they believe it is inappropriate for a Medicare ACO's patient population, given the measure specification's limited age range. One commenter on ACO–44 asked whether plain film radiographs would be included as an imaging modality for the measure.

Response: We agree with commenters that support the proposal to include ACO–44 Use of Imaging Studies for Low Back Pain because it addresses a clinically important gap in quality measurement and aligns with the recommendations made by the Core Quality Measures Collaborative. We also agree with commenters' concerns regarding the narrow age range (18–50 years of age) under the measure specifications, which could result in small case sizes if limited to Medicare beneficiaries assigned to the ACO. With respect to the comment that raised a concern about relying solely on claims data to calculate the measure, we agree that additional clinical data could possibly enhance the measure. However, using additional clinical data would require additional reporting by the ACO. At this time, we do not believe it is appropriate to impose this additional reporting burden, and therefore, we will not be adopting the commenter's suggestion. In response to the commenter that asked whether plain film radiographs would be included in the measure specifications, we note that

the current NQF endorsed measure specifies the use of plain x-ray, MRI, and CT scan. Although we are finalizing our proposal to add this measure to the quality measure set, in light of the concerns raised regarding the age range and potential for small case sizes, we are modifying the proposed timeline for transitioning the measure to pay for performance. In accordance with our policy for newly introduced measures, this measure will be pay for reporting for 2 years. However, rather than phasing in the measure as pay for performance, we are finalizing a policy under which the measure will remain as pay for reporting for all the 3 performance years of an ACO's agreement period.

Comment: Some commenters supported the proposal to retire ACO–9 because patients with COPD are already assessed under ACO–38 All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions (MCC). In addition, commenters supported CMS' proposal to retire ACO–10, because the quality measure set already includes an all-cause admission measure for patients with Heart Failure (ACO–37). Some commenters urged CMS to retain ACO–9 or consider other COPD-related measures for future reporting due to the prevalence of mortality-related COPD. A commenter suggested that the Core Quality Measures Collaborative consider COPD-related measures to include in their core measure set recommendations.

Response: We appreciate the comments supporting our proposal to retire ACO–9 and ACO–10. We agree that COPD and heart failure affect a large volume of beneficiaries and are clinically important areas for quality measurement. However, we note that COPD and heart failure are among the chronic conditions addressed by the specifications for ACO–38 and ACO–37, respectively. Therefore the patient populations for the measures are similar, and we agree with commenters who noted that the measures are redundant. As a result, we are finalizing our proposal to remove ACO–9 and ACO–10 from the ACO quality measure set. We also appreciate the additional COPD measure recommendations and will consider them for future reporting.

Comment: Most commenters supported the proposal to add ACO–43 Ambulatory Sensitive Condition Acute Composite to the measure set. Commenters also appreciated our proposal that the measure would be initially introduced as pay for reporting because it was not included in the Core Quality Measure Collaborative measure set recommendations. One commenter suggested quarterly feedback support for this measure and other commenters suggested this measure be pay for reporting for all performance years in an ACO's agreement period so ACOs can become more familiar with the measure for their own operations. Some commenters raised concerns with the use of the measure at the ACO-level when AHRQ developed the measure at the population level.

Response: We appreciate commenters' support for our proposal to add ACO–43 to the ACO quality measure set. We are finalizing its addition to the ACO quality measure set because it addresses important clinical conditions that could potentially be prevented with coordinated, high-quality outpatient care. Although some commenters suggested maintaining the measure as pay for reporting all 3 years of an ACO's agreement period, we believe ACOs will have sufficient opportunity to become familiar with the measure because, in accordance with the timeline for introducing new measures under § 425.502(a)(4), it will be pay for reporting for 2 years before transitioning to pay for performance under the phase-in schedule indicated in Table 36 of the proposed rule (81 FR 46421–46422). At this time, we do not anticipate providing quarterly quality measure updates, because we only calculate the measure annually; however, we will continue to consider whether it would be feasible to do so. Further, we believe it is appropriate to use this measure at the ACO-level to assess ACO performance. ACOs are required to improve the quality and cost of the care of the fee-for-service patient population assigned to them. In order to be eligible for participation in the Shared Savings Program, the ACO must have at least 5,000 assigned beneficiaries. We therefore believe an ACO's patient population is sufficiently large enough that it is appropriate to apply this measure at the ACO-level. Additionally, ACO–43 is used in and aligns with other CMS quality initiatives; it is currently reported for purposes of the Physician Value-Modifier and has been used for assessing physician performance and was finalized as an informational measure under the QPP final rule with comment period. We have an overarching belief in the importance of collecting information regarding the prevalence of preventable conditions and readmissions and providing this information to clinicians to assist them in developing targeted care improvement processes. To support this goal and to align with other CMS quality initiatives, we believe it is appropriate to include ACO #43 in the ACO quality measure set.

Comment: We received several additional comments regarding the quality measure set that were not directly related to our proposals. A few commenters suggested CMS risk adjust the claims-based quality measures to account for socioeconomic factors. Several commenters stated their support for retaining the Influenza and Pneumonia vaccination measures (ACO–14 and ACO–15). We also received quality measure suggestions for future consideration, such as additional immunization and transitions of care measures.

Response: We appreciate the support for measures that are currently included in the quality measure set. We also thank commenters for their other recommendations regarding quality reporting under the Shared Savings Program. We will keep these suggestions and comments in mind for future consideration.

Final Action: We appreciate the thoughtful comments submitted in response to our proposed changes to the quality measure set. We are finalizing the measure set changes (deletions, additions, and replacement) as proposed for the reasons noted in our responses above and to align with the Core Quality Measures Collaborative and the measures that were finalized in the QPP final rule with comment period. We note that in light of comments received on ACO–44 Use of Imaging Studies for Low Back Pain and its potential for low case sizes, we will add this measure as proposed but will retain it as pay for reporting in all 3 years of the ACO's agreement period. All other measures will be phased in as proposed.

Table 42 lists the Shared Savings Program quality measure set that will be used to assess quality performance starting with the 2017 performance year including the new measures adopted in this final rule. Each measure that is indicated as a new measure will be assessed as a pay for reporting measure for the 2017 and 2018 performance years. After that, the measure will be assessed based on the phase-in schedule noted in Table 42.

As a result of these proposed measure changes, the four domains will include the following number of quality measures (See Table 43 for details.):

- Patient/Caregiver Experience of Care–8 measures
- Care Coordination/Patient Safety–10 measures
- Preventive Health–8 measures

• At Risk Population–5 measures (3 individual measures and a 2-component diabetes composite measure)

Table 43 provides a summary of the number of measures by domain and the total points and domain weights that will be used for scoring purposes under the changes to the quality measure set adopted in this final rule.

TABLE 42—MEASURES FOR USE IN THE ESTABLISHING QUALITY PERFORMANCE STANDARD THAT ACOS MUST MEET FOR SHARED SAVINGS STARTING WITH THE 2017 PERFORMANCE YEAR

Domain	ACO measure #	Measure title	New measure	NQF #/measure steward	Method of data submission	Pay for performance phase in R—reporting P—performance		
						PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience ..	ACO–1	CAHPS: Getting Timely Care, Appointments, and Information.	.....	NQF #0005 AHRQ.	Survey	R	P	P
	ACO–2	CAHPS: How Well Your Providers Communicate.[37]	.....	NQF #0005 AHRQ.	Survey	R	P	P
	ACO–3	CAHPS: Patients' Rating of Provider.[2]	.....	NQF #0005 AHRQ.	Survey	R	P	P
	ACO–4	CAHPS: Access to Specialists	.....	NQF #N/A CMS/AHRQ.	Survey	R	P	P
	ACO–5	CAHPS: Health Promotion and Education.	.....	NQF #N/A CMS/AHRQ.	Survey	R	P	P
	ACO–6	CAHPS: Shared Decision Making.	.....	NQF #N/A CMS/AHRQ.	Survey	R	P	P
	ACO–7	CAHPS: Health Status/Functional Status.	.....	NQF #N/A CMS/AHRQ.	Survey	R	R	R
	ACO–34	CAHPS: Stewardship of Patient Resources.	.....	NQF #N/A CMS/AHRQ.	Survey	R	P	P
Care Coordination/P Patient Safety.	ACO–8	Risk-Standardized, All Condition Readmission.	.....	Adapted NQF #1789 CMS.	Claims	R	R	P
	ACO–35	Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM).	.....	Adapted NQF #2510 CMS.	Claims	R	R	P
	ACO–36	All-Cause Unplanned Admissions for Patients with Diabetes.	.....	NQF#TBD CMS.	Claims	R	R	P
	ACO–37	All-Cause Unplanned Admissions for Patients with Heart Failure.	.....	NQF#TBD CMS.	Claims	R	R	P
	ACO–38	All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions.	.....	NQF#TBD CMS.	Claims	R	R	P
	ACO–43	Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91).	X	AHRQ	Claims	R	P	P
	ACO–11	Use of certified EHR technology.	X	NQF #N/A CMS.	As finalized under the QPP.	R	P	P
	ACO–12	Medication Reconciliation Post-Discharge.	X	NQF #0097 CMS.	CMS Web Interface.	R	P	P
	ACO–13	Falls: Screening for Future Fall Risk.	.....	NQF #0101 NCQA.	CMS Web Interface.	R	P	P
	ACO–44	Use of Imaging Studies for Low Back Pain.	X	NQF #0052 NCQA.	Claims	R	R	R
AIM: Better Health for Populations								
Preventive Health	ACO–14	Preventive Care and Screening: Influenza Immunization.	.....	NQF #0041 AMA–PCPI.	CMS Web Interface.	R	P	P
	ACO–15	Pneumonia Vaccination Status for Older Adults.	.....	NQF #0043 NCQA.	CMS Web Interface.	R	P	P
	ACO–16	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up.	.....	NQF #0421 CMS.	CMS Web Interface.	R	P	P
	ACO–17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.	.....	NQF #0028 AMA–PCPI.	CMS Web Interface.	R	P	P
	ACO–18	Preventive Care and Screening: Screening for Clinical Depression and Follow-up Plan.	.....	NQF #0418 CMS.	CMS Web Interface.	R	P	P
	ACO–19	Colorectal Cancer Screening ...	.....	NQF #0034 NCQA.	CMS Web Interface.	R	R	P
	ACO–20	Breast Cancer Screening	.....	NQF #2372 NCQA.	CMS Web Interface.	R	R	P
	ACO–42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.	.....	NQF #N/A CMS.	CMS Web Interface.	R	R	R

TABLE 42—MEASURES FOR USE IN THE ESTABLISHING QUALITY PERFORMANCE STANDARD THAT ACOS MUST MEET FOR SHARED SAVINGS STARTING WITH THE 2017 PERFORMANCE YEAR—Continued

Domain	ACO measure #	Measure title	New measure	NQF #/measure steward	Method of data submission	Pay for performance phase in R—reporting P—performance		
						PY1	PY2	PY3
Clinical Care for At Risk Population—Depression.	ACO–40	Depression Remission at Twelve Months.		NQF #0710 MNCM.	CMS Web Interface.	R	R	R
Clinical Care for At Risk Population—Diabetes.	ACO–27	Diabetes Composite (All or Nothing Scoring): ACO–27: Diabetes Mellitus: Hemoglobin A1c Poor Control.		NQF #0059 NCQA (individual component).	CMS Web Interface.	R	P	P
	ACO–41	ACO–41: Diabetes: Eye Exam		NQF #0055 NCQA (individual component).	CMS Web Interface.	R	P	P
Clinical Care for At Risk Population—Hypertension.	ACO–28	Hypertension (HTN): Controlling High Blood Pressure.		NQF #0018 NCQA.	CMS Web Interface.	R	P	P
Clinical Care for At Risk Population—Ischemic Vascular Disease.	ACO–30	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.		NQF #0068 NCQA.	CMS Web Interface.	R	P	P

TABLE 43—NUMBER OF MEASURES AND TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD STARTING WITH THE 2017 PERFORMANCE YEAR

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (percent)
Patient/Caregiver Experience	8	8 individual survey module measures	16	25
Care Coordination/Patient Safety	10	10 measures, including double-weighted EHR measure.	22	25
Preventive Health	8	8 measures	16	25
At-Risk Population	5	3 individual measures, plus a 2-component diabetes composite measure that is scored as one measure.	8	25
Total in all Domains	31	30	62	100

b. Improving 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 data ACOs enter into the Web Interface (76 FR 67893 through 67894). 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). In this audit process, CMS selects a subset of Web Interface measures, and selects a random sample of 30 confirmed and completely reported beneficiaries for each measure in the subset. The ACO provides medical records to support the data reported in the Web Interface for those beneficiaries. A measure-specific audit performance rate is then calculated using a multi-phased audit process:

- *Phase 1:* Eight randomly selected medical records for each audited measure are reviewed to determine if the medical record documentation supports what was reported (that is, a match). If all records reviewed support what was reported, the audit ends. If any records do not support what was reported (that is, a mismatch), the audit process continues in a second phase for any measure with a mismatch identified.
- *Phase 2:* The remaining 22 medical records are reviewed for any measure that had a mismatch identified in Phase 1. If less than 90 percent of the medical records provided for a measure support what was reported, the audit process continues to Phase 3.
- *Phase 3:* For each measure with a match rate less than 90 percent, CMS provides education to the ACO about how to correct reporting and the ACO is given an opportunity to resubmit the measure(s) in question.

If at the conclusion of the third phase there is a discrepancy greater than 10 percent between the quality data reported and the medical records provided during the audit, the ACO will not be given credit for meeting the quality target for any measure(s) for which the mismatch rate exists.

As we explained in the proposed rule, since publication of the initial program rules in 2011, we have gained experience in conducting audits and believe that certain modifications to our rules should be made in order to increase the statistical rigor of the audit methodology, streamline audit operations, and more closely align the Quality Measures Validation audit used in Shared Savings Program audits 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 proposed four improvements to our audit process that would address 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.

(2) Proposals

First, we proposed to increase the number of records audited per measure to achieve a high level of confidence that the true audit match rate is within

[37] The quality measure title has been updated to ''Providers'' and is not only referencing ''Doctors.''

5 percentage points of the calculated result. The November 2011 final rule indicated that CMS would review as few as 8 records (Phase 1 only) or as many as 30 records (Phase 1 and 2) per audited measure. With this phased methodology, the total number of records reviewed for each ACO varies (range of 40 to 150 records per audited ACO during the Performance Year 2014 audit). A sample size analysis found that the number of reviewed records needs to increase in order to provide the desired high level of confidence that the audited sample is representative of the ACO's quality reporting performance. We noted that the precise number of records requested for review would necessarily vary, depending on the desired confidence level, the number of measures audited, and the expected match rate. Therefore, we did not propose a specific number of records that would be requested for purposes of ACO quality validation audits in the future. However, based on an analysis using the poorest expected match rate, the highest degree of confidence and an estimated number of measures to be audited, we explained we did not anticipate more than 50 records would be requested per audited measure.

Second, we proposed to modify our regulations in order to conduct the quality validation audit in a single step rather than the current multi-phased process described at § 425.500(e)(2). We proposed to use a more streamlined approach in which all records selected for audit would be reviewed in a single step and some activities currently conducted in phase 3 would be removed from the audit process entirely while others would instead be addressed at the conclusion of the audit. During the proposed single step, we stated we would review all submitted medical records and calculate the match rate. We anticipated that the education we currently provide to ACOs and the opportunity for ACOs to explain the mismatches that occur in Phase 3 of the current process would continue, but would occur at the conclusion of the audit. We stated that under the proposal, there would not be an the opportunity for ACOs to correct and resubmit data for any measure with a >10 percent mismatch because we have learned through our experience with program operations that resubmission of CMS Web Interface measure data after the close of the CMS Web Interface is not feasible. Instead, we proposed that an ACO's quality score would be affected by an audit failure as described below, without requiring re-opening of the CMS Web Interface. We stated we believed that this single step process would allow us to maintain the desired level of confidence that the true audit match rate is within 5 percentage points of the calculated result and to complete the audit in a timely manner. Therefore, we proposed to remove the provision at § 425.500(e)(2) that requires 3 phases of medical record review. In so doing, we proposed to redesignate § 425.500(e)(3) as § 425.500(e)(2).

Third, we proposed to revise the redesignated provision at § 425.500(e)(2) in order to provide for an assessment of the ACO's overall audit match rate across all measures, instead of assessing the ACO's audit mismatch rate at the measure level. Specifically, we proposed to calculate an overall audit match rate which would be derived by dividing the total number of audited records that match the information reported in the Web Interface by the total number of records audited. This would be a change from the current audit performance calculation methodology, which calculates a measure specific mismatch rate. We stated that we believe making this change would be necessary to minimize the number of records that must be requested in order to achieve the desired level of statistical certainty as described in the first proposal discussed in this section. Our analysis suggests that we would have to request a much larger number of records (approximately 200 per measure) from the ACO during a quality validation audit of individual measures to achieve a 90 percent confidence interval for each measure. In addition, combining all records to calculate an overall audit match rate is less subject to variability based on the specific subset of measures chosen for audit each year and better aligns with the methodology used by other CMS quality program audits.

Fourth, we proposed to revise the redesignated provision at § 425.500(e)(2), to indicate that if an ACO fails the audit (that is, has an overall audit match rate of less than 90 percent), the ACO's overall quality score would be adjusted proportional to its audit performance. Currently, our regulation at § 425.500(e)(3) states that if, at the conclusion of the audit process there is a discrepancy greater than 10 percent between the quality data reported and the medical records provided, the ACO will not be given credit for meeting the quality target for any measures for which this mismatch rate exists. In light of our proposed modifications to the quality validation audit process above in which we proposed to assess and validate the ACO's performance overall rather than the ACO's performance on each measure, we explained that we believe a modification to this requirement would be necessary to reflect an overall adjustment. Therefore, we proposed to modify the provision at newly redesignated § 425.500(e)(2) to state that if an ACO fails the audit (that is, has an audit match rate of less than 90 percent), the ACO's overall quality score will be adjusted proportional to the ACO's audit performance. The audit-adjusted quality score would be calculated by multiplying the ACO's overall quality score by the ACO's 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 would be the quality score that is 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.

Finally, we proposed to add a new requirement at § 425.500(e)(3) that in addition to the adjustment to the ACO's overall quality score, any 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 CMS approval. In the CAP, the ACO may be required to explain the cause of its audit performance and how it plans to improve the accuracy of its quality reporting in the future. In addition, we explained that CMS maintains 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 invited comment on the proposed improvements to the process used to validate ACO quality data reporting.

The following is a summary of the comments we received regarding the proposed improvements to the process used to validate ACO quality data reporting.

Comment: Most commenters supported our proposals to improve and better streamline the process for validating the accuracy of data reported through the CMS web interface and to use audit results to adjust the ACO's overall quality performance score. Few commenters opposed the proposed changes to the audit because they like the current process that includes multiple phases of review and is focused on performance on specific measures. Some commenters raised general concerns regarding the administrative burden for ACOs and providers and suppliers who are selected for the audit and must submit records for review. A couple of

commenters recommended delaying implementation of the new process until a single web interface measures information document is available or to allow ACOs additional time to adjust to the proposed changes to the process for conducting the quality validation audits.

Response: We agree with commenters on the importance of validating the accuracy of data reported through the web interface. The accuracy of the reported data is important because it is used by us to conduct certain activities, such as determining shared savings and shared losses. The data is also made available to the public, and we understand that ACOs and ACO providers/suppliers may use it to make business decisions while beneficiaries may rely on it to determine whether to work care from practitioners participating in an ACO. We believe the proposed streamlined approach to quality validation audits will minimize administrative burden associated with the audit for both ACOs and CMS because it reduces the multiple phases of documentation submission contemplated under the existing process to a single phase of supporting documentation submission.

Additionally, we appreciate stakeholder input on our operational documents, such as the suggestion to create a single guidance document that addresses the specifications for and requirements of web interface measures reporting. Currently, educational materials about web interface measures are found in several documents. In response to earlier requests for the creation of a single document, we have been working closely with our colleagues who are responsible for the CMS web interface to develop educational documents that would streamline the information available to all web interface reporters, including ACOs. We intend to continue to work to improve these communications and materials to assist ACOs in their preparation for quality measures submission. However, we believe that information currently available to ACOs, in addition to the support we provide through our help desks, webinars, and other methods of communication as noted below, is sufficient to ensure ACOs' understanding of and compliance with quality measure submission requirements. We therefore will not delay implementation of the new streamlined audit process and will use it beginning in spring 2017 to validate data received from ACOs for the 2016 performance year.

Comment: Some commenters requested more information on the number of measures that would be selected for the audit or suggested that ACOs have an opportunity to correct and resubmit data during the audit process. Some commenters suggested CMS include an appeal process, because of the audit's potential impact on an ACO's overall quality score and on the calculation of shared savings. A few commenters pointed out there is a difference between ACOs selected for audit due to data anomalies and those that are selected randomly and that these groups should be treated differently. One commenter noted that innocent mistakes can be made by those uploading data to CMS systems and that rather than penalizing the ACO there should be an opportunity for the ACO to correct such mistakes. Additionally, while some commenters agreed with the 90 percent match rate, others recommended using a lower confidence interval.

Response: To streamline the process, we proposed to have a single process with a single audit step, regardless of the reason an ACO is selected for the audit. The proposals were intended to streamline the audit process, provide audit feedback to ACOs and validate the accuracy of quality data in a timely manner that, in turn, permits timely feedback and allows accurate information to be used in the reconciliation of the ACO's performance for the prior year. Incorporating an appeals process would severely delay ACO reconciliation, and therefore, we do not agree that such a process should be included. Additionally, we believe that establishing an appeals process would be inconsistent with the statutory preclusion on administrative and judicial review of the assessment of the quality of care furnished by the ACO under section 1899(g) of the Act. Nevertheless, we are sympathetic to comments noting that simple mistakes can be made when reporting quality that, if given the opportunity to be rectified, would not reflect poorly on the actual quality of the care delivered by the ACO. We note, however, that the CMS web interface provides a number of reports that ACOs can access and use to check their data entry in the CMS Web Interface to assist ACOs in monitoring the accuracy of the quality data they submit. These reports can help ACOs to identify and correct errors in their data submission during the timeframe the CMS Web Interface is open for quality data submission. Even so, we believe there may be instances following an audit when CMS may need to employ some discretion related to the adjustment of an ACO's overall quality score. For example, an ACO may have experienced an error when reporting measures electronically (for example, an error in mapping the extensible markup language (XML) specifications) that affects all beneficiaries reported on for a quality measure. In this instance, a mapping error could be out of the control of the ACO that, based on an audit, demonstrated that it had otherwise fulfilled our quality reporting requirements. In the absence of flexibility not to apply an adjustment to the ACO's overall quality score, such an ACO may be unfairly penalized. Therefore, we are modifying our proposed policy. Specifically, we are finalizing a policy under which CMS will adjust an ACO's overall performance score to reflect audit findings when the ACO has an audit mismatch rate of greater than 10 percent. However, we will retain discretion not to apply this adjustment to the ACO's score in certain unusual circumstances where it would be inappropriate to apply the adjustment. We note that we do not intend to employ this discretion to avoid adjusting an ACO's overall performance score in instances when the ACO cannot produce adequate validation of the data submitted or did not interpret the measure specifications correctly. For example, if we determine that the ACO has not produced medical record information sufficient to validate the data the ACO submitted to the web interface, we would not exercise our discretion not to apply the adjustment to the ACO's overall performance score based on results of the audit. We believe it is reasonable to: (1) Hold ACOs accountable for the accuracy of the data submitted according to information they validate from medical record reviews; and (2) require ACOs to produce proof of such accuracy in the event of an audit. Also, if we determine that the ACO did not interpret the measure specifications correctly, we would apply the adjustment to the ACO's overall performance based on audit results because ACOs are provided numerous opportunities to receive assistance from CMS before and during the quality measure submission process. For example, ACOs may access measure specification documents that are available on our Web site, contact the dedicated help desk, and attend webinars that we hold to educate ACOs about measure specifications and reporting requirements. Therefore, we believe that this modification of our proposal addresses stakeholder

concerns while permitting us to perform timely quality validation audits that hold ACOs accountable not only for the quality of the care they provide but also for the accuracy of their quality reporting.

Final Action: For the reasons discussed above, we are finalizing our proposed changes to the audit process with modification. Specifically, we are finalizing 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. We are modifying our regulations in order to reflect the new process of conducting the quality validation audit in a single step by removing the provision at § 425.500(e)(2) that requires 3 phases of medical record review. In so doing, we are redesignating § 425.500(e)(3) as § 425.500(e)(2). We are also revising the newly redesignated provision at § 425.500(e)(2) in order to provide for an assessment of the ACO's overall audit match rate across all measures, instead of assessing the ACO's audit mismatch rate at the measure level. For the reasons noted in our responses to comments above, we are modifying our proposed policy in order to give CMS discretion, in certain unusual circumstances, not to adjust the ACO's overall quality score when the ACO has an audit mismatch rate of greater than 10 percent. Specifically, we are revising the redesignated provision at § 425.500(e)(2), to indicate that if an ACO has an overall audit match rate of less than 90 percent, absent unusual circumstances, CMS will adjust the ACO's overall quality score proportional to its audit performance. Thus, CMS will retain discretion to avoid making the adjustment if circumstances warrant.

Finally, we are finalizing our proposal to add 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 CMS 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 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 will apply these policies to the quality validation audits beginning in 2017 with the quality validation audits of quality reporting for the 2016 performance year.

c. Technical Changes Related to Quality Reporting Requirements

In this section of the CY 2017 PFS proposed rule, we proposed several technical changes to the quality performance standard that an ACO must meet to be eligible to share in savings, as established in the November 2011 final rule. Part of the determination of whether an ACO has met the quality reporting standard in each year is dependent on the ACO meeting the minimum attainment level for certain measures. We discussed how the ''minimum attainment'' requirement has been implemented to date and proposed a modification that we believe is more consistent with our policies for assessing an ACO's performance over time. Finally, we proposed to move references to compliance actions from § 425.502(d)(2)(ii) to a more appropriate provision at § 425.316(c).

First, we proposed to make technical revisions to ensure stakeholder understanding of the definition of the quality performance standard. The quality performance standard is established under Subpart F for each performance year (§ 425.502(a)). For the first performance year of an ACO's first agreement period, the quality performance standard is defined as complete and accurate reporting of all quality measures. For each subsequent performance year, quality measures phase in to pay for performance, and although the ACO must continue to report all measures completely and accurately, the ACO will also be assessed on performance based on the quality performance benchmark and minimum attainment level of certain measures that are designated as pay for performance. The quality performance standard that applies to an ACO's final year in its first agreement period also applies to each year of an ACO's subsequent agreement period (§ 425.502(a)(3)) (79 FR 67925 through 67926). ACOs must meet or exceed the minimum quality performance standard in a given performance year to be eligible to receive payments for shared savings (§ 425.100(b)). Conversely, failure to meet the quality performance standard in a given performance year makes ACOs ineligible to share in savings, even if generated, and such ACOs may be subject to compliance actions.

In the proposed rule, we explained that our intent in the November 2011 final rule was to establish a single quality performance standard that would apply for each performance year in which an ACO participates in the program. Because the quality performance standard changes, depending on the performance year, the ACO may be subject to multiple quality performance standards over the course of its 3-year agreement period. We stated that we recognize that some of the language used in subsequent revisions to our regulations may have generated some confusion related to this issue. We clarified that while there are certain standards that must be met for each measure or in each domain, there is one overall quality performance standard that must be met in each performance year by an ACO. Therefore, we proposed to make conforming changes to the regulations text to remove references to the quality performance standard in contexts where it does not appear to apply to the overall quality performance standard (particularly §§ 425.316(c)(2), 425.502(a)(4), and 425.502(d)(1)). We proposed to retain certain references to multiple quality performance standards, such as the reference at § 425.100(b), because we believe the use of the plural is appropriate in certain contexts as the quality performance standard varies depending on the performance year in question.

Second, we addressed the concept of the minimum attainment level and its use in determining whether an ACO has met the quality performance standard. As noted above, beginning in the second year of an ACO's first agreement period, the quality performance standard is met by complete and accurate reporting on all measures, but also includes meeting the minimum attainment level on ''certain'' measures. As provided at § 425.502(b)(1), we designate a performance benchmark and minimum attainment level for each measure. Pursuant to § 425.502(b)(3), the minimum attainment level is set at 30 percent or the 30th percentile of the performance benchmark. In § 425.502(c)(1) through (c)(2), we state that 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 a measure will receive points on a sliding scale based on the level of performance. Finally, § 425.502(d) outlines quality performance requirements for the four domains, stating that the ACO must report all measures in a domain and must score above the minimum attainment level determined by CMS on 70 percent of the measures in each domain. If the ACO fails to achieve the minimum attainment level on at least 70 percent of the measures in a domain, CMS will take compliance action. Additionally, the ACO must achieve the

minimum attainment level for at least one measure in each of the four domains to be eligible to share in savings. In guidance, we have interpreted the quality performance requirements for domains to apply only to pay for performance measures because minimum attainment applies only to ''certain'' measures according to the definition of the quality performance standard in § 425.502(a)(3), and we have interpreted the reference to ''certain'' measures in § 425.502(a)(2) to mean pay for performance measures. In the proposed rule, we explained that, as a result of this interpretation, we believe an inconsistency in the application of the policy goals outlined in our November 2011 final rule has arisen. In particular, we believe certain current policies are inconsistent with our goal of holding ACOs to higher quality reporting standards over time. Specifically, because measures are phased-in from pay for reporting to pay for performance over the course of an ACO's first 3-year agreement period, there are no pay for performance measures during PY1 and fewer pay for performance measures in each domain in PY2 compared to PY3. Thus, under our current interpretation of the rules, it is not possible to take compliance actions against an ACO in its first performance year for failure to achieve the minimum attainment level on at least 70 percent of the measures in a domain because there are no pay for performance measures on which to assess performance on a domain. Additionally, because there are fewer pay for performance measures in PY2 than in PY3, and because of our policy of designating new measures as pay for reporting, it is more likely that a compliance action would be taken against an ACO due to failure to meet the minimum attainment level on 70 percent of the pay for performance measures in a domain in PY2 than in PY3. We explained that, as a result of this experience, we now believe it would be more consistent with our policy goals to take all measures into account when determining whether a compliance action should be taken against an ACO based on its quality performance in one or more domains.

Therefore, we proposed to take all measures into account when determining ACO performance at the domain level for purposes of compliance actions. Additionally, we stated that we believe compliance actions should be addressed at § 425.316 rather than in the quality reporting section, and therefore, we proposed to move the provisions governing the specific performance levels at which a compliance action would be triggered from § 425.502 to § 425.316.

The following is a summary of the comments we received regarding the proposed technical changes related to the quality performance standard and minimum attainment level.

Comment: We received few comments on the proposed technical changes. Most commenters generally supported these proposals. However, some commenters expressed concerns about including pay for reporting measures in our assessment of whether the ACO could meet the minimum attainment level on 70 percent of measures within a domain. For example, one commenter seemed to believe that we had proposed that an ACO must meet the 30th percent or percentile threshold for all measures, including pay for reporting measures. One commenter expressed concerns about whether an ACO would be able to meet the pay for performance minimum attainment level on newly introduced measures, and therefore, recommended not including pay for reporting measures in our assessment of whether an ACO has met the minimum attainment level on 70 percent of measures in a domain. Commenters also requested that these technical changes be disseminated to all ACOs.

Response: We thank commenters for their support of our proposed policies and wish to clarify several points for those who expressed concerns regarding the proposed changes. First, we emphasize that we proposed to continue to define the ''minimum attainment level'' for pay for performance measures at the level of the 30th percent or 30th percentile. We also wish to clarify that we proposed to define the ''minimum attainment level'' for pay for reporting measures at the level of complete and accurate reporting. In other words, the minimum requirement for attainment on a particular measure is different depending on whether the measure is designated as pay for reporting or pay for performance. Because newly introduced measures are pay for reporting for the first 2 years, the minimum attainment standard level for new measures would be pay for reporting. Second, including all measures in the domain (rather than including only the pay for performance measures) in our assessment of whether the ACO has met the minimum attainment level on 70 percent of the measures in the domain has an end result of insulating many ACOs that would otherwise be subject to a warning letter or CAP. Some domains have very few pay for performance measures and poor performance on just one of those measures increases the likelihood that the ACO will receive a warning letter or CAP. It was not our intent to subject an ACO to compliance action based on its poor performance on just one measure in a domain. Therefore, including pay for reporting measures in this assessment limits the issuance of warning letters and CAPs to only those ACOs that have grossly underperformed in a domain by failing to meet the minimum attainment level on at least 70 percent of the measures in a domain, including measures that are designated as pay for reporting. Therefore, we are finalizing this policy as proposed. We intend to include these changes in the ''Medicare Shared Savings Program Quality Measurement Methodology and Resources'' document posted on the Shared Savings Program Portal where it will be available to all ACOs.

Final Action: We are finalizing the technical changes related to the use of the term ''quality performance standard'' and the application of the ''minimum attainment level'' to determine whether an ACO has met the quality performance standard for a performance year as proposed for the reasons discussed above and in the proposed rule. Specifically, we are making the following modifications to our regulations:

- Revise introductory text at § 425.502(a) to clarify that the quality performance standard is the overall standard the ACO must meet to qualify to share in savings.
- Replace the word ''certain'' in § 425.502(a)(2) and (3) with ''all,'' so that the term ''minimum attainment level'' clearly applies to both pay for reporting and pay for performance measures.
- At § 425.502(a)(4), make modifications to remove the reference to the quality performance standard each time it appears to avoid causing confusion between the standards for individual measures and the overall quality performance standard.
- At § 425.502(b)(3), define ''minimum attainment level'' for both pay for reporting and pay for performance measures. We will set the minimum attainment level for pay for performance measures at the 30th percent or 30th percentile of the quality performance benchmark and for pay for reporting measures at the level of complete and accurate reporting.
- At § 425.502(c)(2), revise the regulation text to specify that only pay for performance measures are assessed on a sliding scale.
- At § 425.502(c)(5), add a provision to specify that pay for reporting measures earn the maximum number of

points for a measure when the minimum attainment level is met.

• Modify § 425.502(d) to refer generally to compliance actions that may be taken for failure to meet quality requirements, including low quality performance.

We are also modifying § 425.316(c)(1) and (c)(2) to address the specific levels of quality performance at which compliance action will be triggered and to reference the single quality performance standard that an ACO must meet in order to remain eligible to participate in the Shared Savings Program.

d. Technical Change to Application of Flat Percentages for Quality Benchmarks

As explained in greater detail in the CY 2017 PFS proposed rule, we previously finalized a methodology to spread clustered measures when setting quality benchmarks to promote a clinically meaningful assessment of ACO quality. Specifically, we finalized a policy that CMS would set quality benchmarks using flat percentages for a clustered measure when the national FFS data results in the 60th percentile for the measure are equal to or greater than 80.00 percent. We noted that the methodology would not apply to measures whose performance rates are calculated as ratios, for example, measures such as the two ACO Ambulatory Sensitive Conditions Admissions and the All Condition Readmission measures. We subsequently finalized a policy to address ''topped out'' measures by setting benchmarks using flat percentages when the 90th percentile is equal to or greater than 95 percent. Although similar to the ''cluster'' policy finalized earlier, we included measures whose performance rates are calculated as ratios. We believed this policy was appropriate because measures calculated and reported as ratios may become topped out and we wanted to treat all topped out measures consistently.

Since these policies were adopted, we have determined that converting measures calculated and reported as ratios into benchmarks expressed as percentiles and percentages creates confusion in the interpretation of quality results and may yield results that are contrary to the intended purpose of using flat percentages. As a result, we proposed to no longer apply the flat percentage policy to performance measures calculated as ratios. In addition, we proposed two technical changes to address typographical errors in § 425.502(a)(1), which contains a duplicative reference to CMS, and in § 425.502(b)(2)(ii), which contains an extra ''t'' at the end of ''percent.''

The following is a summary of the comments we received regarding the proposed technical change to the application of flat percentages for quality benchmarks.

Comment: We received three comments on this proposal. All were supportive of the proposed technical change. One commenter requested that CMS clarify which measures are calculated as percentages versus ratios.

Response: We thank the commenters for their support of this proposed technical change. When we release the quality measure benchmarks for the 2017 performance year as part of our operational documents and guidance, we will indicate which measures are calculated as ratios, and therefore, exempt from our policies with respect to the use of flat percentages.

Final Action: We are finalizing our proposed technical change to the use of flat percentages to set quality performance benchmarks. Specifically, we will no longer use flat percentages to set the quality performance benchmark for quality performance measures calculated as ratios. Such measures will be clearly identified in operational documents posted on our Web site. In addition, we are finalizing the two technical changes to address typographical errors in § 425.502(a)(1), which contains a duplicative reference to CMS, and in § 425.502(b)(2)(ii), which contains an extra ''t'' at the end of ''percent.''

e. Incorporation of Other Reporting Requirements Related to the PQRS

The Affordable Care Act gives the Secretary authority to incorporate reporting requirements and incentive payments from certain Medicare programs into the Shared Savings Program, and to use alternative criteria to determine if payments are warranted. Specifically, section 1899(b)(3)(D) of the Act affords the Secretary discretion to incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848 of the Act, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848, and permits the Secretary to use alternative criteria than would otherwise apply under section 1848 of the Act for determining whether to make such payments. Under this authority, in the November 2011 final rule establishing the Shared Savings Program, we incorporated certain reporting requirements and payment rules related to the PQRS into the Shared Savings Program at § 425.504 for ''eligible professionals'' (EPs) who bill under the TIN of an ACO participant within an ACO. Thus, the Shared Savings Program rules provide that EPs who bill under the TIN of an ACO participant within an ACO may only participate under their ACO participant TIN as a group practice under PQRS under the Shared Savings Program for purposes of qualifying for a PQRS incentive (prior to 2015) or avoiding the payment adjustment (starting in 2015). In other words, the current regulations prohibit ACO participant TINs and the EPs billing through those TINs from participating in PQRS outside of the Shared Savings Program such that these entities may not independently report for purposes of PQRS apart from the ACO.

An ACO, reporting on behalf of its EPs for purposes of PQRS, is required to satisfactorily submit through the CMS web interface all of the ACO GPRO measures that are part of the Shared Savings Program quality performance standard. Under § 425.504(c), for 2016 and subsequent years, if an ACO fails to satisfactorily report all of the ACO GPRO measures through the CMS web interface each EP who bills under the TIN of an ACO participant within the ACO will receive a downward adjustment, as described in § 414.90(e) for that year. In the 2017 PFS proposed rule, we noted that the current regulations do not provide any mechanism for these EPs to report separately or otherwise avoid the downward payment adjustment if the ACO fails to satisfactorily report on their behalf. We also summarized the reasons discussed in the November 2011 final rule for not allowing EPs who bill under the TIN of an ACO participant to report outside their ACO for purposes of PQRS.

Since publication of the November 2011 final rule, we have gained experience with these policies and program operations, and now believe there may be limited instances in which it would be appropriate to use data that is reported by these EPs outside their ACO for purposes of PQRS. Therefore, we proposed a change in policy in order to be able to accept and use data that is separately reported outside the ACO by EPs billing through the TIN of an ACO participant within an ACO for purposes of PQRS under limited circumstances for the final 2 years of PQRS before it sunsets and is replaced by the Quality Payment Program (QPP). We stated that we continue to believe that in most cases it is appropriate to assess EPs that

bill through the TIN of an ACO participant under the PQRS as a group practice because as noted in the November 2011 final rule, the Shared Savings Program is concerned with measuring the quality of care furnished to an assigned population of FFS beneficiaries by the ACO, as a whole, and not that of individual ACO providers/suppliers. We explained that we believe this framework promotes clinical integration among the ACO providers/suppliers, which is an important aspect of the Shared Savings Program. In addition, it is consistent with the requirement under § 425.108(d) that each ACO provider/supplier must demonstrate a meaningful commitment to the mission of the ACO to ensure its likely success. Because an ACO cannot be successful in the Shared Savings Program without satisfying the quality reporting requirements, we believe a meaningful commitment by ACO providers/suppliers to the mission of the ACO includes assisting with and engaging in annual quality reporting through the ACO. Further, ACO reporting reduces burden for those in small or solo practices, and places a focus on population health by encouraging care coordination by ACO providers/suppliers to improve the health of the broader patient population for which they are responsible. Finally, we believe that such group reporting is consistent with group reporting under various other CMS initiatives, and therefore, we stated that we did not intend to remove the requirement that ACOs report on behalf of the EPs who bill under the TIN of an ACO participant. As a corollary, we stated our intent to continue to use ACO data preferentially for purposes of assessing or determining an EP's quality performance for purposes of programs such as PQRS or, by extension, the VM.

However, we went on to explain in the proposed rule that we believe that when an ACO does not satisfactorily report for purposes of PQRS, it may be appropriate to accept and use data that is reported outside the ACO. In order to be able to accept and use data reported outside the ACO for purposes of PQRS, we noted that we must modify the provision at § 425.504 prohibiting EPs that bill under the TIN of an ACO participant in an ACO from reporting separately for purposes of PQRS. We therefore proposed to modify § 425.504 to lift the prohibition on separate reporting for purposes of the 2017 and 2018 PQRS payment adjustment. We explained that we believe this change to our program rules was necessary for several reasons.

First, we stated that we believe it is necessary to protect EPs that participate in ACOs that fail to satisfactorily report all of the ACO GPRO measures. Although 98 percent of ACOs successfully complete required quality reporting annually, there have been a few instances where an ACO has failed to report all of the required measures, for example, where an ACO has terminated its participation in the Shared Savings Program and did not quality report on behalf of the EPs that bill under the TIN of an ACO participant at the end of the performance year as required under our close-out procedures. In other instances, some ACOs continued to participate in the Shared Savings Program but failed to complete quality reporting in a timely manner. In these instances, the lack of complete quality reporting by the ACO translated into a failure for the EPs within the ACO to receive a PQRS incentive (or to avoid the PQRS downward adjustment) for that year.

Second, PQRS has transitioned away from providing incentive payments to applying only downward payment adjustments to payments under the Medicare Physician Fee Schedule, making it even more important for EPs to ensure they comply with the reporting requirements for PQRS. Under the current rules, EPs who bill under the TIN of an ACO participant within an ACO must ultimately rely on the ACO to report on their behalf. These EPs are only able to encourage and facilitate ACO reporting, but lack the ability to ensure that the ACO satisfactorily reports in order to prevent application of the payment adjustment. The proposed change to allow EPs to report separately would provide them a mechanism over which they have direct control to ensure satisfactory reporting occurs. Additionally, we noted that because there are no more payment incentives under the PQRS, there is no longer any concern that an EP may inadvertently receive duplicative PQRS incentive payments from CMS. We address the specific issues and policies related to the use of data reported by EPs apart from an ACO for purposes of avoiding the PQRS payment adjustment for payment years 2017 and 2018 in section III.H. of this final rule.

Third, under the VM, groups and solo practitioners that bill under the TIN of an ACO participant are evaluated under a quality tiering methodology and could qualify for an upward payment adjustment if the ACO satisfactorily reports on their behalf. However, if the ACO does not satisfactorily report quality data as required under § 425.504 then groups and solo practitioners that bill under the TIN of an ACO participant fall into Category 2 for the VM and are subject to a downward payment adjustment. Our proposed and final policies for how quality data reported by EPs billing under the TINs of ACO participants that is reported apart from the ACO will be used for purposes of avoiding the VM downward payment adjustment for 2017 and 2018 are discussed in section III.L.3.b of this final rule.

For the reasons noted above, we stated that we believed it would be appropriate to retain the provisions under § 425.504 that require the ACO to report all of the ACO GPRO measures to satisfactorily report on behalf of the EPs who bill under the TIN of an ACO participant for purposes of the PQRS payment adjustment; however, we proposed to modify the provisions that prohibit EPs that bill under the TIN of an ACO participant from reporting apart from the ACO. Specifically, we proposed to add a redesignated and revised paragraph at § 425.504(d) to address the requirement that the ACO report on behalf of the eligible professionals who bill under the TIN of an ACO participant for purposes of the 2017 and 2018 PQRS payment adjustment. Under this revised provision the prohibition on separate quality reporting for purposes of the PQRS payment adjustment for 2017 and 2018 would be removed. We also proposed to make a technical change to § 425.504 to move existing § 425.504(d) to § 425.504(c)(5) because the intent of this provision was to parallel the language of § 425.504(b)(6) for purposes of the payment adjustment for 2016 and subsequent years. We reiterated our intent that data reported by an ACO would continue to be preferentially used for purposes of other CMS initiatives that rely on such data, including the PQRS and the VM. If an EP who bills under the TIN of an ACO participant chooses to report apart from the ACO, the EP's data may be used for purposes of PQRS and VM only when complete ACO reported data is not available. Additionally, we noted that under the Shared Savings Program, only the quality data reported by the ACO as required under § 425.500 would be used to assess the ACO's performance under the Shared Savings Program. In other words, quality data submitted separately from the ACO would not be considered under the Shared Savings Program. We requested comments on this proposal.

The following is a summary of the comments we received regarding our proposed changes to the reporting requirements under the Shared Savings Program related to PQRS.

Comment: Commenters supported the proposal to allow EPs to report apart from the ACO to meet PQRS reporting requirements and to avoid the PQRS adjustment. Additionally, commenters supported maintaining this policy as CMS transitions to the Quality Payment Program (QPP). Several commenters raised issues related to PQRS proposals discussed in section III.H related to reporting requirements and timing, and suggested alternatives to allow EPs who bill under the TIN of an ACO participant to avoid the PQRS downward payment adjustment when their ACO fails to report. For example, several commenters were concerned about the effort and expense that would be incurred by EPs to report apart from their ACO without first knowing if the ACO had satisfactorily reported. A few commenters recommended that EPs be held harmless and not incur a downward payment adjustment under PQRS or the VM if their ACO failed to report.

Response: We appreciate commenters' support for our proposal to modify program rules to permit EPs to report quality apart from an ACO. Additional comments having to do with EP reporting for purposes of PQRS and the VM are addressed in sections III.H and III.L.3.b of this final rule, respectively. Comments related to timing and submission of quality data apart from the ACO for purposes of the QPP have been shared with the appropriate staff.

Final Action: We are finalizing our proposal to allow EPs that bill under the TIN of an ACO participant to report for purposes of PQRS apart from the ACO. For the reasons noted above, we are also finalizing our proposal to add a redesignated and revised paragraph at § 425.504(d) to address the requirement that the ACO report on behalf of the eligible professionals who bill under the TIN of an ACO participant for purposes of the 2017 and 2018 PQRS payment adjustment. We are also finalizing our proposal to make a technical change to § 425.504 to move existing § 425.504(d) to § 425.504(c)(5) because the intent of this provision was to parallel the language of § 425.504(b)(6) for purposes of the payment adjustment for 2016 and subsequent years. Details regarding the requirements for reporting quality data apart from the ACO and the use of such quality data for purposes of PQRS and the VM are addressed in sections III.H. and III.L.3.b. of this final rule, respectively. We reiterate, however, that these revisions to our regulations in order to allow quality data to be submitted apart from the ACO and for such quality data to be used under other programs (such as PQRS or the VM) does not alter or impact our assessment of an ACO's quality under the Shared Savings Program. Only quality data reported by the ACO as required under § 425.500 will be used to assess the ACO's performance under the Shared Savings Program.

f. Alignment With the Quality Payment Program (QPP)

1. Background and Introduction to the Quality Payment Program

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015), amended title XVIII of the Act to repeal the Medicare sustainable growth rate (SGR) and strengthen Medicare access by improving physician payments and making other improvements. The statute established the Merit-Based Incentive Payment System (MIPS), a new program for certain Medicare-participating practitioners. MIPS consolidates components of three existing programs, the PQRS, the Physician Value Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for EPs. The statute also established incentives for participation in certain alternative payment models (APMs). On April 27, 2016, the Department of Health and Human Services (HHS) issued a proposed rule to implement key provisions of the MACRA and establish a new Quality Payment Program (QPP) (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 28162 through 28586) (the QPP proposed rule)). On October 19, 2016, HHS issued the final rule with comment period establishing the Quality Payment Program (QPP final rule with comment period). (The rule will publish in the November 4, 2016 **Federal Register** and can be accessed at *https://qpp.cms.gov/education*.) The Quality Payment Program (QPP) replaces a patchwork system of Medicare reporting programs with a flexible system that allows practitioners to choose from two paths that link quality to payments: The Merit-Based Incentive Payment System (MIPS) and the APM incentive participation in Advanced Alternative Payment Models (APMs). MIPS and the APM incentive will impact practitioner payments beginning in payment year 2019 based on 2017 reporting. MIPS is a new program that combines parts of the Physician Quality Reporting System (PQRS), Value Modifier (VM) and Medicare Electronic Health Record (EHR) Incentive Program into a single program in which eligible clinicians (ECs) will be measured over 4 categories which include quality, resource use, clinical practice improvement, and advancing care information. The rulemaking implementing the QPP specifically addresses ECs that participate in APMs and Advanced APMs, such as the Shared Savings Program. Specifically, for ECs participating in APMs, the QPP final rule with comment period:

- Establishes criteria for reporting under each of the 4 categories. For example, the QPP final rule with comment period establishes a policy for the quality performance category to use quality information submitted by the ACO through the CMS Web interface to assess each EC billing under the TIN of an ACO participant. To assess performance in the category of advancing care information performance category for ECs billing under the TIN of an ACO participant, we will aggregate EC-reported data to calculate an ACO score which will be applied to each participating EC. Under the QPP final rule with comment period, this reporting by ECs will be accomplished by each ACO participant TIN reporting on the advancing care information as specified in § 414.1375(b). We note that under the QPP final rule with comment period, ECs for whom a sufficient percentage of payments for covered professional services, or a sufficient percentage of patients, are attributable to services furnished through an Advanced APM for a year will be qualifying APM participants (QPs) for the year. In addition to earning a 5 percent APM Incentive Payment, QPs are exempt from the MIPS reporting requirements and payment adjustment for the year.
- Defines an Advanced APM as one that meets several criteria including requiring participants to use certified EHR technology (CEHRT). Under the QPP final rule with comment period, only Tracks 2 and 3 of the Shared Savings Program have the potential to meet all criteria necessary for designation as an Advanced APM. In order for Tracks 2 and 3 of the Shared Savings Program to meet the CEHRT requirement for Advanced APMs, the Shared Savings Program must hold ACOs accountable for their participating eligible clinicians' use of CEHRT by applying a penalty or reward based on the degree of use of CEHRT (such as the percentage of EPs that are using CEHRT or the care coordination or other activities performed using CEHRT).

In the 2017 PFS proposed rule, we reviewed the Shared Savings Program

rules and identified several modifications to program rules that we believed needed to be made in order to support and align with the QPP. These modifications included the following:

- Revisions to §§ 425.504 and 425.506 to sunset Shared Savings Program alignment with PQRS and the EHR Incentive Program starting with quality reporting period 2017 (corresponding to payment year 2019).
- Addition of new paragraph § 425.506(e) and section § 425.508 to align with the proposed Quality Payment Program, including rules addressing annual assessment of the use of CEHRT by ECs participating in ACOs and for ACO reporting of certain quality measures to satisfy the quality performance category on behalf of the eligible clinicians who bill under the TIN of an ACO participant.
- Modifications to the EHR measure title and specifications necessary to align with the proposed QPP criteria for determining Advanced APM status, including scoring requirements for the limited circumstances when the measure is designated as pay for reporting.

2. Proposals Related to Sunsetting PQRS and EHR Incentive Program Alignment and Alignment With APM Reporting Requirements Under the Quality Payment Program

The Shared Savings Program has established rules at §§ 425.504 and 425.506 incorporating reporting requirements related to PQRS and the EHR Incentive Program. The current provision at § 425.504(c), addresses the PQRS payment adjustment for 2016 and subsequent years. Under current Shared Savings Program rules, EPs who bill under the TIN of an ACO participant within an ACO may only participate under their ACO participant TIN as a group practice under the PQRS Group Practice Reporting Option for purposes of the PQRS payment adjustment under the Shared Savings Program. ACOs must submit all of the ACO GPRO measures to satisfactorily report on behalf of their eligible professionals for purposes of the PQRS payment adjustment. If an ACO does not satisfactorily report, each EP participating in the ACO receives a payment adjustment under PQRS. As discussed in this final rule, we are finalizing a policy that will allow EPs who bill under the TIN of an ACO participant within an ACO to report separately from their ACO for purposes of the PQRS payment adjustment for 2017 and 2018.

At § 425.506, we address alignment with the EHR Incentive Program. Specifically, at § 425.506(a), we state that ACOs, ACO participants, and ACO providers/suppliers are encouraged to develop a robust EHR infrastructure, which aligns with our eligibility criteria under § 425.112 that require ACOs to define care coordination processes, which may include the use of enabling technologies such as CEHRT. At § 425.506(b) and (c) we state that the quality measure regarding EHR adoption is measured based on a sliding scale and that it is weighted twice that of any other measure for scoring purposes and determining compliance with quality performance requirements for domains. To align with the EHR incentive program we state in § 425.506(d), that EPs participating in an ACO under the Shared Savings Program satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when the EP extracts data necessary for the ACO to satisfy the quality reporting requirements under the Shared Savings Program from CEHRT and when the ACO reports the ACO GPRO measures through a CMS Web interface. EPs are responsible for meeting the rest of the EHR incentive program requirements apart from the ACO.

As noted above, the VM, PQRS and the EHR incentive programs are sunsetting and the last quality reporting period under these programs will be 2016, which will impact payments in 2018. Quality reporting under the QPP, as proposed and subsequently finalized, will begin in 2017 for payment year 2019. In order to align with the policies proposed in the QPP proposed rule (and that were subsequently finalized in the QPP final rule with comment period), we proposed to amend §§ 425.504 and 425.506 to indicate that these reporting requirements would apply to ACOs and their EPs through the 2016 performance year. Specifically, at § 425.504(c) we proposed to remove the phrase ''for 2016 and subsequent performance years'' each time it appears and add in its place the phrase ''for 2016.'' As discussed above, we proposed and are finalizing a technical change to redesignate paragraph (d) as paragraph (c)(5) and then to add new paragraph (d) to address the PQRS alignment rules for the 2017 and 2018 PQRS payment adjustment. Similarly, at § 425.506, we proposed to revise paragraph (d) to indicate that the last reporting year for the EHR Incentive Program is 2016.

In addition, in the CY 2017 PFS proposed rule, we proposed to require ACOs, on behalf of the ECs who bill under the TIN of an ACO participant, to report quality measures through the CMS Web interface in order to satisfy the QPP quality performance category. Currently, ACOs are required under § 425.504 to report certain quality measures on behalf of the EPs who bill under the TIN of an ACO participant for purposes of PQRS. Under the policy proposed in the QPP proposed and subsequently adopted in the QPP final rule with comment period, the quality data submitted to the CMS Web interface by ACOs will satisfy the quality performance category for ECs participating in the ACO. Therefore, in order to align with the QPP, we proposed to add a new paragraph at § 425.508(a) that parallels the current requirement at § 425.504 for reporting on behalf of EPs who bill under the TIN of an ACO participant for purposes of PQRS. Specifically, we proposed to require that ACOs, on behalf of ECs who bill under the TIN of an ACO participant, must submit all the ACO CMS Web interface measures required by the Shared Savings Program using a CMS Web interface, to meet reporting requirements for the quality performance category under MIPS. Because we proposed to maintain flexibility for EPs to report quality performance category data separately from the ACO for purposes of PQRS, we did not propose to include a provision that would restrict an EC from reporting outside the ACO for purposes of the QPP. While the intent of these proposals was to permit flexibility in reporting quality data, we reiterated that no quality data reported apart from the ACO would be considered for purposes of assessing the quality performance of the ACO under the Shared Savings Program.

The following is a summary of the comments we received regarding our proposals to sunset PQRS and EHR Incentive Program alignment and to align with the reporting requirements under the QPP.

Comment: Commenters were supportive of our efforts to align Shared Savings Program ACO quality reporting with the MIPS quality performance category. In addition, commenters supported the proposal to allow ECs to report outside of the ACO for purposes of the QPP, in the event that the ACO fails to satisfactorily report.

Response: We appreciate commenters' support for our proposals to align ACO quality reporting with the sunsetting of PQRS and the EHR Incentive Program and the new reporting requirements under the QPP.

Final Action: We are finalizing our proposal to sunset PQRS and EHR Incentive Program alignment and to align with the reporting requirements under the QPP. Specifically, we will amend §§ 425.504 and 425.506 to

indicate that the PQRS and EHR Incentive Program reporting requirements apply to ACOs and their EPs through the 2016 performance year.

To align with the reporting requirements under the QPP, we are finalizing our proposal to add a new provision at § 425.508 that parallels the current requirement at § 425.504 that ACOs report on behalf of EPs who bill under the TIN of an ACO participant for purposes of PQRS. Specifically, we are finalizing our proposal to require that ACOs, on behalf of ECs who bill under the TIN of an ACO participant, must submit all the CMS Web interface measures required by the Shared Savings Program using a CMS Web interface, to meet reporting requirements for the quality performance category under the QPP. As discussed elsewhere in this final rule, we are also finalizing a policy to maintain flexibility for EPs to report quality data separately from the ACO for purposes of PQRS and the VM, and therefore, are not including a provision that would restrict an EC from reporting outside the ACO for purposes of the QPP. While the intent of this policy is to permit flexibility in reporting quality data for purposes of the QPP, we reiterate that no quality data reported apart from the ACO will be considered for purposes of assessing the quality performance of the ACO under the Shared Savings Program.

3. Proposals Related to Alignment With the Quality Payment Program (QPP)

In the QPP proposed rule (81 FR 28296) and in the subsequent QPP final rule with comment period, we outlined and defined the criteria for Advanced APMs, APMs through which ECs would have the opportunity to become Qualified Participants (QPs) as specified in section 1833(z)(3)(C) and (D) of the Act. First, under MACRA, for an APM to be considered an Advanced APM, it must meet three requirements: (1) Require participants to use certified EHR technology; (2) provide payment for covered professional services based on quality measures comparable to those used in the quality performance category of MIPS; and (3) either be a Medical Home Model expanded under section 1115A(c) of the Act or require the participants to bear more than a nominal amount of risk for monetary losses. In the rulemaking implementing the QPP, we established criteria for each of these requirements. As proposed and subsequently finalized, under the QPP, significant distinctions between the design of different tracks or options within an APM mean that certain tracks or options could meet the Advanced APM criteria while other tracks or options may not. Under the approach discussed in the QPP proposed rule and as subsequently adopted in the QPP final rule with comment period, while all Tracks of the Shared Savings Program would meet the criterion to provide for payment based on quality measures comparable to those used in the quality performance category of MIPS, only Tracks 2 and 3 meet the proposed financial risk standard to bear more than a nominal amount of risk for monetary losses.

In the rulemaking to establish the QPP, we adopted an alternative criterion that would allow all three tracks of the Shared Savings Program to satisfy the EHR criterion if ACOs are held accountable for their ECs' use of CEHRT. In the QPP final rule with comment period, we adopted a definition of CEHRT at § 414.1305 for purposes of MIPS and the APM incentive. We noted that section 1833(z)(3)(D)(i)(I) of the statute does not specify how the APM must require participants to use CEHRT in order to be an Advanced APM. For this reason, we stated that we believed it was reasonable to use discretion when determining the details of how APMs might meet this criterion. For purposes of the APM incentive under the QPP, we proposed and subsequently finalized a policy that an Advanced APM must require at least 50 percent of ECs who are enrolled in Medicare (or each hospital if hospitals are the APM participants) to use the certified health IT functions outlined in the definition of CEHRT to document and communicate clinical care with patients and other health care professionals. However, although the Shared Savings Program requires ACOs to encourage and promote the use of enabling technologies (such as EHRs) to coordinate care for assigned beneficiaries, the Shared Savings Program does not require a specific level of CEHRT use for participation in the program. Instead, the Shared Savings Program, as noted above, includes an assessment of EHR use as part of the quality performance standard which directly impacts the amount of shared savings/shared losses generated by the ACO. Therefore, in the rulemaking to establish the QPP, we proposed and subsequently finalized an alternative criterion available only to the Shared Savings Program. Specifically, we proposed and subsequently finalized an alternative criterion that would allow the Shared Savings Program to satisfy the EHR criterion to be an Advanced APM if it holds APM Entities accountable for their ECs' use of CEHRT by applying a financial penalty or reward based on the degree of CEHRT use (such as the percentage of ECs that use CEHRT or the engagement in care coordination or other activities using CEHRT). In the rulemaking for the QPP, we noted that the current EHR quality measure at ACO #11 assesses the degree to which certain ECs in the ACO successfully meet the requirements of the EHR Incentive Program, and we stated that ''[s]uccessful reporting of the measure for a performance year gives the ACO points toward its overall quality score, which in turn affects the amount of shared savings or shared losses an ACO could earn or be liable for, respectively.'' Finally, we stated that we believed the alternative criterion meets the statutory requirement because the alternative criterion builds on established Shared Savings Program rules and incentives that directly tie the level of CEHRT use to the ACO's financial reward which in turn has the effect of directly incentivizing ever-increasing levels of CEHRT use among participating clinicians.

In the CY 2017 PFS proposed rule, we proposed several modifications to our program rules in order to align with the policies proposed for the QPP.

First, we proposed to modify the title and specifications of the EHR quality measure (ACO #11). This measure is currently titled Percent of PCPs Who Successfully Meet Meaningful Use Requirements. Under the current Shared Savings Program rules, ACOs must report on and are held accountable for certain measures that make up the quality reporting standard. One of these measures, ACO #11, assesses the degree of CEHRT use by primary care physicians participating in the ACO and performance on this measure is weighted twice that of any other measure for scoring purposes. To calculate this measure, CMS collects information submitted by PCPs through the EHR Incentive Program and determines the rate of CEHRT use by PCPs participating in the ACO. Specifically, as explained in our guidance [*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2015-ACO11-Percent-PCP-Successfully-Meeting-Meaningful-Use-Requirement.pdf*], the denominator is based on all PCPs who are participating in the ACO in the reporting year under the Shared Savings Program and the numerator for the measure is based on the PCPs included in the denominator who successfully qualify to participate in either the Medicare or Medicaid EHR Incentive Program in the year indicated.

Results of this measure are used in determining the ACO's overall quality score which in turn determines the ACO's final sharing/loss rate and the amount of shared savings earned (or shared losses owed) by the ACO.

In the QPP proposed rule, we proposed that ECs participating in an ACO would satisfy the Advancing Care Information performance category under the MIPS by reporting meaningful use of EHRs apart from the ACO (81 FR 28247, Table 15). We subsequently finalized this policy in the QPP final rule with comment period. Similar to the process currently used under the Shared Savings Program to determine what practitioners have met criteria for meaningful use for the ACO #11 measure, we will access EC-reported data under the Advancing Clinical Information performance category to assess the ACO's overall use of CEHRT. Because the current EHR measure at ACO–11 only assesses the degree of use of CEHRT by primary care physicians participating in the ACO, in the CY 2017 PFS proposed rule we proposed to modify the EHR measure to align with the policy proposed for the QPP. Specifically, we proposed to change the specifications of the EHR measure in order to assess the ACO on the degree of CEHRT use by all providers and suppliers designated as ECs under the QPP that are participating in the ACO, rather than narrowly focusing on the degree of use of CEHRT of only the primary care physicians participating in the ACO. We stated that we believed this modification to the specifications for ACO #11 would better align with the QPP and ensure a subset of ACOs in the Shared Savings Program could qualify to be Advanced APM entities by participating in an Advanced APM. We also proposed to modify the title of the measure to remove the reference to PCPs. We stated that we believed the modification in the specifications of ACO #11 would be extensive and ECs would also have to gain familiarity with the reporting requirements under the QPP. We therefore proposed that this measure would be considered a newly introduced measure and set at the level of complete and accurate reporting for the first 2 reporting periods for which reporting of the measure is required according to our rules at § 425.502(a)(4). Thus, the measure would be pay for reporting for the 2017 and 2018 performance years. We further proposed to define requirements specific to this measure for the limited circumstances in which it is designated as pay for reporting. Specifically, we proposed to include the requirement at § 425.506(e)(1) that during years in which ACO #11 is designated as a pay for reporting measure, in order for us to determine that the ACO has met requirements for complete and accurate reporting, at least one EC, as that term is defined for purposes of the QPP, participating in the ACO must meet the reporting requirements under the Advancing Clinical Information performance category under the QPP. We stated that we believed this proposal would safeguard the ability of Tracks 2 and 3 to fully meet all criteria for designation as Advanced APMs by ensuring the letter and spirit of the statutory criteria are met, even in the limited circumstances when ACO #11 is designated as pay for reporting under the Shared Savings Program. Beginning in the 2019 performance year, we proposed that ACO #11 would be assessed according to the phase-in schedule indicated in Table 36 of the proposed rule (81 FR 46421–46422) which is consistent with the current phase-in schedule for the measure. We further proposed to add § 425.506(e)(2) reiterating our current requirement at § 425.506(b) that during pay for performance years, the quality measure regarding EHR adoption is measured based on a sliding scale. We stated that we did not intend our proposal to use this measure to assess the degree of CEHRT use by ECs participating in the ACO for purposes of meeting the CERHT criterion for Advanced APMs under the QPP to change the way we treat the measure under pay for performance now. Similar to the current method used by the Shared Savings Program to calculate the EHR measure, we stated that the data would continue to be derived using EC reported EHR data that is required and collected for purposes of MIPS. Additionally, we stated that we intended for the measure to remain double weighted. We proposed to retain the existing EHR measure requirements at § 425.506(a)–(c) and to modify § 425.506(d) to sunset the current EHR reporting requirement as discussed in the prior section.

We also stated that we did not believe that any additional modifications or exceptions to current Shared Savings Program rules (other than the ones proposed, specifically, that the measure specifications and title of ACO #11 be modified to include all ECs and not just PCPs, and the proposal for how an ACO would demonstrate complete and accurate reporting) must be made in order to be consistent with the spirit and intent of the statute and the Advanced APM criteria, as proposed in the QPP proposed rule. Rather, we stated that we believe the existing Shared Savings Program rules are sufficient to permit Tracks 2 and 3 to meet the criteria to be designated as Advanced APMs because the EHR quality measure will always be used to impact the amount of shared savings or losses of an ACO, regardless of whether it is designated as pay for performance or pay for reporting. We noted that the EHR measure has an especially significant impact on the overall quality scoring for an ACO because it is double-weighted compared to any other measure. In spite of this, we indicated that we were considering additional options regarding the treatment of the EHR measure under the Shared Savings Program in order to further enhance the importance of this measure and its impact on an ACO's quality performance score and to improve alignment with the intent of the policies proposed in the QPP proposed rule. Specifically, we were considering whether to finalize a policy that would require the EHR measure to be pay for performance in all performance years, including the first year of an ACO's first agreement period. Additionally, we were considering whether to finalize a policy that would require the EHR measure to remain pay for performance, even when a new EHR measure is introduced or there are significant modifications to the specifications for the measure. We noted that such modifications may require additional changes or alternative approaches to certain current Shared Savings Program rules related to quality benchmarking and scoring. We anticipated that if such modifications were made, they would only apply to the EHR measure and would not impact current scoring and benchmarking rules for other quality measures that make up the quality performance standard. We solicited comment on how best to conform to the intent and spirit of the QPP requirements to ensure that clinicians have assurance they are participating in an Advanced APM. We specifically solicited comment on our proposals and the alternatives considered.

Furthermore, we noted that the CMS Web interface measures, including those proposed in the QPP proposed rule, are consistent across CMS reporting programs. We stated that we do not believe it is beneficial to propose CMS Web interface measures for ACO quality reporting separately. Therefore, to avoid confusion and duplicative rulemaking, we proposed that any future changes to the CMS Web interface measures would be proposed and finalized through rulemaking for the QPP, and that such

changes would be applicable to ACO quality reporting under the Shared Savings Program.

The following is a summary of the comments we received regarding our proposals to align with QPP.

Comment: Many commenters were supportive of our proposed changes to the title and specifications of the EHR measure (ACO–11) to align with the QPP. In contrast, several commenters opposed the proposed modifications to the measure or made additional suggestions. For example, some commenters requested that CMS keep the current version of the measure that assesses PCPs (not all ECs). Another commenter suggested that CMS assess ACOs using two EHR measures. This commenter recommended keeping the current version of the measure focused on primary care physicians as pay for performance while adding the modified version of the measure, which would be assessed under pay for reporting for 2 years like all new measures, before transitioning to pay for performance. In contrast, one commenter suggested that the EHR measure be removed from the ACO measure set entirely. Another commenter suggested that the proposed modifications to the measure specifications should apply only to ACOs participating in Shared Savings Program tracks that could meet the criteria for designation as Advanced APMs under the QPP.

Response: We are finalizing the proposal to modify the EHR measures (ACO–11) to align with the Advanced APM criteria under the QPP. We appreciate commenters' support for these changes. We believe the modification to ACO–11 to require reporting by all ECs better aligns with the QPP and will ensure that a subset of ACOs participating in the Shared Savings Program are able to qualify to be designated as Advanced APM entities by participaing in an Advanced APM. Accordingly, ACO participants in ACOs under all tracks of the Shared Savings Program must report data on the Advancing Care Information performance category on behalf of all ECs billing through the TIN of the ACO participant according to the MIPS requirements as specified at § 414.1375(b) in order to report for purposes of ACO #11.

We note that under the QPP final rule with comment period, eligible clinicians who become QPs by participating in Advanced APMs will be exempt from reporting in the advancing care information performance category for purposes of MIPS. However, under § 425.500(c), ACOs must submit data on ACO quality performance measures according to the method of submission established by CMS. Thus, in the QPP final rule with comment period, we established a policy that all eligible clinicians participating in ACOs under all tracks of the Shared Savings Program must report for purposes of the advancing care information performance category according to the MIPS requirements found at § 414.1375(b) regardless of whether they are excluded from MIPS for the year by virtue of their participation in an Advanced APM, in order for the Shared Savings Program to assess the ACO's performance on ACO–11, as required by the Advanced APM CEHRT use criterion.

We appreciate the suggestion that the old measure (based on percent of primary care physician use of CEHRT) be retained in addition to establishing a new EHR measure that assesses EC use of CEHRT. We decline to retain the old measure at this time because the nature of the data being submitted to us is changing and primary care physicians are included in the new measure as a subset of the ECs participating in the ACO. Although we decline to hold ACOs accountable for both measures of CEHRT use at this time, we will continue to consider whether in the future it would be useful to calculate the percent of primary care physicians using CEHRT and share this information with ACOs.

Comment: Many commenters supported the proposal to treat ACO–11 as a new measure and set it at the level of pay for reporting for the first 2 years of its use, consistent with our existing approach to implementing new measures. Other commenters disagreed with the proposal to transition the measure to pay for performance according to the phase-in schedule indicated in Table 36 of the proposed rule (81 FR 46421–46422) and requested that it remain pay for reporting for all 3 years of an ACO's agreement period. One commenter encouraged CMS to set new benchmarks for the new EHR measure.

Response: We recognize that reporting use of CEHRT under the QPP's Advancing Care Information performance category according to MIPS requirements will be new for many ECs and that it will take some time for ACOs and their ECs to gain some familiarity with the new reporting requirements for ACO–11. For this reason, we proposed and are finalizing a policy to treat ACO–11 as a newly introduced measure and to hold the ACO accountable for pay for reporting only for the first 2 years after the revised measure is introduced. However, to stress the importance of care coordination and support the use of CEHRT, we intend to phase in the measure to pay for performance according to the schedule outlined in Table 36 of the proposed rule (81 FR 46421–46422) and as indicated in Table 42 of this final rule. Consistent with our established policies for setting quality performance benchmarks for new measures, a new benchmark for this measure will be set based on the data gathered during the two pay for reporting years after the measure is introduced.

Comment: One commenter expressed concerns over including ECs in the EHR measure who are excluded from MIPS and thus have the option of not reporting under the Advancing Care Information performance category (for example, low volume providers and QPs). They recommended ECs excluded from MIPS be excluded from the denominator of ACO–11.

Response: As noted above, in the QPP final rule with comment period, we established a requirement at § 414.1370(g)(4)) that each ACO participant TIN participating in a Shared Savings Program ACO (regardless of Track) must submit data on the advancing care information performance category as specified in MIPS as finalized at § 414.1375(b). Additionally, it is necessary for ACO participant TINs to submit such data to meet the requirements under MIPS and for the calculation of the final score under the APM scoring methodology. All ECs participating in Track 1 ACOs will be subject to MIPS as will ECs participating in ACOs under Tracks 2 and 3 that do not qualify as QPs. We plan to align closely with the QPP when developing our operational guidance and the measure specifications to ensure a clear understanding of the data submission requirements for ACO participant TINs under MIPS.

Comment: We received one comment supporting our proposal that future changes to the measures an ACO is required to report through the CMS Web Interface be finalized through rulemaking for the QPP in order to maintain alignment with QPP.

Response: We appreciate the support for our proposal. We believe a single rulemaking process for adding and removing Web interface quality measures will be less confusing for stakeholders and streamline alignment of ACO and MIPS APM reporting. Therefore, we are finalizing our proposal that future revisions to the Web interface quality measures will be adopted through rulemaking for the QPP to avoid confusion or duplicative rulemaking.

Comment: Many commenters submitted questions or comments related to MIPS scoring of the advancing care information performance category and also requested further clarification regarding the CEHRT criteria for Advanced APMs.

Response: These comments are out of the scope of the CY 2017 PFS proposed rule. However, we have shared these comments with our colleagues who have responsibility for the QPP. We also note that the QPP final rule with comment period responds to comments received on the QPP proposed rule and further describes the CEHRT criteria for Advanced APMs.

Final Action: We are finalizing our policies regarding alignment with the QPP as proposed. Specifically, we are modifying the title and specifications of the EHR quality measure (ACO#11) to align with the QPP. We are changing the specifications of the EHR measure in order to assess the ACO on the degree of CEHRT use by all providers and suppliers that are participating in the ACO and that are designed as ECs under the QPP rather than narrowly focusing on the degree of CEHRT use by the primary care physicians participating in the ACO. Additionally, as noted above, although certain eligible clinicians are exempt from reporting under MIPS, we will require all ACO participant TINs, regardless of track, to submit data for the advancing care information performance category.

Because the specifications for this measure are changing, we are finalizing our proposal to consider it a newly introduced measure and to set it at the level of complete and accurate reporting for the first 2 reporting periods for which reporting of the measures is required consistent with our existing rule at § 425.502(a)(4). Specifically the measure will be pay for reporting for all ACOs for the 2017 and 2018 performance years. We are also finalizing our proposal to include a requirement at § 425.506(e)(1) that during years in which ACO #11 is designated as a pay for reporting measure, in order for us to determine that an ACO has met requirements for complete and accurate reporting, at least one EC participating in the ACO must meet the reporting requirements under the Advancing Clinical Information performance category under the QPP. Beginning in the 2019 performance year, ACO #11 will be assessed according to the phase-in schedule noted in Table 42. We are finalizing our proposal to add § 425.506(e)(2) reiterating our current requirement at § 425.506(b) that during pay for performance years, assessment of EHR adoption will be measured based on a sliding scale.

Finally, we are finalizing a policy that any future changes to the CMS Web interface measures will be adopted through rulemaking for the QPP, and that such changes will be applicable to ACO quality reporting under the Shared Savings Program.

4. Incorporating Beneficiary Preference Into ACO Assignment

a. Background

Under section 1899(c) of the Act, beneficiaries are required to be assigned 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, and they retain the right to seek Medicare-covered services from any Medicare-enrolled provider or supplier of their choosing. 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 furnished by physicians and certain non-physician practitioners that are ACO professionals in the ACO, determines the beneficiary's assignment to an ACO under the Shared Savings Program. As discussed in detail in the November 2011 Medicare Shared Savings Program final rule (76 FR 67851 through 67870), we finalized a claims-based hybrid approach (called preliminary prospective assignment with retrospective reconciliation) for assigning beneficiaries to an ACO. Under this approach, beneficiaries are preliminarily assigned to an ACO at the beginning of a performance year to help the ACO refine its care coordination activities, but final beneficiary assignment is determined at the end of 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 with the ACO's desire to have information about the FFS beneficiaries that are likely to be assigned at the end of the performance year. We believe this methodology accomplishes an appropriate balance because ACOs have the greatest opportunities to impact the quality and cost of the care of beneficiaries that choose to receive care from providers and suppliers participating in the ACO during the course of the year.

A beneficiary is eligible for assignment to an ACO under § 425.402 if the beneficiary had a primary care service with a physician who is an ACO professional, and thus, is eligible for assignment to the ACO under the statutory requirement to base assignment on utilization of primary care services furnished by physicians who are ACO professionals in the ACO. The beneficiary is then assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary 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 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 TIN. The second step of the assignment process considers the remainder of beneficiaries who have received at least one primary care service from an ACO physician with a specialty designation specified in § 425.402(c), but have received no services 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 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 by physicians with such specialty designations in another ACO or who are not affiliated with any ACO and are identified by a Medicare-enrolled TIN. The ''two step'' assignment process simultaneously maintains the requirement to focus on 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. We revised this two-step claims based methodology in the June 2015 Final Rule as discussed in detail in that final rule (80 FR 32743 through 32758) and finalized a policy that would exclude services provided by certain physician specialties from step 2 of the assignment process.

Additionally, 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. Under Track 3, beneficiaries are

prospectively assigned to the ACO at the beginning of the performance year using the same two-step methodology, based on the most recent 12 months for which data are available, which reflects where beneficiaries have chosen to receive primary care services during that period. The ACO is held accountable for beneficiaries that are prospectively assigned to it for the performance year. Under limited circumstances, a beneficiary may be excluded from the prospective assignment list, for example, if the beneficiary enrolls in Medicare Advantage or no longer lives in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records at the end of the performance year. A beneficiary is not excluded from the ACO's prospective assignment list at the time of reconciliation because 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 at the time of reconciliation because a beneficiary chose to receive a plurality of his or her primary care during the performance year from ACO professionals participating in the ACO. 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 aligned beneficiaries who meet the exclusion criteria specified in § 425.401(b) during the performance year will not be aligned to the ACO at the end of the year; and further, as noted, beneficiaries remain free under FFS Medicare to choose the healthcare providers from whom they receive services.

Because of uncertainty inherent in FFS Medicare where there is no beneficiary lock-in or enrollment, both patient advocacy groups and ACOs have expressed interest in and support for enhancing claims-based assignment of beneficiaries to ACOs by taking into account beneficiary attestation regarding the healthcare provider that they consider to be responsible for coordinating their overall care. Stakeholders believe that incorporating this information and giving beneficiaries the opportunity to voluntarily ''align'' with the ACO in which their primary healthcare provider participates will improve the patient centeredness of the assignment methodology, and possibly reduce year-to-year ''churn'' in beneficiary assignment lists.

The Center for Medicare & Medicaid Innovation (Innovation Center) began conducting a test of beneficiary attestation (which was referred to as voluntary alignment, a term that we will also use in the context of the Shared Savings Program) in the Pioneer ACO Model (see *https://innovation.cms.gov/initiatives/Pioneer-aco-model/*) for the 2015 performance year. In the Pioneer ACO Model, for a Pioneer ACO to participate in voluntary alignment for performance year four (Pioneer ACO contract year 2015), the Pioneer ACO was required to submit an application to CMS in the summer of performance year three (Pioneer ACO contract year 2014) in which the ACO explained its plan for contacting beneficiaries. ACOs that were approved to participate in voluntary alignment were limited to contacting only those beneficiaries who appeared on the ACO's then current (Pioneer ACO contract year 2014) and prior year's (Pioneer ACO contract year 2013) prospective assignment lists.

The ACOs sent letters to beneficiaries during a specified period asking the beneficiaries to confirm whether a listed Pioneer Provider/Supplier was their ''main doctor.'' The Innovation Center imposed certain safeguards on the participating ACOs to protect against actions that could improperly influence a beneficiary's decision to complete the voluntary alignment form. The ACOs collected responses and turned them in to CMS in fall 2014, before the start of the 2015 performance year. Beneficiaries who confirmed a care relationship with the Pioneer Provider/Supplier listed on the form, and met all other eligibility criteria for alignment, were prospectively aligned to the Pioneer ACO for the upcoming performance year, regardless of whether or not the practitioners participating in the Pioneer ACO rendered the plurality of the beneficiary's primary care services during the alignment period. We refer to the procedures used under the Pioneer ACO Model as ''the manual process.''

Beneficiary and ACO participation in and experience with voluntary alignment under the Pioneer ACO Model to date has been mixed. Initially, beneficiaries often seemed confused about the implications of attesting to a care relationship with a Pioneer Provider/Supplier, based on the letters they received from Pioneer ACOs. Beneficiaries, for example, were often unfamiliar with the name of the Pioneer ACO. Although most Pioneer ACOs initially expressed high interest in beneficiary attestation, only half participated. Those that did not participate cited cost/benefit concerns. To address concerns expressed by ACOs and beneficiaries, the beneficiary attestation process was updated for the Pioneer ACO Model for PY 2016, with letters sent to beneficiaries during the summer of 2015. The new beneficiary attestation process includes updated language in the letters to beneficiaries and the attestation form to reduce beneficiary confusion. The letters now include plainer language, refer to a specific healthcare provider (in addition to the ACO), and Pioneer Providers/Suppliers are permitted to discuss beneficiary attestation with beneficiaries and respond to questions. Other significant changes to the process are discussed in the proposed rule (81 FR 46432). We would note that for performance year five (Pioneer ACO contract year 2016), CMS changed the criteria to allow beneficiaries to voluntarily align into the performance year five aligned population if, among other requirements, the beneficiary had at least one paid claim for a Qualified E/M service, as defined in section 2.4 of Appendix C of the Pioneer ACO Agreement, furnished by a Pioneer Provider/Supplier on or after January 1, 2013. Based on some initial feedback, beneficiaries appear to be wary of the implications of designating a ''main doctor'' but are much more amenable to this type of information request when it comes from their physician or other practitioner, rather than from an ACO. However, information is not yet available on the impact or results of the modifications made to the beneficiary attestation process in the Pioneer ACO Model. The Next Generation ACO Model, which started operation on January 1, 2016, includes a beneficiary attestation policy similar to the updated manual process used under the Pioneer ACO Model. In order for a Medicare FFS beneficiary to be eligible to voluntarily align with a Next Generation ACO for performance year two (Next Generation ACO contract year 2017), the beneficiary must have had at least one paid claim for a qualified evaluation and management service on or after January 1, 2014, with an entity that was a Next Generation Participant during performance year one, among other requirements.

To date, the Innovation Center has done limited analyses of the updated voluntary alignment process for effects on beneficiary engagement. Early experience indicates that for the participating ACOs, the number of prospectively assigned beneficiaries per ACO increased by 0.2 to 2.7 percent relative to the number of beneficiaries who would have otherwise been assigned. However, there is not yet enough information to determine whether beneficiary attestation under the manual process has had an impact on increasing certainty that a beneficiary will continue to choose to receive primary care or other services from practitioners participating in an ACO.

We note that a similar manual process for sending letters to beneficiaries to provide them notice of their opportunity to opt out of claims data sharing was removed from the Shared Savings Program in the June 2015 final rule (see 80 FR 32743). This data sharing opt out process was removed because it was resource intensive and cumbersome for ACOs and CMS, and was confusing for beneficiaries. Instead, based on stakeholder comments, we finalized a process to provide beneficiaries the opportunity to decline claims data sharing directly by contacting the Medicare program (through 1–800–MEDICARE) rather than through the ACO. This more direct process started at the end of 2015 and so far appears to be working well, as it has not generated the number of complaints and concerns raised by the initial manual process.

b. Proposals

In the CY 2017 PFS proposed rule, we proposed to incorporate beneficiary attestation into the assignment of beneficiaries to ACOs participating in the Shared Savings Program, to supplement and enhance the current claims-based algorithm driven methodology as described in more detail in this section of the final rule.

We indicated that we believed that it would be appropriate to implement, at a minimum, a voluntary alignment process under the Shared Savings Program that would be similar to the updated manual process we have implemented under the Pioneer ACO Model and that is used under the Next Generation ACO Model. Supplementing the current claims-based assignment process with a voluntary alignment process that incorporates beneficiary attestation about their ''main doctor'' could help ACOs to increase patient engagement, improve care management and health outcomes, and lower expenditures for beneficiaries, while also helping to assure that beneficiaries are assigned to ACOs based on their relationship with providers that they believe to be truly responsible for their overall care. However, based on the valuable knowledge and experience we have gained through these Innovation Center models, we also expressed our concern that the manual voluntary alignment process used for the Pioneer ACO Model and that is used under the Next Generation ACO Model is resource intensive for both ACOs and CMS.

Because of the limitations of the manual process, we proposed to implement an automated approach under which we could determine which healthcare provider a FFS beneficiary believes is responsible for coordinating their overall care (their ''main doctor'') using information that is collected in an automated and standardized way directly from beneficiaries (through a system established by us, such as *MyMedicare.Gov*), rather than requiring individual ACOs, ACO participants, or ACO professionals to directly obtain this information from beneficiaries annually and then communicate these beneficiary attestations to CMS.

We proposed to make such an automated mechanism available for beneficiaries to voluntarily align with the provider or supplier that they believe is responsible for coordinating their overall care starting early in 2017, making it possible for us to use beneficiary attestations for assigning beneficiaries to ACOs in all three tracks for the 2018 performance year. We indicated that voluntary alignment data would be accessed and incorporated in the beneficiary assignment process each time we run the assignment algorithm. Under the automated approach, beneficiaries would be able to change their attestation about their ''main doctor'' at any time; however, we noted there may be a lag in using the information to update an ACO's assignment list depending on the timing of the beneficiary's updated designation and the track under which the ACO is participating. For example, as described in more detail in the CY 2017 PFS proposed rule, we proposed for Track 3 to incorporate the beneficiary's designation annually prior to the start of the performance year at the time beneficiaries are prospectively assigned for that performance year.

Further, we proposed to incorporate voluntary alignment for ACOs in Tracks 1 and 2 on a quarterly basis. We stated that we believe this policy would be appropriate because it aligns with the current timing for updates to Track 1 and 2 ACO assignment lists. We also proposed that if a beneficiary voluntarily aligns with a provider or supplier whose services would be considered in assignment but who is not participating in an ACO as an ACO professional, the beneficiary would not be eligible for alignment to an ACO, even if the beneficiary would have otherwise been assigned to an ACO under our claims-based approach.

We further proposed that, if an automated voluntary alignment process is not operationally ready for implementation by spring 2017, we would implement a manual voluntary alignment process for Track 3 ACOs only that builds upon experience previously gained under the Pioneer ACO Model. We explained our view that it would be appropriate to initially limit the manual process to ACOs participating in the Shared Savings Program under Track 3 because the process and timing for sending letters to beneficiaries regarding voluntary alignment under the manual process was developed specifically for prospective alignment under the Pioneer and Next Generation ACO Models and for a limited number of ACOs. We indicated that we believe implementing such a manual process for the hundreds of ACOs in Track 1 and Track 2 whose beneficiaries are preliminarily prospectively assigned with retrospective reconciliation would result in operational challenges for ACOs and CMS and could have unintended consequences that could be confusing or harmful to beneficiaries. We therefore proposed that if an automated process is not available to allow beneficiaries to designate their primary healthcare provider in time for the information to be considered for beneficiary assignment for PY 2018, we would implement an alternative manual voluntary alignment process (similar to the updated process used under the Pioneer ACO Model and described in more detail in the CY 2017 PFS proposed rule) to allow beneficiaries to align with Track 3 ACOs for the 2018 performance year and until such time as an automated process is available.

Regardless of process (manual or automatic), we proposed to begin to incorporate beneficiary attestation into the assignment methodology for the Shared Savings Program, effective for assignment for the 2018 performance year. In brief, under the proposal, an eligible beneficiary would be assigned to an ACO based on the existing claims-based assignment process unless the beneficiary has designated a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of § 425.402, or a nurse practitioner, physician

assistant, or clinical nurse specialist as being responsible for their overall care. If an eligible beneficiary has made such a designation then the voluntary alignment would override the claims-based assignment process if certain additional conditions are met. We proposed to revise the regulation governing the assignment methodology to add a new paragraph (e) to § 425.402 to address the voluntary alignment process. Further, we proposed to prohibit ACOs, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions or services related to ACO activities from directly or indirectly committing any act or omission, or adopting any policy that coerces or otherwise influences a Medicare beneficiary's decision to designate or not designate an ACO professional as responsible for coordinating their overall care.

We stated that to maintain flexibility for ACOs, ACO participants, ACO providers/suppliers, ACO professionals, beneficiaries, and CMS, we would intend to provide further operational details regarding the voluntary alignment process and the applicable implementation timelines through subregulatory guidance and other outreach activities.

We solicited comments on this proposal, on the effective date, and on any other related issues that we should consider for the final rule to address issues related to voluntary alignment under the Shared Savings Program. In particular, we solicited comment on a variety of topics such as whether voluntary alignment is an appropriate mechanism for assigning beneficiaries retrospectively to an ACO, whether ACOs should be permitted to opt into or out of voluntary alignment, and whether we should exclude a beneficiary from an ACO's prospective assignment list for a performance year if later during the performance year the beneficiary voluntarily aligns with a healthcare provider that is not an ACO professional in the ACO. We also solicited input on how concerns about ACO avoidance of at risk beneficiaries might be addressed.

We also noted that under the proposed automated voluntary alignment process, a beneficiary's designation of a healthcare provider as responsible for coordinating their overall care would stay in effect until the beneficiary chose to make a subsequent change. We indicated that under the proposal we would rely on appropriate information shared with beneficiaries at the point of care to ensure the beneficiary's designation is kept up to date. We solicited comment on this issue and our proposal under the automated system to continue to use a beneficiary's designation of the healthcare provider responsible for coordinating their overall care until it is changed.

We also welcomed suggestions regarding the operational process, implementation timelines, and related issues regarding the process for beneficiaries to voluntarily align with an ACO, including how to strengthen ACOs' beneficiary engagement activities. We noted that although we proposed to establish a process under which beneficiaries may designate their ''main doctor'' who they consider responsible for coordinating their overall care, in establishing the operational processes for allowing beneficiaries to designate their ''main doctor'' we may not explicitly use the phrase ''responsible for coordinating overall care'' which we included in the proposed provision at § 425.402(e). Instead, we indicated that we may consider using other terminology based on focus group testing and/or other feedback from beneficiary representatives. We welcomed comments on what terminology would be preferable to ensure beneficiaries understand the significance of designating a provider or supplier as responsible for coordinating their overall care. We indicated we would consider such suggestions further as we develop program guidance and outreach activities for beneficiaries and ACOs.

The following is a summary of the comments we received regarding voluntary alignment under the Shared Savings Program.

Comment: Commenters supported the incorporation of voluntary alignment into the Shared Savings Program, citing the potential for patient engagement and a more stable beneficiary population. Commenters indicated that voluntary alignment is appropriate for ACOs that have either retrospective or prospective assignment. One commenter indicated that providing beneficiaries with the opportunity to align voluntarily with an ACO would balance the important considerations of beneficiaries' freedom to choose their providers with ACOs' interest in reducing patient turnover or ''churn,'' thus providing a more defined and stable beneficiary population. The commenter suggested this would allow ACOs to better target their efforts to manage and coordinate care for beneficiaries for whose care they will ultimately be held accountable.

Another commenter suggested there are many times where for a particular year the current claims-based assignment algorithm may not be an accurate reflection of the beneficiary's wishes and normal care pattern. Examples provided by this commenter of when the current algorithm could lead to inappropriate attribution were in cases where a beneficiary is dealing with an acute illness or condition requiring specialized evaluation and management services, is experiencing an extended time away from a primary residence, is a low health care utilizer where a single service plays a big role in determining the plurality of primary care services, or is switching primary care physicians when entering a skilled nursing facility (SNF). Commenters indicated that allowing beneficiaries to attest to the provider they believe is managing their care may also help increase beneficiary engagement in that care. A number of commenters expressed support for the proposal to exclude from alignment to an ACO any beneficiaries who voluntarily align with a healthcare provider who is not an ACO professional, as that respects the beneficiary's preference.

Response: We agree with stakeholders that supplementing the current assignment process with a voluntary alignment process that incorporates beneficiary attestation could help ACOs to increase patient engagement, improve care management and health outcomes, and lower expenditures for beneficiaries. Incorporating beneficiary attestation into the beneficiary assignment process could further strengthen the current claims-based, two-step assignment process. Supplementing the claims-based assignment algorithm with beneficiary attestations could further assure that beneficiaries are assigned to ACOs based on their relationship with providers and suppliers that they believe to be truly responsible for their overall care. Therefore, we plan to begin to incorporate beneficiary attestation into the assignment methodology for the Shared Savings Program, effective for assignment for the 2018 performance year. Based on comments, we will incorporate beneficiary attestation as proposed, with certain modifications as discussed in this section.

Comment: Many of the commenters who supported voluntary alignment strongly urged CMS to prioritize development and timely implementation of an automated voluntary alignment process for attestation that minimizes the burden for beneficiaries and ACOs, and that would be accessible to ACOs in all three tracks beginning with performance year 2018. Some commenters further noted that the process should be automated from the beginning even if it were to

result in a delay in implementation. Commenters indicated that using an automated approach for voluntary alignment would be less burdensome for both ACOs and CMS, and would allow for more robust participation by ACOs and beneficiaries. Otherwise, the commenters believe that differences in how beneficiary attestation is handled for the three tracks would cause unnecessary confusion for beneficiaries. These commenters indicated that the manual voluntary alignment approach used under the Pioneer and Next Generation ACO Models has been very cumbersome and confusing, and therefore, has been pursued by only about one-half of eligible ACOs because of cost/benefit concerns. One commenter expressed concern that a manual process would increase the likelihood of errors.

Response: We agree with the commenters who urge us to prioritize development and implementation of an automated voluntary alignment process for all three ACO tracks rather than to develop concurrently a manual process limited to Track 3 ACOs that would be implemented only in the event that an automated system for all three Tracks is not available. We also agree the process should be automated from the beginning even if it were to result in a delay in implementation because a manual process might increase the likelihood of errors, and an automated approach would be more efficient for ACOs and their ACO participants, ACO providers/suppliers, and ACO professionals, as well as for beneficiaries and CMS. Based on valuable experience gained through development and testing of beneficiary attestation processes through the Pioneer ACO Model, the manual process developed thus far appears to be resource intensive for both ACOs and CMS and may not significantly impact beneficiary assignment to ACOs.

Comment: Some commenters raised concerns regarding the potential burden of a voluntary alignment process (whether manual or automated) and suggested that further testing be done prior to implementation. For example, one commenter suggested testing voluntary alignment under Track 1 on a small scale to assess whether it impacts ACO performance and beneficiary health. Another commenter suggested that voluntary alignment should not be implemented unless there is a tested automated process. One commenter supported the testing of both of the manual and automated models to determine which approach presents lower burden for providers, CMS, and, most importantly, Medicare beneficiaries.

Response: We believe that the development and testing of manual beneficiary attestation processes through the Pioneer ACO Model has been very valuable, and, along with the very helpful public comments received in response to our proposals, provides a good foundation for development and implementation of an automated process. Other than our intent to determine appropriate terminology through focus groups and to perform other systems quality assurance testing and the like, we do not believe additional testing of the automated process is needed because it will incorporate the same or similar policies as the manual process that has already undergone testing in Innovation Center models. Therefore, we will prioritize the development of procedures to implement voluntary alignment using an automated process with the intent of incorporating beneficiary attestations into the claims-based assignment algorithm beginning with the 2018 performance year. We do not intend to develop a manual beneficiary attestation process under the Shared Savings Program.

Comment: A few commenters suggested that ACOs be permitted to opt in or out of the use of beneficiary designations in assignment. In contrast, some other commenters disagreed that ACOs should be given this option in order to ensure all beneficiaries have the opportunity to be aligned with the ACO in which the provider or supplier that the beneficiary considers responsible for their overall care participates.

Response: We agree with the commenters who suggested it would be inappropriate to permit ACOs to opt into or out of voluntary alignment under an automated voluntary alignment approach. We agree that, to the extent feasible, all beneficiaries would benefit by being provided with the option of designating a healthcare provider responsible for their overall care.

Comment: One commenter supported voluntary alignment, but urged that beneficiary designations only be considered, and used to override otherwise applicable assignment rules, for beneficiaries who have been assigned to an ACO under the claims-based assignment algorithm.

Response: We disagree. We believe that assignment to ACOs and beneficiary engagement under the Shared Savings Program would be better enhanced by taking into account all beneficiary attestations and not just the beneficiary attestations for those who would have otherwise been assigned to an ACO under the claims-based assignment algorithm.

Comment: Some commenters expressed support for a quarterly process to incorporate voluntary alignment for Track 1 and 2 ACOs, and for keeping beneficiaries who are prospectively assigned to a Track 3 ACO but designate a provider or supplier outside of the ACO as responsible for their overall care assigned to the ACO until the end of the benchmark or performance year. A few other commenters supported the proposal to incorporate the beneficiary attestations annually for Track 3 ACOs at the time beneficiaries are prospectively assigned for a performance year, but for Track 1 and 2 ACOs, the commenters recommended changes to the proposal to incorporate voluntary alignment on a quarterly basis. For Track 1 and 2 ACOs, the commenter suggested that only beneficiary attestations made in the previous year or the during the first 3 months of the performance year should be effective for that performance year; voluntary alignments made later in the performance year would not go into effect until the next performance year. The commenter indicated this timing would allow ACOs to identify new voluntarily aligned beneficiaries on the quarterly reports beginning with the first or second quarter reports, thus enabling the ACO to identify and focus efforts on these beneficiaries. The commenter indicated this would enable ACOs to be able to better target care for beneficiaries likely to be retrospectively assigned to the ACO in order to make a meaningful difference for the performance year. Another commenter supported keeping a beneficiary who has voluntarily aligned with a Track 1 or Track 2 ACO assigned to that ACO for the entire performance year, even if the beneficiary later designates a provider or supplier outside the ACO as responsible for their overall care in the middle of the performance year, because it would avoid adding confusion in the administration of the program. Similarly, another commenter suggested that variations in the policies regarding voluntary alignment by track could lead to confusion for ACOs and difficulty in tracking the effect of voluntary alignment on assignment, and therefore, recommended that, for all three tracks, voluntary alignment should be based simply on the most current choice of primary care physician at the end of the performance year.

Another commenter expressed concerns that voluntary alignment under a retrospective assignment methodology (Tracks 1 and 2) could increase adverse incentives for ACOs to selectively encourage some beneficiaries

to stay aligned to the ACO and others to leave it. For example, the commenter suggested that a beneficiary having a hip replacement in the next few months might be inappropriately encouraged to voluntarily align with a healthcare provider outside the ACO to avoid having the high cost of a hip replacement included in the ACO's expenditures.

Response: We proposed to incorporate voluntary alignment for ACOs in Tracks 1 and 2 on a quarterly basis because this approach aligns with the current timing for updates to the assignment lists for ACOs in Tracks 1 and 2. However, following further consideration and based on our review of the comments on this issue, we now agree with the commenters who indicated that incorporating beneficiary attestation less frequently under Tracks 1 and 2 could help ACOs to better focus their efforts to target care for beneficiaries likely to be assigned to the ACO and make a meaningful difference for the performance year. Further, we believe that incorporating beneficiary attestations annually, prior to the beginning of a performance year, for all three tracks, rather than incorporating beneficiary attestations quarterly for Tracks 1 and 2, could be less confusing for ACOs and beneficiaries. This timeline aligns with other annual beneficiary election/designation processes such as Medicare's annual enrollment period which would simplify our education and outreach efforts. This approach might also at least partially address the commenter's concern that voluntary alignment under Tracks 1 and 2 could increase possible adverse incentives for ACOs to encourage some beneficiaries to stay aligned to the ACO and others to leave it. We believe such adverse incentives under voluntary alignment for Tracks 1 and 2 would be reduced if we were to incorporate beneficiary attestation annually, as we proposed for Track 3 ACOs. Accordingly, we are modifying our proposed policy in order to take beneficiary attestations into account and to voluntarily align beneficiaries annually and prospectively to ACOs participating in all tracks at the beginning of each performance year, provided the beneficiary is eligible for assignment to the ACO. Although we assign beneficiaries to ACOs under Tracks 1 and 2 using a preliminary prospective with retrospective reconciliation approach for purposes of the claims-based assignment methodology, when incorporating beneficiary voluntary alignment information, we would assign beneficiaries that have attested to a care relationship with an ACO provider/supplier to the ACO at the beginning of each performance year and these beneficiaries would ''stick'' on the assignment list for the full performance year for ACOs under all tracks. In other words, beneficiaries who voluntarily align to an ACO participating in Track 1 or Track 2 would be prospectively assigned to that ACO for the entire performance year even if they would not be retrospectively assigned to the ACO under the claims-based assignment methodology or later align with another provider or supplier outside the ACO during the performance year (we note that in such cases, the change in designation would be taken into account at the beginning of the next performance year).

In brief, if a beneficiary designates an ACO professional that they believe is responsible for coordinating their overall care as their ''main doctor'', the beneficiary will be assigned to the ACO in which that ACO professional is participating, as long as the ACO professional's specialty is used in assignment and the beneficiary has received at least one primary care service from a physician in that ACO and does not meet the criteria for exclusion. If these criteria are met, the beneficiary's selection of his or her ''main doctor'' and, ultimately, assignment to the ACO would take precedence over any assignment to an ACO based on claims. For example, if a beneficiary selects a physician in ACO 1 as his or her main doctor, the beneficiary's designation would take precedence over claims-based assignment, as long as the physician's specialty is used in assignment and the beneficiary received a primary care service from a physician in ACO 1. This will be the case even if the beneficiary would have otherwise been assigned to ACO 2 through claims-based assignment.

However, if a beneficiary designates a physician or practitioner in an ACO and the conditions for assignment are not met, then the claims-based assignment methodology will be used to determine the beneficiary's assignment. For example, if a beneficiary designates a physician in ACO 1, he or she could not be assigned to ACO 1 based on the attestation if he or she did not receive at least one primary care service from a physician in ACO 1. Similarly, if a beneficiary designates an ACO professional in ACO 1 whose services are not used in assignment, the claims-based assignment methodology would be used to determine whether the beneficiary will be assigned to ACO 1, another ACO, or to no ACE. Relatedly, if a beneficiary designates a practitioner with a specialty used in assignment and the practitioner is not affiliated with an ACO, then the beneficiary will not be eligible for assignment to an ACO, even if the beneficiary would have otherwise been assigned to an ACO through claims-based assignment.

Finally, we also clarify that consistent with § 425.400(a)(1), the assignment methodology described under § 425.402 also applies to benchmarking years. Accordingly, when determining beneficiary assignment for a benchmark year, we will incorporate beneficiary designations that were in place during the assignment window for the benchmarking year.

Comment: One commenter supported aligning beneficiaries that choose a ''main doctor'' indefinitely until the beneficiary changes his or her designation, drawing an analogy with the way beneficiaries who select an MA Plan continue under that MA Plan until the beneficiary chooses otherwise. Another commenter expressed concern that this policy could result in an ACO being inappropriately held responsible for the costs of a beneficiary's care even in cases where the ACO no longer has a relationship with the beneficiary and has not furnished services to that beneficiary for years. The commenter recommended that voluntary alignment override the existing assignment methodology only when a beneficiary has at least one qualified primary care service during the previous or current performance year with an ACO professional that would be considered under Step 1 or Step 2 of the Shared Savings Program assignment methodology (based on the existing services used for Shared Savings Program assignment). Another commenter recommended that if the beneficiary does not update their selection annually, reverting to the claims-based alignment should be the default because that will be updated regularly as beneficiaries express their preference through their healthcare provider visits.

Response: We continue to believe that it would be appropriate, under an automated voluntary alignment process, for a beneficiary's designation of a healthcare provider as being responsible for coordinating their overall care to stay in effect until the beneficiary voluntarily changes his or her designation. We intend to remind beneficiaries to make a selection and update it annually; however, we believe it would be burdensome to require beneficiaries make this designation each year. We also agree that it would be

inappropriate for an ACO to be held responsible for the costs of a beneficiary's care in cases where the ACO no longer has a relationship with the beneficiary and has not furnished services to that beneficiary for years. However, we believe the voluntary alignment policy directly addresses this concern because, under the proposal, beneficiaries that have voluntarily aligned with an ACO by designating an ACO professional whose services are used in assignment as responsible for coordinating their overall care would be added to the ACO's list of assigned beneficiaries for a performance year or benchmark year only if certain conditions are met. One of these required conditions is that a beneficiary must have had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in § 425.402(c). In this final rule, we are amending the proposed regulations text at § 425.402(e)(2)(i) to clarify that in order for a beneficiary to be eligible for assignment under voluntary alignment this service must have been received during the ''assignment window'' for the applicable benchmark or performance year as defined at § 425.20. This requirement will ensure that a beneficiary cannot remain aligned to an ACO for an extended period if the beneficiary's designation is outdated and the beneficiary is no longer receiving services from any ACO providers/suppliers in the ACO.

Comment: Several commenters raised specific concerns over the use of certain phrases such as ''main doctor'' and recommended testing such terminology with beneficiaries through focus groups or other methods. For example, some commenters believe the term ''main doctor'' is too ambiguous. Other commenters requested that CMS revise physician-centric language such as ''main doctor'' to avoid miscommunication given that certain non-physician practitioners are also included in the assignment process. A commenter suggested that CMS should also work with other payers to align terms.

Response: We appreciate receiving the helpful comments regarding what terminology would be preferable to ensure beneficiaries understand the significance of designating a provider or supplier as responsible for coordinating their overall care. We will consider these suggestions further as we implement voluntary alignment and develop program guidance and outreach activities for beneficiaries and ACOs. We note that the terms used in the Innovation Center models have undergone beneficiary focus group testing. However, we may conduct further beneficiary focus group testing if necessary to ensure the terms used are appropriate and understandable to beneficiaries.

Comment: One commenter recommended EHR-compatible transfer of information about beneficiary attestations.

Response: We are not entirely certain what the commenter had in mind, but we believe it is a request that we consider building in a method to electronically alert a practitioner that the beneficiary has designated him or her as their ''main doctor. We agree that such a feedback loop could be desirable to encourage and enhance the relationship beneficiaries have with their practitioners. In the future we may consider such possibilities but at this time we plan to prioritize development and implementation of an automated voluntary alignment process within MyMedicare.gov, as discussed in this section.

Comment: Several commenters requested more detail regarding the process and timing for beneficiaries to designate their ''main doctor'' and how ACOs would be educated about the voluntary alignment process and applicable program requirements.

Response: We will notify beneficiaries of this opportunity and encourage them to designate their ''main doctor'' or primary healthcare provider responsible for coordinating their overall care and explain how to do this through beneficiary outreach materials such as through the Medicare & You Handbook (see *https://www.medicare.gov/medicare-and-you/medicare-and-you.html*), the required Shared Savings Program notifications under § 425.312, and/or other beneficiary outreach activities or materials. We intend to issue, either directly or indirectly through template language (for example, template language that would be incorporated into the ACO's required written notifications under § 425.312), written communications to beneficiaries detailing the automated process for voluntary alignment. The designation must be made in the form and manner and by a deadline determined by CMS. Additionally, as noted above, in the proposed rule we stated that to maintain flexibility for ACOs, ACO participants, ACO providers/suppliers, ACO professionals, beneficiaries, and CMS, we would intend to provide further operational details regarding the voluntary alignment process and the applicable implementation timelines through subregulatory guidance and other outreach activities. We anticipate ensuring ACO and practitioner understanding and compliance with program rules using typical methods, for example, through guidance, programmatic webinars, newsletter articles, email notifications, and communications with the ACO's designated CMS coordinator. We intend to monitor beneficiary use of the voluntary alignment process and the ACO's compliance with program rules.

Comment: One commenter expressed concerns about using MyMedicare.gov or 1–800–Medicare as the only avenue to collect beneficiary attestations, questioning how frequently beneficiaries are actively engaging with Medicare through these vehicles. The commenter also recommended that the designation of a ''main doctor'' should be independent of the ''favorites'' indication in MyMedicare.gov, suggesting that being designated as a ''favorite'' is not a good indicator of being a ''main doctor''.

Response: The operational process for beneficiaries to voluntarily align with an ACO by designating a ''main doctor'' or primary healthcare provider responsible for coordinating their overall care will be incorporated into existing processes to the extent feasible. As we indicated in the proposed rule, examples by which such a process could be automated include using MyMedicare.gov, 1–800–Medicare, or Physician Compare. We anticipate that for the first year of the automated process, we will enable beneficiaries to voluntarily align with an ACO by designating a ''main doctor'' or primary healthcare provider responsible for coordinating their overall care through MyMedicare.gov. Beneficiaries or their representatives that call 1–800–Medicare during the early implementation of the automated voluntary alignment process in order to designate a ''main doctor'' or primary healthcare provider will be provided with information about how to make the designation in MyMedicare.gov. Subsequently, we plan to consider expanding the use of 1–800–Medicare as a way for beneficiaries to make a designation and in order to provide additional avenues or technical assistance to support beneficiaries in making a designation. As we and our stakeholders gain experience with the automated process, we intend to continue to refine and build upon the automated process. More information will be forthcoming as we gather additional input from beneficiaries, ACOs, and other stakeholders. We agree that designating ''favorite'' providers is

not the same as designating a ''main doctor'' and that these two things should be independent.

Comment: A few commenters suggested beneficiaries also be offered the opportunity to attest in person, during a visit to an ACO provider/supplier, if that is their preference.

Response: We are not providing an option for beneficiaries to attest in person during a visit with an ACO provider/supplier or other healthcare provider because we are concerned that such an option would lead to additional program complexity and could defeat the purpose of having an automated process that is designed to relieve stakeholder burden experienced when such designations are made manually made at the point of care. However, as noted above in this section, we plan to provide written educational material and template language that ACOs and healthcare providers can use at the point of care to inform and educate beneficiaries about the ability to designate a healthcare provider in MyMedicare.gov as responsible for the beneficiary's overall care.

Comment: Other commenters questioned whether seniors would keep their ''main doctor'' attestation up to date given their varied and often unpredictable care needs, and therefore, asked that CMS explicitly allow physicians and other appropriately qualified individuals involved with patient care to assist beneficiaries in keeping their ''main doctor'' attestation up to date.

Response: We believe it is important to promote engagement and discussion between beneficiaries and their healthcare providers. ACOs, ACO participants, ACO providers/suppliers, and ACO professionals may provide a beneficiary with accurate descriptive information about the potential patient care benefits of designating an ACO professional as responsible for the beneficiary's overall care. However, we do not intend for the voluntary alignment process to be used as a mechanism for ACOs (or their ACO participants, ACO providers/suppliers, ACO professionals or other individuals or entities performing functions or services on behalf of the ACO) to target beneficiaries for whose treatment the ACO might expect to earn shared savings, or to avoid those for whose treatment the ACO might be less likely to generate shared savings.

Comment: One commenter recommended that rather than asking beneficiaries to designate a specific doctor, that they be asked to designate the ACO they generally identify as where they receive health services because this approach better aligns with ACO-level accountability and avoids some of the confusion over ''main doctor.'' Another commenter suggested beneficiaries should be provided information about the process for opting-out of alignment with an ACO.

Response: Our experience with the Pioneer ACO Model indicates that beneficiaries are less likely to identify with an ACO as compared to an individual healthcare provider; that is, when given the option, beneficiaries are more likely to align with their practitioner, not with an organization. Accordingly, we continue to believe it is appropriate under an automated system for beneficiaries to be given the option to voluntarily align with an individual healthcare provider rather than to an ACO with which the beneficiary may not be familiar. For the same reason, we do not believe it is necessary or appropriate to give beneficiaries the option of ''opting out'' of assignment to an ACO. The intent of the voluntary alignment process is to seek to improve beneficiary engagement with a selected practitioner that he/she designates as being responsible for his/her overall care, regardless of whether the practitioner is participating in an ACO.

Comment: One commenter recommended information be provided to an ACO as soon as the attestation is updated within the CMS designated system when one of its assigned beneficiaries designates a new ''main doctor.'' The commenter believed this notification would allow ACOs time to make any updates to their management of their ''participation programs'' and properly manage their patient populations, and it would give them guidance on how to set up for their next performance year.

Response: We are considering possible ways of notifying ACOs that a beneficiary has designated one of their ACO providers/suppliers as their ''main doctor;'' however, we note that the under the modified policy we are adopting in this final rule, ACOs in all tracks will have advanced notice when a beneficiary is assigned to them based on the voluntary alignment methodology because such beneficiaries will be prospectively assigned to the ACO for that performance year and will appear on the ACO's assignment list at the beginning of the performance year.

Comment: A commenter suggested CMS should provide beneficiaries with a list of providers that they have seen recently (based on claims) to simplify their selection and help them accurately select their ''main doctor.'' The commenter believed this approach would mitigate the risk of beneficiaries accidentally selecting doctors with similar names, for example.

Response: We agree this information could be useful for beneficiaries. This is a feature that already exists in MyMedicare.gov where beneficiaries can access their claims information which includes information such as the name of the practitioner that submitted the claim. We note this information can be used currently to build the beneficiary's ''favorites'' list. Similarly, the beneficiary could use the information to assist in making their ''main doctor'' designation.

Comment: A commenter suggested an alternative approach for assigning beneficiaries to ACOs using claims submitted by providers and suppliers using only the codes for initial Medicare visits, annual wellness visits, chronic care management, and advanced care planning; the commenter believed this alternative approach would be less cumbersome for CMS to administer and a simpler and more streamlined approach for beneficiaries and the primary care physician.

Response: We will continue to consider suggestions that might further improve the beneficiary assignment methodology. However, we are giving priority to supplementing the current claims-based assignment process with a voluntary alignment process that incorporates beneficiary attestation about their ''main doctor'' which we believe will more directly help ACOs to increase patient engagement, improve care management and health outcomes, and lower expenditures for beneficiaries. The process may also be advantageous for beneficiaries by improving engagement between the beneficiary and the practitioner they believe is primarily responsible for their overall care.

Comment: A commenter suggested CMS provide incentives for beneficiaries who designate an ACO professional within the ACO.

Response: We are unclear as to what incentives this commenter was suggesting but we would note that we do not believe we have authority under the Shared Savings Program to provide incentives for beneficiaries who designate an ACO professional within the ACO as their ''main doctor.'' Further, the ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals and entities performing functions and services related to ACO activities are prohibited from providing or offering gifts or other remuneration to Medicare beneficiaries as inducements to influence a Medicare beneficiary's decision to designate or not designate an

ACO professional as responsible for coordinating their overall care.

Comment: We received several comments supporting the proposals to prohibit ACOs from directly or indirectly influencing a Medicare beneficiary's decision to designate or not designate an ACO professional as responsible for coordinating their overall care. The commenters indicated this could help ensure that ACOs do not ''cherry-pick'' the healthiest patients or ''lemon-drop'' patients with certain complex, costly diseases. Some commenters also urged CMS to put in place mechanisms to monitor the impact of voluntary alignment on the composition of ACOs' assigned beneficiary populations, especially with regard to any changes in the prevalence of patients with certain complex, costly diseases within a specific ACO.

Response: We intend to monitor the implementation of voluntary alignment. As noted above in this section, we emphasize that we do not intend for the voluntary alignment process to be used as a mechanism for ACOs (or their ACO participants, ACO providers/suppliers, ACO professionals or other individuals or entities performing functions or services on behalf of the ACO) to target beneficiaries for whose treatment the ACO might expect to earn shared savings, or to avoid those for whose treatment the ACO might be less likely to generate shared savings. However, we believe it is important to promote engagement and discussion between beneficiaries and their healthcare providers. Therefore ACOs, ACO participants, ACO providers/suppliers, and ACO professionals are not prohibited from providing a beneficiary with accurate descriptive information about the potential patient care benefits of designating an ACO professional as responsible for the beneficiary's overall care.

Final Action: We are finalizing our proposal to incorporate beneficiary preference into ACO assignment as proposed with two modifications as noted above. In addition, we are making a minor editorial revision to paragraph (b) of § 425.402 in order to more clearly identify beneficiaries assigned by the claims-based assignment methodology.

- We no longer intend to develop a manual voluntary alignment process as an alternative for ACOs participating in Track 3 in the event an automated process is not ready for performance year 2018, and instead will focus on developing and implementing an automated voluntary alignment process with the intent of incorporating beneficiary designations into the current claims-based assignment algorithm beginning with the 2018 performance year. If an automated system is not available during the assignment window for the 2018 performance year, then voluntary alignment would not be used for performance year 2018.
- We are modifying our proposed policy to incorporate new or revised beneficiary attestations and align such beneficiaries to ACOs in Tracks 1 and 2 on a quarterly basis and instead will incorporate these updates and align such beneficiaries prospectively for all tracks at the beginning of each performance and benchmark year, provided the beneficiary is eligible for assignment to the ACO in which their designated ''main doctor'' is participating.
- We are modifying § 425.402, paragraph (b), by removing the phrase ''beneficiaries to an ACO:'' and adding in its place the phrase ''beneficiaries to an ACO based on available claims information.'' This revision is necessary to ensure understanding that the procedure described under paragraph (b) is based on claims data, not on other data that may be available (such as voluntary alignment data).

We are also revising the regulations governing the assignment methodology to amend § 425.402(b) and add a new paragraph (e) to § 425.402. Beginning in performance year 2018, if a system is available to allow beneficiaries to designate a provider or supplier as responsible for coordinating their overall care and for CMS to process the designation electronically, beneficiaries that have voluntarily aligned with an ACO by designating an ACO professional whose services are used in assignment as responsible for coordinating their overall care will be added to the ACO's list of assigned beneficiaries, for a benchmark or performance year under the following conditions:

- The beneficiary must have had at least one primary care service during the assignment window as defined under § 425.20 with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 of this subpart or who has one of the primary specialty designations included in § 425.402(c).
- The beneficiary must meet the assignment eligibility criteria established in § 425.401(a), and must not be excluded by the criteria at § 425.401(b). Such exclusion criteria shall apply to all tracks for purposes of alignment based on beneficiary designation information.
- The beneficiary must have designated an ACO professional who is a primary care physician as defined at § 425.20 of this part, a physician with a specialty designation included at § 425.402(c) of this subpart, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for their overall care.
- The designation must be made in the form and manner and by a deadline determined by CMS.

In contrast, if a beneficiary designates a provider or supplier outside the ACO, who is a primary care physician as defined at § 425.20 of this part, a physician with a specialty designation included at § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year or benchmark year, even if the beneficiary would otherwise be included in the ACO's assigned beneficiary population under the assignment methodology in § 425.402(b).

Further, we are finalizing our proposal that the ACO and its ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions or services related to ACO activities are prohibited from providing or offering gifts or other remuneration to Medicare beneficiaries as inducements to influence a Medicare beneficiary's decision to designate or not designate an ACO professional under § 425.402(e). The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions or services related to ACO activities must not directly or indirectly, commit any act or omission, nor adopt any policy that coerces or otherwise influences a Medicare beneficiary's decision to designate or not designate an ACO professional as responsible for coordinating their overall care, including but not limited to the following:

- Offering anything of value to the Medicare beneficiary as an inducement to influence the Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care. Any items or services provided in violation of this prohibition will not be considered to have a reasonable connection to the medical care of the beneficiary, as required under § 425.304(a)(2).
- Withholding or threatening to withhold medical services or limiting or threatening to limit access to care.

We will provide further operational details regarding the voluntary alignment process and the applicable

implementation timelines through subregulatory guidance and other outreach activities.

3. SNF 3-Day Rule Waiver Beneficiary Protections

a. 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), 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 for their prospectively assigned beneficiaries when they are admitted to certain ''SNF affiliates,'' that is, SNFs with whom the ACO has executed SNF affiliate agreements. (See § 425.612(a)(1)). Waivers are effective upon CMS notification 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 that have been approved to implement the waiver that 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 a waiver applies to SNF services furnished to a particular beneficiary 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) during the performance year), so it will be clearer to a Track 3 ACO 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 for ACOs, ACO providers/suppliers, SNF affiliates, and beneficiaries with respect to the SNF 3-day rule waiver under the Shared Savings Program. All ACOs electing to participate in Track 3 will be 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. We began accepting the first SNF 3-day rule waiver applications from Track 3 ACOs this past summer.

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 at § 425.612(a)(1)(ii).

For a SNF to be eligible to partner with ACOs for purposes of the waiver, the SNF must have an overall quality rating of 3 or more stars under the CMS 5 Star Quality Rating System, and must sign a written agreement with the ACO, which we refer to as the ''SNF affiliate agreement,'' that includes elements determined by CMS, including: A clear indication of the effective dates of the SNF affiliate agreement; agreement to comply with Shared Savings Program rules, including but not limited to those specified in the participation agreement between the ACO and CMS; agreement to validate beneficiary eligibility to receive covered SNF services under the waiver prior to admission; remedial processes and penalties for noncompliance with the terms of the waiver, and other requirements set forth at § 425.612(a)(1)(iii). The SNF affiliate agreement must include these elements to ensure that the SNF affiliate understands its responsibilities related to implementation of the SNF 3-day rule waiver.

We indicated in the June 2015 final rule that the SNF 3-day rule waiver would be effective no earlier than January 1, 2017; thereafter, the waiver will be effective upon CMS notification to the ACO of approval for the waiver or the start date of the ACO's participation agreement, whichever is later, and will not extend beyond the term of the ACO's participation agreement.

We also indicated in the June 2015 final rule that we established the timeline for implementation of the SNF 3-day rule waiver to allow for development of additional subregulatory guidance, including necessary education and outreach for ACOs, ACO participants, ACO providers/suppliers, and SNF affiliates. We noted 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. We indicated that in the event we determined that additional safeguards or protections for beneficiaries or other changes were necessary, such as to incorporate additional protections for beneficiaries into the ACO's participation agreement or SNF affiliate agreements, we would propose the necessary changes through future rulemaking.

In considering additional beneficiary protections that may be necessary to ensure proper use of the SNF 3-day rule waiver under the Shared Savings Program, we note that there are existing, well established payment and coverage policies for SNF services based on sections 1861(i), 1862(a)(1), and 1879 of the Act that include protections for beneficiaries from liability for certain non-covered SNF charges. These existing payment and coverage policies for SNF services continue to apply to SNF services furnished to beneficiaries assigned to ACOs participating in the Shared Savings Program, including services furnished pursuant to the SNF 3-day rule waiver. (For example, see the Medicare Claims Processing Manual, Chapter 30—Financial Liability Protections, section 70, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/*

Downloads/clm104c30.pdf; Medicare Coverage of Skilled Nursing Facility Care beneficiary booklet, Section 6: Your Rights & Protections, available at *https://www.medicare.gov/Pubs/pdf/10153.pdf*; and Medicare Benefit Policy Manual, Chapter 8—Coverage of Extended Care (SNF) Services Under Hospital Insurance available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c08.pdf*). In general, CMS requires that the SNF inform a beneficiary in writing about services and fees before the beneficiary is admitted to the SNF (§ 483.10(b)(6)); the beneficiary cannot be charged by the SNF for items or services that were not requested (§ 483.10(c)(8)(iii)(A)); a beneficiary cannot be required to request extra services as a condition of continued stay (§ 483.10(c)(8)(iii)(B)); and the SNF must inform a beneficiary that requests an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be (§ 483.10(c)(8)(iii)(C)). (See also section 6 of Medicare Coverage of Skilled Nursing Facility Care at *https://www.medicare.gov/Pubs/pdf/10153.pdf*.)

b. Proposals

Since publication of the June 2015 final rule, we have continued to learn from implementation and refinement of the SNF 3-day rule waiver in the Pioneer ACO Model (see *https://innovation.cms.gov/initiatives/Pioneer-aco-model/*) and the Next Generation ACO Model (see *https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model*). Based on these experiences, we indicated in the proposed rule that we believe there are situations where it would be appropriate to require additional beneficiary financial protections under the SNF 3-day rule waiver for the Shared Savings Program. Specifically, we are concerned about potential beneficiary financial liability for non-covered Part A SNF services that might be directly related to use of the SNF 3-day rule waiver under the Shared Savings Program.

First, one example of a scenario under which a beneficiary may be at financial risk relates to the quarterly exclusions from a Track 3 ACO's prospective assignment list. For example, assume a beneficiary was prospectively assigned to a Track 3 ACO that has been approved for the SNF 3-day rule waiver (a waiver-approved ACO), but during the first quarter of the year, the beneficiary's Part B coverage terminated and the beneficiary is therefore no longer eligible to be assigned to the ACO. As a result, the beneficiary would be excluded from the ACO's prospective assignment list because the beneficiary meets one or more of the exclusion criteria specified at § 425.401(b). That is, although SNF services are covered under Part A, not Part B, the beneficiary would be dropped from the ACO's prospective assignment list if during the performance year the beneficiary is no longer enrolled in Part B and thus no longer eligible to be assigned to the ACO. We are concerned about some very limited situations, such as when a beneficiary's Part B coverage terminates during a quarter when the beneficiary is also receiving SNF services. The beneficiary may be admitted to a SNF without a prior 3-day inpatient hospital stay after his or her Part B coverage ended, but before the beneficiary appears on a quarterly exclusion list. It is not operationally feasible for CMS to notify the ACO and for the ACO, in turn, to notify its SNF affiliates, ACO participants, and ACO providers/suppliers immediately of the beneficiary's exclusion. The lag in communication may then cause the SNF affiliate to unknowingly admit a beneficiary who no longer qualifies for the waiver without a prior 3-day inpatient hospital stay. Absent specific beneficiary protections, we are concerned that the beneficiary could be charged for such non-covered SNF services. We do not believe it would be appropriate for CMS to hold the beneficiary or the SNF affiliate financially liable for such services. We believe we should allow for a reasonable amount of time for CMS to communicate beneficiary exclusions to an ACO and for the ACO to communicate the exclusions to its SNF affiliates, ACO participants, and ACO providers/suppliers. Typically there would be no way for the SNF affiliate to verify in real-time that a beneficiary continues to be prospectively assigned to the ACO; the SNF affiliate must rely upon the assignment list and quarterly exclusion lists provided by CMS to the ACO and communicated by the ACO to its SNF affiliates, ACO participants, and ACO providers/suppliers. Further, the beneficiary does not receive a notification regarding his or her eligibility for the SNF 3-day rule waiver prior to receiving SNF services under the waiver, so beneficiaries are not able to check their own eligibility.

To address delays in communicating beneficiary exclusions from the prospective assignment list, the Pioneer ACO Model and Next Generation ACO Model provide for a 90-day grace period that functionally acts as an extension of beneficiary eligibility for the SNF 3-day rule waiver and permits some additional time for the ACO to receive quarterly exclusions lists from CMS and communicate beneficiary exclusions to its SNF affiliates. In the proposed rule, we stated that we believe it would be appropriate, in order to protect beneficiaries from potential financial liability related to the SNF 3-day rule waiver under the Shared Savings Program, to establish a similar 90-day grace period in the case of a beneficiary who was prospectively assigned to a waiver-approved ACO at the beginning of the performance year but is later excluded from assignment to the ACO.

Therefore, we explained that we believe it is necessary for purposes of carrying out the Shared Savings Program to allow formerly assigned beneficiaries to receive covered SNF services under the SNF 3-day rule waiver when the beneficiary is admitted to a SNF affiliate within a 90-day grace period following the date that CMS delivers the quarterly beneficiary exclusion list to an ACO. The equitable and efficient implementation of the SNF 3-day rule waiver is necessary to further support ACOs' efforts to increase quality and decrease costs under two-sided performance-based risk arrangements. (See 80 FR 32804 for a detailed discussion of the rationale for establishing the SNF 3-day rule waiver.) Based upon the experience in the Pioneer ACO Model, we believe it is not possible to adopt such a waiver without providing some protection for certain beneficiaries who were prospectively assigned to the ACO at the start of the year, but are subsequently excluded from assignment. Accordingly, we proposed to modify the waiver to include a 90-day grace period to allow sufficient time for CMS to notify the ACO of any beneficiary exclusions, and for the ACO then to inform its SNF affiliates, ACO participants, and ACO providers/suppliers of those exclusions.

More specifically, we proposed to modify the waiver under § 425.612(a)(1) to include a 90-day grace period that would permit payment for SNF services provided to beneficiaries who were initially on the ACO's prospective assignment list for a performance year but were subsequently excluded during the performance year. CMS would make payments for SNF services furnished to such a beneficiary under the terms of the SNF 3-day rule waiver if the following conditions are met:

- The beneficiary was prospectively assigned to a waiver-approved ACO at the beginning of the performance year

but was excluded in the most recent quarterly exclusion list.

- The SNF affiliate services are furnished to a beneficiary admitted to the SNF affiliate within 90 days following the date that we deliver the quarterly exclusion list to the ACO.
- We would have otherwise made payment to the SNF affiliate for the services under the SNF 3-day rule waiver, but for the beneficiary's exclusion from the waiver-approved ACO's prospective assignment list.

We further noted that we anticipate that there would be very few instances where it would be appropriate for SNF services to qualify for payment under this 90-day grace period. This is because this waiver only allows for payment for claims that meet all applicable requirements except the requirement for a prior 3-day inpatient hospital stay. For example, assume that a beneficiary who had been assigned to a waiver-approved ACO was admitted to a SNF without a prior 3-day inpatient hospital stay after his or her enrollment in an MA Plan, but before the beneficiary appears on a quarterly exclusion list. In this case, these SNF services would not be covered under FFS because the waiver does not expand coverage to include services furnished to Medicare beneficiaries enrolled in MA Plans. Both beneficiaries and healthcare providers are expected to know that the beneficiary is covered under an MA plan and not FFS Medicare.

Second, we are concerned that there could be other more likely scenarios where a beneficiary could be charged for non-covered SNF services that were a result of an ACO's or SNF's inappropriate use of the SNF 3-day rule waiver. Specifically, we are concerned that a beneficiary could be charged for non-covered SNF services if a SNF affiliate were to admit a FFS beneficiary who is not prospectively assigned to the waiver-approved ACO, and payment for SNF services is denied for lack of a qualifying inpatient hospital stay.

We believe this situation could occur as a result of a breakdown in one or more of processes the ACO and SNF affiliate are required to have in place to implement the waiver. For example, the SNF affiliate and the admitting ACO provider/supplier may not verify that the beneficiary appears on the ACO's prospective assignment list prior to admission, as required under the SNF 3-day rule waiver (§ 425.612(a)(1)(iii)(B)(4)) and the terms of the SNF's affiliate agreement with the ACO. In this scenario, Medicare would deny payment of the SNF claim under existing FFS rules because the beneficiary did not have a qualifying inpatient hospital stay. We are concerned that, once the claim is rejected, the beneficiary may not be protected from financial liability, and thus could be charged by the SNF affiliate for these non-covered SNF services that were a result of an inappropriate attempt to use the waiver, potentially subjecting the beneficiary to significant financial liability. However, in this scenario, a SNF with a relationship to the ACO submitted the claim that was rejected for lack of a qualifying inpatient hospital stay, but that otherwise would have been paid by Medicare. In this circumstance, we proposed to assume the SNF's intent was to rely upon the SNF 3-day rule waiver, but the waiver requirements were not met. We believe it is reasonable to assume the SNF's intent was to use the SNF 3-day rule waiver because, as a SNF affiliate, the SNF should be well aware of the ability to use the SNF 3-day rule waiver and, by submitting the claim, demonstrated an expectation that CMS would pay for SNF services that would otherwise have been rejected for lack of a 3-day inpatient hospital stay. We believe that in this scenario, the rejection of the claim under the SNF 3-day rule waiver could easily have been avoided if the ACO, the admitting ACO provider/supplier, and the SNF affiliate had confirmed that the requirements for use of the SNF 3-day rule waiver were satisfied. Because each of these entities is in a better position to know the requirements of the waiver and ensure that they are met than the beneficiary is, we believe that the ACO and/or the SNF affiliate should be accountable for such rejections and the SNF affiliate should be prevented from attempting to charge the beneficiary for the non-covered SNF stay.

To address situations similar to this scenario where the beneficiary may be subject to financial liability due to an eligible SNF submitting a claim that is not paid only as a result of the lack of a qualifying inpatient hospital stay, the Next Generation ACO Model generally places the financial responsibility on the SNF, where the SNF knew or reasonably could be expected to have known that payment would not be made for the non-covered SNF services. In such cases, CMS makes no payment for the services and the SNF may not charge the beneficiary for the services and must return any monies collected from the beneficiary. Additionally, under the Next Generation ACO Model, the ACO must indemnify and hold the beneficiary harmless for payment for the services. We believe it is appropriate to propose to adopt a similar policy under the Shared Savings Program because, under § 425.612(a)(1)(iii)(B), to be a SNF affiliate, a SNF must agree to validate the eligibility of a beneficiary to receive covered SNF services in accordance with the waiver prior to admission to the SNF, and otherwise comply with the requirements and conditions of the Shared Savings Program. SNF affiliates are required to be familiar with the SNF 3-day rule and the terms and conditions of the SNF 3-day rule waiver for the Shared Savings Program, and should know to verify that a FFS Medicare beneficiary who is a candidate for admission has completed a qualifying hospital stay or that the admission meets the criteria under a waiver of the SNF 3-day rule that is properly in place. Additionally, ACOs and their SNF affiliates are required to develop plans that will govern communication and beneficiary evaluation and admission prior to use of the SNF 3-day rule waiver. In these circumstances, we believe it is reasonable that the ultimate responsibility and liability for a non-covered SNF admission should rest with the admitting SNF affiliate.

Therefore, to protect FFS beneficiaries from being charged in certain circumstances for non-covered SNF services related to the waiver of the SNF 3-day rule under the Shared Savings Program, potentially subjecting such beneficiaries to significant financial liability, we proposed to add certain beneficiary protection requirements in § 425.612(a)(1). These requirements would apply to SNF services furnished by a SNF affiliate that would otherwise have been covered except for the lack of a qualifying hospital stay preceding the admission to the SNF affiliate. Specifically, we proposed that we would make no payment to the SNF, and the SNF may not charge the beneficiary for the non-covered SNF services, in the event that a SNF that is a SNF affiliate of a Track 3 ACO that has been approved for the SNF 3-day rule waiver admits a FFS beneficiary who was never prospectively assigned to the waiver-approved ACO (or was assigned but later excluded and the 90 day grace period has lapsed), and the claim is rejected only for lack of a qualifying inpatient hospital stay.

In this situation, we proposed that we would apply the following rules:

- We would make no payment to the SNF affiliate for such services.
- The SNF affiliate must not charge the beneficiary for the expenses incurred for such services, and the SNF affiliate must return to the beneficiary any monies collected for such services.

• The ACO may be required to submit a corrective action plan to CMS for approval as specified at § 425.216(b) addressing what actions the ACO will take to ensure that the SNF 3-day rule waiver is not misused in the future. If after being given an opportunity to act upon the corrective action plan the ACO fails to come into compliance, approval to use the waiver will be terminated in accordance with § 425.612(d). We noted that in accordance with our existing program rules at §§ 425.216 and 425.218, CMS retains the authority to take corrective action, including terminating an ACO for non-compliance with program rules. A misuse of a waiver under § 425.612 would constitute non-compliance with program rules. Accordingly, we proposed to codify at new provision at § 425.612(d)(4) providing that misuse of a waiver under § 425.612 may result in CMS taking remedial action against the ACO under §§ 425.216 and 425.218, up to and including termination of the ACO from the Shared Savings Program.

We proposed that if the SNF submitting the claim is a SNF affiliate of a waiver-approved ACO, and the only reason for the rejection of the claim is lack of a qualifying inpatient hospital stay, then CMS would assume the SNF intended to rely upon the SNF 3-day rule waiver. We would not assume the SNF intended to rely upon the SNF 3-day rule waiver if the SNF is not a SNF affiliate of a waiver-approved ACO because the waiver is not available to SNFs more broadly. We explained that we believe intended reliance on the waiver is an important factor in determining whether the proposed additional beneficiary protections should apply. Outside the context of an intent to rely on the SNF 3-day rule waiver, we do not believe it would be necessary to include additional beneficiary protections under the Shared Savings Program because there is no reason for either the beneficiary or the SNF to expect that different coverage rules would apply to SNF services. In these other situations, the beneficiary protections generally applicable under traditional FFS Medicare, noted earlier in this section, continue to apply.

We solicited comments on these proposals. We noted that under our proposed beneficiary protection provision, a SNF affiliate would be prohibited from charging a beneficiary for non-covered SNF services even in cases where the beneficiary explicitly requested or agreed to being admitted to the SNF in the absence of a qualifying 3-day hospital stay if all other requirements for coverage are met. We therefore specifically solicited comment on whether it is reasonable to hold SNFs that are SNF affiliates responsible for all claims that are rejected solely as a result of lack of a qualifying inpatient hospital stay. We also solicited comment on whether the ACO rather than or in addition to the SNF affiliate, should be held liable for such claims and under what circumstances. We also solicited comment on our proposal to modify the waiver under § 425.612(a)(1) to include a 90-day grace period for beneficiaries prospectively assigned to a waiver-approved ACO at the start of the performance year but later excluded. We solicited comment on the proposed length of the grace period, and in particular whether the grace period should be less than 90 days, given our expectation that ACOs will share the quarterly beneficiary exclusion lists with their SNF affiliates, ACO participants, and ACO providers/suppliers in a timely manner. Finally, we solicited comment on any other related issues that we should consider in connection with these proposals to protect beneficiaries from significant financial liability for non-covered SNF services related to the waiver of the SNF 3-day rule under the Shared Savings Program.

The following is a summary of the comments we received on these proposals.

Comment: Commenters, in general, supported the proposed enhanced beneficiary protections under the SNF 3-day rule waiver that are largely consistent with the beneficiary protections in place under the Next Generation ACO Model. Commenters agreed that it would be appropriate to hold beneficiaries harmless for non-covered SNF services if a SNF affiliate admitted a beneficiary who was not qualified for the waiver without a qualifying inpatient stay. Commenters also generally agreed that a 90-day grace period from the date that CMS delivers the quarterly beneficiary exclusion list to ACOs is a reasonable period to allow ACOs to incorporate beneficiary exclusions into their processes, including communicating the updated beneficiary information to ACO participants, ACO providers/suppliers, and SNF affiliates. Although most commenters supported the proposals without additional elaboration, a few commenters expressed other specific concerns or made additional suggestions which are addressed in this section.

Response: We appreciate commenters' support for our proposal to incorporate enhanced beneficiary protections under the SNF 3-day rule waiver that are largely consistent with the beneficiary protections in place under the Next Generation ACO Model.

Comment: A commenter recommended that the first grace period of the calendar year be extended to accommodate a very large exclusion file that is distributed in July. This commenter further noted that the July exclusion file often includes a change in file format or other criteria for files transmitted to ACOs, such that it requires significant time to work through the data file transmission and loading process.

Response: We are a somewhat unclear about the concerns regarding the exclusion file referenced in this comment and believe they may perhaps relate to an EHR measure exclusion file that is unrelated to the quarterly beneficiary exclusion process. Regardless, we believe a 90-day grace period is more than sufficient time for the appropriate communications to occur regarding exclusions from the prospective assignment list. Under the rules governing the SNF 3-day rule waiver, the ACO must have a communication plan, a beneficiary evaluation and admission plan, and a care management plan in place prior to our approval of the ACO for use of the waiver. The requirement that an ACO have these plans in place should help to mitigate concerns regarding the length of the grace period by ensuring that the ACO has established procedures in place to govern communications between the ACO, its SNF affiliates, ACO participants, and ACO providers/suppliers regarding beneficiary eligibility and admissions under the terms of the waiver. Thus, we continue to believe that a 90-day grace period is a sufficient time period for an ACO to process the quarterly exclusion list and transmit any beneficiary exclusions to its ACO participants, ACO providers/suppliers, and SNF affiliates.

Comment: Some commenters supported our proposal that no payments would be made to SNF affiliates for SNF services furnished without a qualifying inpatient hospital stay to beneficiaries who are not assigned to the ACO or who are not in the 90-day grace period. These commenters agreed that the financial responsibility for SNF stays that do not meet the waiver criteria should lie with the SNF because, in accordance with our rules for use of the waiver by SNF affiliates, SNF affiliates are responsible for confirming a beneficiary's eligibility to receive services under the waiver prior to admission. Some commenters disagreed with this aspect of the proposal, suggesting that ACOs should be responsible for at least some the

liability. One commenter indicated that, SNF affiliates should not be accountable for identifying waiver-eligible beneficiaries and suggested that CMS ''require hospitals to share the list of waiver-eligible Track 3-enrolled beneficiaries with all of their ACOs and partner SNFs.'' This commenter also requested that CMS explore additional policies that would give SNF affiliates independent access to beneficiary waiver eligibility information that they could access prior to admission to verify if a beneficiary meets the eligibility requirements for the waiver. To illustrate possibilities, the commenter suggested that CMS could: (1) Make it a requirement for SNF affiliate agreements that the ACO provide all SNF affiliates with timely, accurate lists of waiver-eligible beneficiaries; or (2) CMS could integrate information regarding eligibility for the SNF 3-day rule waiver into the Common Working File so that SNFs may independently verify a beneficiary's eligibility under the waiver.

Response: After reviewing the comments, we continue to believe the proposed policy, which is based on beneficiary protections under the Next Generation ACO Model, is also appropriate under the Shared Savings Program. Under § 425.612(a)(1)(iii)(B), in order to be a SNF affiliate, a SNF must agree to validate the eligibility of a beneficiary to receive covered SNF services in accordance with the waiver prior to admission to the SNF, and otherwise comply with the requirements and conditions of the Shared Savings Program. As a result, we do not believe it is unreasonable to hold the SNF affiliate financially responsible if it admits a beneficiary that is neither prospectively assigned to a Track 3 ACO nor in a 90-day grace period without a qualifying inpatient hospital stay. We also believe it is reasonable to hold the SNF affiliate fully responsible under these circumstances because a SNF affiliate is obligated under the terms and conditions of the SNF 3-day rule waiver to validate the beneficiary's eligibility for use of the waiver prior to admission.

Further, we do not believe that it is necessary to include the suggested additional requirements for SNF affiliate agreements. The current requirements provide SNFs with the flexibility to address, in their SNF affiliate agreements with Track 3 ACOs, any concerns they may have about the processes used by ACOs to communicate which beneficiaries are eligible to receive covered SNF services under the waiver.

ACOs must create and implement a communication plan between the ACO and all of its SNF affiliates as required at § 425.612(a)(1)(i)(A)(1). In accordance with our SNF waiver guidance on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SNF-Waiver-Guidance.pdf*, the communication plan should include detailed communication processes including for example, identifying and designating person(s) at the ACO with whom SNF affiliates will communicate and coordinate admissions, and explaining how the ACO will respond to questions and complaints related to the ACO's use of the SNF 3-day waiver from SNF affiliates, ACO participants, ACO providers/suppliers, beneficiaries, acute care hospitals, and other stakeholders.

ACOs are also required to establish a beneficiary evaluation and admission plan for beneficiaries admitted to a SNF affiliate under the SNF 3-day rule waiver that is approved by the ACO medical director and the healthcare professional responsible for the ACO's quality improvement and assurance processes under § 425.112. Further, as part of their waiver application, ACOs are required to describe how they plan to evaluate and periodically update their plan (see section 6 of the guidance at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SNF-Waiver-Guidance.pdf*). It is also recommended in the guidance that the beneficiary evaluation and admission plan include detailed requirements including, for example, a protocol for an ACO provider/supplier who is a physician to evaluate and approve admissions to a SNF affiliate pursuant to the waiver and consistent with the beneficiary eligibility requirements described at § 425.612(a)(1)(ii) and a protocol for educating and training SNF affiliates regarding waiver requirements and the ACO's communications plan, beneficiary evaluation and admission plan, and care management plan for purposes of the SNF 3-Day Waiver.

We believe these requirements adequately address the commenter's concerns about SNF affiliates' ability to verify beneficiaries' eligibility to receive covered SNF services under the SNF 3-day rule waiver. However, as we develop operational procedures and guidance documents, we will further consider whether it would be feasible to develop a mechanism that could permit SNF affiliates to verify, though a source other than the ACO, a beneficiary's eligibility to receive SNF services under the waiver.

Comment: A few commenters suggested that ACOs should not be required to submit a corrective action plan in cases where the SNF affiliate, not the ACO, is responsible for inappropriate use of the waiver, as such corrective action plans could be resource intensive for ACOs.

Response: We continue to believe that in some circumstances it could be appropriate for an ACO to be required to submit a corrective action plan, including in some cases where a SNF affiliate may be responsible for inappropriate use of the SNF 3-day rule waiver. The possibility of compliance action provides an incentive for ACOs to work together with their SNF affiliates to ensure that the SNF 3-day rule waiver is used appropriately, and reflects the requirement that ACOs must enter into agreements with their SNF affiliates that contain detailed requirements providing for the proper use of the waiver. We are finalizing the proposal that in cases where a SNF affiliate of a Track 3 ACO has misused the SNF 3-day rule waiver, the ACO may be required to submit a corrective action plan to CMS for approval as specified at § 425.216(b) addressing what actions the ACO will take to ensure that the SNF 3-day rule waiver is not misused in the future. We are also finalizing the proposal to codify a new provision at § 425.612(d)(4) providing that misuse of a waiver under § 425.612 may result in CMS taking remedial action against the ACO under §§ 425.216 and 425.218, up to and including termination of the ACO from the Shared Savings Program.

Comment: One commenter suggested that CMS should also modify the existing financial protections in the Medicare Claims Processing Manual Chapter 30—Financial Protections at section 70.2.2.2 to address the SNF 3-day rule waiver rules.

Response: We will further consider whether revisions are necessary to the Medicare Claims Processing Manual and/or other guidance documents related to SNF discharges and billing.

Final Action: We are finalizing the SNF 3-day rule waiver beneficiary protections described in this section as proposed. Specifically, we are modifying the SNF 3-day rule waiver under § 425.612(a)(1) to include a 90-day grace period that will permit payment for SNF services provided to beneficiaries without a qualifying inpatient stay who were initially on the ACO's prospective assignment list for a performance year but were subsequently excluded during the performance year, if such services would otherwise be covered under the SNF 3-day rule waiver. In addition, in the event that a SNF that is a SNF affiliate of a Track 3 ACO that has been approved for the

SNF 3-day rule waiver admits a FFS beneficiary who was never prospectively assigned to the ACO (or was assigned but later excluded and the 90-day grace period has lapsed), and the claim is rejected only for lack of a qualifying inpatient hospital stay, we will make no payment to the SNF, and the SNF may not charge the beneficiary for the non-covered SNF services. In this circumstance, the SNF affiliate will be prohibited from charging a beneficiary for non-covered SNF services even in cases where the beneficiary explicitly requested or agreed to being admitted to the SNF in the absence of a qualifying 3-day hospital stay, if all other requirements for coverage are met. We are also adding a provision at § 425.612(d)(4) providing that misuse of a waiver under § 425.612 may result in CMS taking remedial action against the ACO under §§ 425.216 and 425.218, up to and including termination of the ACO from the Shared Savings Program.

We strongly believe it is important to ensure that beneficiaries have appropriate financial protections, including financial protection against misuse of the waiver prior to approving any SNF 3-day rule waiver applications from Track 3 ACOs. We also recognize that ACOs and their SNF affiliates could be reluctant to enter into a SNF affiliate agreement without there being clarity as to their potential responsibility for non-covered SNF services related to the waiver. For these reasons, we are also developing a process for Track 3 ACOs that have already applied for the SNF 3-day rule waiver for the 2017 performance year to confirm that they and their SNF affiliates agree to comply with all requirements related to the SNF 3-day rule waiver, including the new requirements we are adopting in this rulemaking. ACOs and SNF affiliates that do not agree to comply with all requirements will be ineligible to offer services under the SNF 3-day rule waiver. We note that this confirmation process may delay approval of ACOs' applications for the SNF 3-day rule waiver for the 2017 performance year; however, we do not anticipate approval will be delayed beyond the first quarter of 2017.

4. Technical Changes

a. Financial Reconciliation for ACOs That Fall Below 5,000 Assigned Beneficiaries

Section 1899(b)(2)(D) of the Act includes a requirement that a participating ACO must have a minimum of 5,000 Medicare FFS beneficiaries assigned to it. Currently, the regulations at § 425.110(b) indicate that if at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO may be subject to the actions described in §§ 425.216 and 425.218; the regulations further indicate at § 425.110(b)(1) that while under a CAP, the ACO remains eligible for shared savings and losses and the MSR and MLR (if applicable) is set at a level consistent with the number of assigned beneficiaries. We have applied this rule in the past to perform financial reconciliation for ACOs that fell below 5,000 assigned beneficiaries. In these cases, the ACO was subject to a CAP and financial reconciliation was based on a variable MSR/MLR that was determined by the number of assigned beneficiaries. For example, we have calculated the ACO's MSR based on an expanded sliding scale that includes a range of 3,000 to 4,999 assigned beneficiaries with a corresponding MSR range of 5.0 to 3.9 percent.

However, ACOs under risk-based tracks are not limited to financial reconciliation under a variable MSR/MLR that is based on the number of assigned beneficiaries. In the June 2015 final rule (see 80 FR 32769–32771, and 32779–32780), we finalized a policy that provides ACOs under two-sided performance-based risk tracks with an opportunity to choose among several options for establishing their MSR/MLR. In addition to being able to choose a symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries, ACOs under two-sided performance-based risk tracks can also choose from a menu of non-variable MSR/MLR options (either a 0 percent MSR/MLR or a symmetrical MSR/MLR in a 0.5 percent increment between 0.5 through 2.0 percent).

We stated in the CY 2017 PFS proposed rule that we believe it is important to clarify the policy regarding situations where an ACO under a two-sided performance-based risk track has chosen a non-variable MSR/MLR at the start of the agreement period but has fallen below 5,000 assigned beneficiaries at the time of financial reconciliation. As discussed in detail in the June 2015 final rule, we continue to believe that ACOs under two-sided performance-based risk tracks are best positioned to determine the level of risk that they are prepared to accept. Therefore, we proposed to update the regulations at § 425.110(b)(1) to be consistent with the regulatory changes in the June 2015 final rule that permit ACOs under a two-sided performance-based risk track (Track 2 and Track 3) to choose their own MSR/MLR from a menu of options. Specifically, we proposed to update the regulations at § 425.110(b)(1) to indicate that in the event an ACO falls below 5,000 assigned beneficiaries at the time of financial reconciliation, the ACO participating under a two-sided risk track will be eligible to share in savings (or losses) and the MSR/MLR will be set at a level consistent with the choice of MSR/MLR that the ACO made at the start of the agreement period. If the Track 2 or Track 3 ACO selected a symmetrical MSR/MLR option based on a fixed percentage (for example, zero percent or a percentage between 0.5 and 2 percent) regardless of ACO size, then the current methodology for use of a variable MSR/MLR based on the ACO's number of assigned beneficiaries would not apply. For example, if at the beginning of the agreement period the ACO chose a 1.0 percent MSR/MLR and the ACO's assigned population falls below 5,000, the MSR/MLR will remain 1.0 percent for purposes of financial reconciliation while the ACO is under a CAP. Further, as we noted in earlier rulemaking, if the ACO has elected a variable MSR/MLR, the methodology for calculating the variable MSR/MLR under a two-sided model is consistent with the methodology for calculating the variable MSR that is required under the under the one-sided model (Track 1) (see 80 FR 32769 through 32771; 32779 through 32780). Under the one-sided shared savings model (Track 1), we have accounted for circumstances where an ACO's number of assigned beneficiaries falls below 5,000, by expanding the variable MSR range based on input from the CMS Office of the Actuary (OACT). Thus, in the case where a Track 2 or Track 3 ACO selects a variable MSR/MLR based on its number of assigned beneficiaries, and the ACO's number of assigned beneficiaries falls below 5,000, we proposed to continue to use an approach for determining the MSR/MLR range consistent with the approach for calculating the MSR range under the one-sided model.

The following is a summary of the comments we received on these proposals.

Comment: Commenters supported this proposal. One commenter suggested, without providing a justification, that in the event an ACO's assigned beneficiary population falls below 5,000, the MSR be capped at 3.9 percent in cases where the MSR/MLR varies based on the number of beneficiaries. The commenter did not expressly make a similar recommendation for capping the MLR.

Response: We appreciate the support for this proposal. For ACOs with a

variable MSR and MLR (if applicable), the MSR and MLR (if applicable) will be set at a level consistent with the number of assigned beneficiaries. For ACOs with a fixed MSR/MLR, the MSR/MLR will remain fixed at the level consistent with the ACO's choice of MSR and MLR that the ACO made at the start of the agreement period. In addition, we disagree that it would be appropriate to cap the MSR (but not the MLR) at 3.9 percent in cases where the MSR/MLR varies based on the number of beneficiaries in the event the ACO falls below 5,000 assigned beneficiaries beneficiaries.

Section 1899(d)(1)(B)(i) of the Act specifies that the Secretary shall determine the appropriate percent by which an ACO's expenditures must be lower than its benchmark in order for the ACO to be eligible to share in savings to account for normal variation in expenditures under Title XVIII. Consistent with the statute, this percentage must be based upon the number of Medicare fee-for-service beneficiaries assigned to the ACO. As explained in the November 2011 final rule, we believe that the most appropriate policy concerning determination of the ''appropriate percent'' for the MSR would achieve a balance between the advantages of making incentives and rewards available to successful ACOs and prudent stewardship of the Medicare Trust Funds (76 FR 67927). Capping the MSR for Track 1 ACOs would not be consistent with the statute and our established policy for computing the MSR for Track 1 ACOs. Capping only the MSR but not the MLR for Track 2 or 3 ACOs would create an asymmetry that would make it easier for the ACO to share in savings but not in losses. To the extent that the commenter was recommending capping both the MSR and MLR for ACOs in Tracks 2 and 3 that choose a variable MSR/MLR, we believe this could be an approach worthy of consideration in future rulemaking because the approach would equalize the risk for the ACO and CMS.

Final Action: We are finalizing this policy and the revisions to § 425.110(b)(1) as proposed, but are making a minor editorial revision to paragraph (b)(1)(ii) in order to eliminate a redundant reference.

b. Requirements for Merged or Acquired TINs

ACOs frequently request that we take into account the claims billed by the TINs of practices that have been acquired by sale or merger for the purpose of meeting the minimum assigned beneficiary threshold, establishing a more accurate financial benchmark, and determining the prospective or preliminary prospective assignment list for the upcoming performance year. In response to these inquiries, we initially developed subregulatory guidance that allowed claims billed under the TIN of a merged or acquired entity to be considered in certain circumstances. In that guidance we indicated that the merged or acquired entity's TIN may no longer be used to bill Medicare. In the June 2015 final rule, we codified the policies outlined in this guidance allowing for consideration of claims billed under merged or acquired entities' TINs for purposes of beneficiary assignment and establishing the ACO's benchmark, provided certain requirements were met (§§ 425.204(g), 425.118(a)(2)). However, the regulation at § 425.204(g) indicates that an ACO may request that CMS consider, for purposes of beneficiary assignment and establishing the ACO's benchmark under § 425.602, claims billed by ''Medicare-enrolled'' entities' TINs that have been acquired through sale or merger by an ACO participant. Because the regulation at § 425.204(g) refers to such merged or acquired TINs as ''Medicare-enrolled,'' we have received inquiries from ACOs regarding whether such merged or acquired TINs must continue to be Medicare-enrolled after the merger or acquisition has been completed and the TINs are no longer used to bill Medicare.

We stated in the CY 2017 PFS proposed rule that it was not our intent to establish such a requirement. We stated we do not believe there would be a program purpose to require the TIN of a merged or acquired entity to maintain Medicare enrollment if it is no longer used to bill Medicare. Therefore, to address this issue, we proposed a technical change to § 425.204(g) to clarify that the merged/acquired TIN is not required to remain Medicare enrolled after it has been merged or acquired and is no longer used to bill Medicare.

The following is a summary of the comments we received on these proposals.

Comment: The few comments received on this issue supported the proposal.

Response: We appreciate the support for this proposal.

Final Action: We are finalizing the technical change to § 425.204(g) as proposed.

L. Value-Based Payment Modifier and Physician Feedback Program

1. Overview

Section 1848(p) of the Act requires that we establish a value-based payment modifier (VM) and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015, and to all physicians and groups of physicians by January 1, 2017. On or after January 1, 2017, section 1848(p)(7) of the Act provides the Secretary discretion to apply the VM to eligible professionals (EPs) as defined in section 1848(k)(3)(B) of the Act. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. The VM and Physician Feedback program continue CMS' initiative to recognize and reward 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 MACRA was enacted on April 16, 2015. Under section 1848(p)(4)(B)(iii) of the Act, as amended by section 101(b)(3) of MACRA, the VM shall not be applied to payments for items and services furnished on or after January 1, 2019. Section 1848(q) of the Act, as added by section 101(c) of MACRA, establishes the 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 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.

3. Provisions of This Final Rule

As a general summary, we proposed to update the VM informal review policies and establish how the quality and cost composites under the VM would be affected for the CY 2017 and CY 2018 payment adjustment periods in the event that unanticipated program issues arise.

a. Expansion of the Informal Inquiry Process To Allow Corrections for the VM

Section 1848(p)(10) of the Act provides that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

- The establishment of the VM.
- The evaluation of the quality of care composite, including the establishment of appropriate measures of the quality of care.
- The evaluation of the cost composite, including the establishment of appropriate measures of costs.
- The dates of implementation of the VM.
- The specification of the initial performance period and any other performance period.
- The application of the VM.
- The determination of costs.

These statutory requirements regarding limitations of review are reflected in § 414.1280. We previously indicated in the CY 2013 PFS final rule with comment period (77 FR 69326) that we believed an informal review mechanism is appropriate for groups of physicians to review and to identify any possible errors prior to application of the VM, and we established an informal inquiry process at § 414.1285.

In the CY 2016 PFS final rule with comment period (80 FR 71294 through 71295), for the CY 2017 and CY 2018 payment adjustment periods, we finalized a deadline of 60 days that would start after the release of the QRURs for the applicable performance period for a group or solo practitioner to request a correction of a perceived error related to the VM calculation. We also finalized the continuation of the process for accepting requests from groups and solo practitioners to correct certain errors made by CMS or a third-party vendor (for example, PQRS-qualified registry). We stated we would continue the approach of the initial corrections process to classify a TIN as ''average quality'' in the event we determine a third-party vendor error or CMS made an error in the calculation of the quality composite and the infrastructure was not available to allow for recomputation of the quality measure data. Additionally, we finalized that we would reclassify a TIN as Category 1 when PQRS determines on informal review that at least 50 percent of the TIN's EPs meet the criteria to avoid the PQRS downward payment adjustment for the relevant payment adjustment year. If the group was initially classified as Category 2, then we would not expect to have data for calculating their quality composite, in which case they would be classified as ''average quality''; however, if the data is available in a timely manner, then we would recalculate the quality composite.

As we noted in the CY 2017 PFS proposed rule (81 FR 46443 through 46444), as a result of issues that we became aware of prior to and during the CY 2016 VM informal review process, we learned that re-running QRURs and recalculating the quality composite is not always practical or possible, given the diversity and magnitude of the errors, timing of when we become aware of an error, and practical considerations in needing to compute a final VM upward payment adjustment factor after the performance period has ended, based on the aggregate amount of downward payment adjustments. Furthermore, this approach can create uncertainty for groups and solo practitioners about their final VM payment adjustment making it difficult for them to plan and make forecasts.

Due to the volume and complexities of the informal review issues, the inconsistency of available PQRS data to calculate a TIN's quality composite, the case-by-case nature of the informal review process, and the condensed timeline to calculate an accurate VM upward payment adjustment factor, we expressed our belief that we needed to update the VM informal review policies and establish in rulemaking how the quality and cost composites under the VM would be affected if unanticipated issues were to arise (for example, the program issues described in the CY 2017 PFS proposed rule), errors made by a third-party such as a vendor, or errors in our calculation of the quality and/or cost composites). We noted that the intent of these proposals is not to provide relief for EPs and groups who fail to report under PQRS, but rather to provide a mechanism for addressing unexpected issues such as the data integrity issues discussed in the proposed rule.

We further noted that limiting the potential movement of TINs between VM quality tiers based on informal review may result in a more accurate adjustment factor calculation and provide greater predictability for the CMS' Office of the Actuary (OACT) in making assumptions around the adjustment factor including assumptions around the impact of outstanding informal reviews at the time of the calculations. We expressed our belief that our proposals would help groups and solo practitioners to better predict the outcome of their final VM adjustment and reduce uncertainty as we continue to improve our systems. We requested comment on all four of the scenarios we proposed. We provide a combined summary of comments received on the four scenarios later in this section of this final rule, following the individual descriptions of the scenarios proposed.

Table 44 summarizes our proposals.

TABLE 44—QUALITY AND COST COMPOSITE STATUS FOR TINS DUE TO INFORMAL REVIEW DECISIONS AND WIDESPREAD QUALITY AND COST DATA ISSUES

	Scenario 1: TINS moving from Category 2 to Category 1 as a result of PQRS or VM informal review process		Scenario 2: Non-GPRO Category 1 TINs with additional EPs avoiding PQRS payment adjustment as a result of PQRS informal review process		Scenario 3: Category 1 TINs with widespread quality data issues		Scenario 4: Category 1 TINs with widespread claims data issues	
	Initial composite	Revised composite	Initial composite	Revised composite	Initial composite	Revised composite	Recalculated composite	Revised composite
Quality	N/A	Average	Low	Average	N/A	Average	Low	Average.
	N/A	Average	Average	Average	N/A	Average	Average	Average.
	N/A	Average	High	High	N/A	Average	High	High.
Cost	Low	Low	Low	Low	Low	Low	Low	Low.
	Average	Average	Average	Average	Average	Average	Average	Average.
	High	Average	High	High	High	Average	High	Average.

Scenario 1: TINs Moving From Category 2 to Category 1 as a Result of PQRS or VM Informal Review Process

As finalized in the CY 2016 PFS final rule with comment period, for the CY 2017 VM, Category 1 will include those groups that meet the criteria to avoid the CY 2017 PQRS payment adjustment as a group practice participating in the PQRS Group Practice Reporting Option (GPRO) in CY 2015 and groups that have at least 50 percent of the group's EPs meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals (80 FR 71280). Category 1 also includes those solo practitioners that meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals. Category 2 will include groups and solo practitioners that are subject to the CY 2017 VM and do not fall within Category 1 (79 FR 67939). We finalized a similar two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners in 2016 (80 FR 71280 through 71281).

In the CY 2017 PFS proposed rule, we proposed that, if a TIN were initially classified as Category 2, and subsequently, through the PQRS or VM informal review process, it was reclassified as Category 1, then we would classify the TIN's quality composite as ''average quality,'' instead of attempting to calculate the quality composite (81 FR 46444). We also proposed to calculate the TIN's cost composite using the quality-tiering methodology. If the TIN were classified as ''high cost'' based on its performance on the cost measures, then we proposed to reclassify the TIN's cost composite as ''average cost.'' If the TIN were classified as ''average cost'' or ''low cost'', then we proposed that the TIN would retain the calculated cost tier designation. We noted that in the CY 2016 PFS final rule with comment period (80 FR 71280), we finalized a policy for the CY 2017 and 2018 payment adjustment periods that when determining whether a group would be included in Category 1, we would consider whether the 50 percent threshold had been met, regardless of whether the group registered to participate in the PQRS GPRO for the relevant performance period. We expressed our belief that this policy would allow groups that register for a PQRS GPRO, but fail as a group to meet the criteria to avoid the PQRS payment adjustment an additional opportunity for the quality data reported by individual EPs in the group to be taken into account for the purposes of applying the VM. We noted that consequently, because of this policy we anticipate that the number of TINs who could fall into Scenario 1 would be minimal; however, we believe it is necessary to have a policy in place, in the event that CMS determines on informal review that Category 2 TINs had been negatively impacted by a third-party vendor error or CMS made an error in the calculation of the quality composite. We proposed to apply these policies for the CY 2017 VM and CY 2018 VM.

Calculating a quality composite for a TIN that was initially classified as Category 2, then reclassified as Category 1 during the informal review process would be operationally complex, given a number of factors: The timeline for determining and applying the VM adjustments for all TINs subject to the VM; the volume of informal reviews; the need to calculate the VM upward payment adjustment factor as close to the beginning of the payment adjustment period as possible; and uncertainty about the availability of the PQRS quality data. Therefore, classifying the quality composite as ''average quality'' would offer a predictable decision for all informal reviews where a TIN changes classification from Category 2 to Category 1.

Our proposal to calculate the cost composite and assign ''average cost'' if the cost composite was initially classified as ''high cost'' would alleviate concerns from stakeholders that a TIN may receive a downward VM payment adjustment under the quality-tiering methodology as a result of being classified as average quality and high cost. Under our proposal discussed above, for TINs in Scenario 1, we would not consider a TIN's actual performance on the quality measures or calculate a quality composite score; rather, we would classify the TIN's quality composite as average quality for the reasons stated above. In this scenario, we do not believe that we should retain a TIN's ''high cost'' designation when the TIN's actual cost performance is not being compared to the TIN's actual quality performance, as it is possible the TIN might have scored high quality if actual performance had been considered. We believe that these proposals would help groups and solo practitioners who receive a favorable determination on informal review to better predict the outcome of their final VM adjustment and reduce uncertainty about the impact of the informal review. Additionally, it is important to note that groups or solo practitioners who submit an informal review request would not automatically be covered by the policy proposed for Scenario 1. In the CY 2017 PFS proposed rule, we stated that we would verify on informal review that the group or solo practitioner did submit complete and accurate data and did meet the criteria to avoid the PQRS payment adjustment to be included in Category 1.

Scenario 2: Non-GPRO Category 1 TINs With Additional EPs Avoiding PQRS Payment Adjustment as a Result of PQRS Informal Review Process

As finalized in the CY 2016 PFS final rule with comment period, for the CY 2017 VM, Category 1 will include groups that have at least 50 percent of

the group's EPs meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals (80 FR 71280). A similar policy was finalized for the CY 2018 VM (80 FR 71280). In the CY 2017 PFS proposed rule (81 FR 46455), we proposed that, if a TIN were classified as Category 1 for the CY 2017 VM by having at least 50 percent of the group's EPs meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals, and subsequently, through the PQRS informal review process, it is determined that additional EPs that are in the TIN also meet the criteria to avoid the CY 2017 PQRS payment adjustment as individuals, then the following policies would be used to determine the TIN's quality and cost composites:

- If the TIN's quality composite is initially classified as ''low quality'', then we proposed to reclassify the TIN's quality composite as ''average quality.'' If the TIN's quality composite is initially classified as ''average quality'' or ''high quality'', then we proposed that the TIN would retain that quality tier designation.
- We would maintain the cost composite that was initially calculated.

We proposed to apply these policies for the CY 2017 VM and CY 2018 VM. Under these policies, we would not recalculate the TIN's quality composite to include the additional EPs that were determined to have met the criteria to avoid the PQRS payment adjustment as individuals through the PQRS informal review process. As discussed under Scenario 1, recalculating the quality composite is operationally complex, and we may not have PQRS data for the additional EPs, because they were initially determined not to have met the criteria to avoid the PQRS payment adjustment. In addition, we seek to avoid a situation where by recalculating the quality composite, a TIN may be subject to a lower quality tier designation because a few EPs in the TIN independently pursued PQRS informal reviews. As stated above, we proposed to reclassify a TIN's quality composite as average quality if it is initially classified as ''low quality'' in order to avoid a situation where we do not have the PQRS quality data for those few EPs whose quality performance could have bumped the TIN up from a low quality designation as the EPs did not meet the criteria to avoid the PQRS payment adjustment during the initial determination. Additionally, it is important to note that TINs whose EPs submit an informal review request would not automatically be covered by the policy proposed for Scenario 2. We stated in the CY 2017 PFS proposed rule that we would verify on informal review that an EP did submit complete and accurate data and did meet the criteria to avoid the PQRS payment adjustment as an individual in order for the TIN to be included in Category 1.

Scenario 3: Category 1 TINs With Widespread Quality Data Issues

In cases where there is a systematic issue with any of a Category 1 TIN's quality data that renders it unusable for calculating a TIN's quality composite, we proposed to classify the TIN's quality composite as average quality. For this proposal, we consider widespread quality data issues, as issues that impact multiple TINs and we are unable to determine the accuracy of the data submitted via these TINs (for example, the EHR and QCDR issues for the CY 2014 performance period as described in the CY 2017 PFS proposed rule (81 FR 46455). This proposal would offer a predictable designation for all TINs under this scenario.

We also proposed to calculate the TIN's cost composite using the quality-tiering methodology. If the TIN were classified as ''high cost'' based on its performance on the cost measures, then we proposed to reclassify the TIN's cost composite as ''average cost.'' If the TIN were classified as ''average cost'' or ''low cost'', then we proposed that the TIN would retain the calculated cost tier designation. We proposed to apply these policies for the CY 2017 VM and CY 2018 VM.

As discussed under Scenario 1, our proposal to calculate the cost composite and assign ''average cost'' if the cost composite is initially classified as ''high cost'' would alleviate concerns from stakeholders that a TIN may receive a downward VM payment adjustment under the quality-tiering methodology as a result of being classified as average quality and high cost. Similarly, for TINs in Scenario 3, we would not consider a TIN's actual performance on the quality measures or calculate a quality composite score; rather, we would classify the TIN's quality composite as average quality for the reasons stated above. In this scenario, we do not believe that we should retain a TIN's high cost designation when the TIN's actual cost performance is not being compared to the TIN's actual quality performance, as it is possible the TIN might have scored high quality if actual performance had been considered. We would continue to show and designate these groups as high cost in their annual QRURs so they have the opportunity to understand and improve their performance, but under our proposal, we would classify their cost composite as average cost for purposes of determining their VM adjustment.

In the CY 2017 PFS proposed rule, we noted that we expect quality data issues to be significantly limited moving forward, due to newly-added front-end edits. Additionally, we noted that TINs are ultimately responsible for the data that are submitted by their third-party vendors and that we expect that TINs are holding their vendors accountable for accurate reporting. We noted that, while we understand that data submission requirements are evolving and that both vendors and CMS are developing capabilities for reporting and assessing performance, we are considering further policies to promote complete and accurate reporting by registries and other third-party entities that submit data on behalf of groups and EPs.

Scenario 4: Category 1 TINs With Widespread Claims Data Issues

If we determine after the release of the Quality and Resource Use Reports (QRURs) that there is a widespread claims data issue that impacts the calculation of the quality and/or cost composites for Category 1 TINs, we propose to recalculate the quality and cost composites for affected TINs. For this proposal, we consider widespread claims data issues, as issues that impact multiple TINs and require the recalculation of the quality and/or cost composites (for example, the incomplete claims identification and specialty adjustment issues described in the CY 2017 PFS proposed rule (81 FR 46446)

After recalculating the composites, if the TIN's quality composite is classified as low quality, then we proposed to reclassify the quality composite as average quality, and if the TIN's cost composite is classified as high cost, we proposed to reclassify the cost composite as average cost. If the TIN is classified as average quality, high quality, average cost or low cost, then we proposed that the TIN would retain the calculated quality or cost tier designation. We made the proposals because, after a claims data issue is identified, it would take approximately 6 weeks to recalculate the composites and notify groups and solo practitioners about their recalculated VM. Given that the VM informal review period lasts for 60 days after the release of the QRURs and the timing of when we become aware of an error, we would likely not be able to notify groups and solo practitioners about their recalculated VM before the end of the informal review period. Further, we expressed our belief that the proposed policies are necessary to provide certainty for

groups and solo practitioners about their final VM payment adjustment and due to the condensed timeline to calculate an accurate VM upward payment adjustment factor.

We proposed to apply these policies for the CY 2017 VM and CY 2018 VM.

The following is a summary of the comments we received regarding these proposals.

Comment: Many commenters supported our proposals to modify a TIN's quality and cost composites based on informal review determination or widespread quality and cost data issues, agreeing that assigning ''average quality'' would not unfairly penalize those that fall into these scenarios. Many of these commenters urged CMS to continue efforts to address data integrity and calculation issues. A few commenters agreed that limiting the potential movement between the VM quality tiers based on informal review would result in a more predictable adjustment factor calculation. Some of these commenters noted that assignment of an ''average quality'' designation does not recognize the significant resources invested by physicians and other eligible professionals in reporting quality data, particularly through agency-preferred electronic methods. One commenter suggested CMS could shorten the informal review timeframe or eliminate mid-year reports, in order to allow more resources for recalculation of the quality composite. Several commenters were not supportive of our proposals, stating that CMS should instead correct the underlying issues necessitating such scenarios, with several expressing added concern that the MIPS program will be even more complex. One commenter stated that the proposed changes to the informal review process would hold practices accountable for performance without a mechanism in place to ensure the accuracy of the data, thus reclassifying a solo practitioner or group practice's performance based on an incomplete understanding of their performance. Another commenter believes it is important to hold solo practitioners and group practices harmless from penalties resulting from errors made by external parties. However, they expressed concerns that solo practitioners and group practices have no opportunity to resubmit their data allowing their quality composite scores to be recalculated to reflect all the available data. They suggest that this would deprive them of upward adjustments to payments because measures were reported or calculated inaccurately through no fault of their own.

Response: We thank the commenters for their feedback and support of our policies. We acknowledge commenters' concerns about the complexity of the underlying data and their suggestions that we correct the underlying issues, rather than establish policies to address these scenarios through the informal review process. We note that scenarios three and four were proposed to address unforeseen issues with reported quality data or CMS claims data, respectively. Additionally, we note that as discussed in this final rule, we expect quality data issues to be significantly limited moving forward. We have worked to resolve PQRS program and receiving system data issues impacting the VM by reprioritizing scheduled deliverables and implementing enhancements to improve 2016 submissions. While some issues may still need to be handled through the informal review process, enhanced reporting functionality, with the removal of constraints around ACO reporting outside of a group, will be supported by both the program and the receiving system. In 2017, the MIPS receiving systems will provide further enhanced real-time feedback to submitters in a more rapid and accurate manner to identify errors earlier and will further accept the most accurate data submitted. We are finalizing the policies for Scenarios 1, 2, 3 and 4 as proposed. Additionally we note that under Scenarios 1 and 3, consistent with the policy adopted in the CY 2013 PFS final rule with comment period (77 FR 69325), for groups of physicians or solo practitioners classified as average quality/low cost as a result of informal review, we would apply an additional upward payment adjustment of +1.0x to those that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population). We note further that, under Scenarios 2 and 4, for groups of physicians or solo practitioners classified as high quality/low cost, high quality/average cost, or average quality/low cost as a result of informal review, we would apply an additional upward payment adjustment of +1.0x to those that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population). We would apply this additional upward +1.0x adjustment, because the results of informal review under the policy being finalized here, would qualify these solo practitioners and groups for the additional upward adjustment, based on the policy previously finalized at 77 FR 69325.

b. Application of the VM to Participant TINs in Shared Savings Program ACOs That Do Not Complete Quality Reporting

In the CY 2015 PFS final rule with comment period (79 FR 67946), for groups and solo practitioners, as identified by their TIN, that participate in a Shared Savings Program ACO, we finalized the same policy that is generally applicable to groups and solo practitioners that fail to satisfactorily report or participate under PQRS and thus fall in Category 2 and are subject to an automatic downward adjustment under the VM in CY 2017. We stated that, consistent with the application of the VM to other groups and solo practitioners that report under PQRS, if the ACO does not successfully report quality data as required by the Shared Savings Program under § 425.504, all groups and solo practitioners participating in the ACO will fall in Category 2 for the VM, and therefore, will be subject to a downward payment adjustment. We finalized this policy for the 2017 payment adjustment period for the VM. In the CY 2016 PFS proposed rule (80 FR 41899), we proposed to continue this policy in the CY 2018 payment adjustment period for all groups and solo practitioners subject to the VM that participate in a Shared Savings Program ACO and finalized our proposal in the CY 2016 PFS final rule with comment period (80 FR 71285).

As discussed in sections III.H. and III.K.1.e. of this final rule, we proposed to remove the prohibition on EPs who are part of a group or solo practitioner that participates in a Shared Savings Program ACO, for purposes of PQRS reporting for the CY 2017 and CY 2018 payment adjustments, to report outside the ACO. As a result of this proposed policy, the EPs in groups and those who are solo practitioners would be allowed to report to the PQRS as a group (using one of the group registry, QCDR, or EHR reporting options) or individually (using the registry, QCDR, or EHR reporting option) outside of the ACO. This section addresses how we proposed to use the PQRS data reported by EPs outside of the ACO for the CY 2018 VM when the ACO does not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504.

For the CY 2018 payment adjustment period, if a Shared Savings Program ACO does not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504, then we proposed to use the

data reported to the PQRS by the EPs under the participant TIN (as a group (using one of the group registry, QCDR, or EHR reporting options) or as individuals (using the registry, QCDR, or EHR reporting option)) outside of the ACO to determine whether the TIN would fall in Category 1 or Category 2 under the VM. We proposed to apply the two-category approach finalized for the CY 2018 VM (80 FR 71280) 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 noted that the proposed policy was consistent with our policy for groups and solo practitioners who are subject to the VM and do not participate in the Shared Savings Program, and we believe it would further encourage quality reporting by EPs in the event the ACO does not successfully report quality data as required by the Shared Savings Program under § 425.504. For example, 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 using one of the group registry, QCDR, or EHR reporting options or have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option by reporting quality data to PQRS outside of the ACO, then they would 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 using the registry, QCDR, or EHR reporting option, then they would also be included in Category 1. Category 2 would include those groups and solo practitioners subject to the CY 2018 VM that participate in a Shared Savings Program ACO and do not fall within Category 1.

As finalized for the CY 2018 payment adjustment period (80 FR 71285), all groups and solo practitioners that participate in a Shared Savings Program ACO and fall in Category 2 will be subject to an automatic downward payment adjustment under the VM. In the CY 2017 PFS proposed rule, we proposed that, for groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data as required by the Shared Savings Program under § 425.504 and are in Category 1 as a result of reporting quality data to the PQRS outside of the ACO, we would classify their quality composite for the VM for the CY 2018 payment adjustment period as ''average quality (81 FR 46447).'' 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 will be classified as ''average cost.'' Because we would not have the ACO's quality data for these groups and solo practitioners, we expressed our belief that it would be appropriate to use the quality data they reported to the PQRS outside the ACO to determine whether they avoided the PQRS payment adjustment and whether they would be in Category 1 or 2 for purposes of the VM, but not to calculate a quality composite using the quality-tiering methodology. As we stated previously, we continue to believe that it is appropriate to calculate a quality composite for groups and solo practitioners participating in the Shared Savings Program based on the ACO's quality data (79 FR 67944). We noted that the proposal was not intended to encourage groups and solo practitioners that participate in a Shared Savings Program ACO to report to the PQRS outside the ACO, but in the event the ACO does not successfully report quality data on behalf of their EPs for purposes of PQRS, to provide them with a safeguard that would allow them to avoid the PQRS payment adjustment and the automatic downward adjustment under the VM. We encourage groups and solo practitioners to continue to report through the ACO in order to promote clinical and financial integration within the ACO and for the Medicare beneficiaries they treat. For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504, we will calculate their VM for the CY 2018 payment adjustment period according to the policies established in the CY 2015 PFS final rule with comment period (79 FR 67941 to 67947 and 79 FR 67956 to 67957) and CY 2016 PFS final rule with comment period (80 FR 71283 to 71286 and 80 FR 71294). We solicited comment on these proposals and also proposed corresponding revisions to § 414.1210(b)(2).

As discussed in section III.H. of this final rule, to allow affected EPs that participate in an ACO to report separately for the CY 2017 PQRS payment adjustment, we proposed a secondary PQRS reporting period for EPs that were in an ACO that did not successfully report quality data on behalf of the EPs in the group and those who are solo practitioners. Specifically, we proposed that affected individual EPs or groups, who report under an ACO, may separately report outside the ACO either as individual EPs (using the registry, QCDR, or EHR reporting option) or using one of the group registry, QCDR, or EHR reporting options (note these EPs and groups would not need to register for one of these group reporting options, but rather could mark the data as group-level data in their submission) during a secondary PQRS reporting period for the CY 2017 PQRS payment adjustment if they were a participant in an ACO that did not successfully report quality data on their behalf during the established reporting period for the CY 2017 PQRS payment adjustment. We proposed the secondary PQRS reporting period for the CY 2017 PQRS payment adjustment would coincide with the reporting period for the CY 2018 PQRS payment adjustment (that is, January 1, 2016 through December 31, 2016).

This section addresses how we proposed to use, for purposes of the CY 2017 VM, the PQRS data reported by the EPs in the group and those who are solo practitioners outside of the ACO using the secondary PQRS reporting period when the ACO did not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504 for the CY 2017 PQRS payment adjustment. For the CY 2017 payment adjustment period, if a Shared Savings Program ACO did not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504 for the CY 2017 PQRS payment adjustment, then we propose to use the data reported to the PQRS by the EPs (as a group using one of the group registry, QCDR, or EHR reporting options or as individuals using the registry, QCDR, or EHR reporting option) under the participant TIN) outside of the ACO during the secondary PQRS reporting period to determine whether the TIN would fall in Category 1 or Category 2 under the VM. We proposed to apply the two-category approach finalized for the CY 2017 VM (79 FR 67938 to 67939 and as revised in 80 FR 71280 to 71281) 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. As discussed in section III.H. of this final rule, we proposed to 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, we proposed that groups that meet the criteria to avoid PQRS payment adjustment for CY 2018 as a group practice participating in the PQRS GPRO (using one of the group registry, QCDR, or EHR reporting options) or have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals (using the registry, QCDR, or EHR reporting option), based on data submitted outside the ACO and during the secondary PQRS reporting period, would be included in Category 1 for the CY 2017 VM. We also proposed that solo practitioners that meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option, based on data submitted outside the ACO and during the secondary PQRS reporting period, would be included in Category 1 for the CY 2017 VM. Category 2 would 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.

As finalized for the CY 2017 payment adjustment period (79 FR 67946), all groups and solo practitioners that participate in a Shared Savings Program ACO and fall in Category 2 will be subject to an automatic downward payment adjustment under the VM. For groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data as required by the Shared Savings Program under § 425.504 and are in Category 1 as a result of reporting quality data to the PQRS outside of the ACO using the secondary PQRS reporting period, we propose to classify their quality composite for the VM for the CY 2017 payment adjustment period as ''average quality'' for the same reasons described above for the CY 2018 payment adjustment period. 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 will be classified as ''average cost.''

If EPs who are part of a group or are solo practitioners who participated in a Shared Savings Program ACO in 2015 that did not successfully report quality data on their behalf decide to use the secondary PQRS reporting period, it is important to note that such groups and solo practitioners should expect to be initially classified as Category 2 and receive an automatic downward adjustment under the VM for items and services furnished in CY 2017 until CMS is able to determine whether the group or solo practitioner met the criteria to avoid the PQRS payment adjustment as described above. First, we would need to process the data submitted for 2016. Second, we would need to determine whether or not the group or solo practitioner would be classified as Category 1 or Category 2 for the CY 2017 VM and notify the group or solo practitioner if there is a change in the VM status. Third, 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. Since groups and solo practitioners taking advantage of this secondary reporting period for the 2017 VM will have missed the deadline for submitting an informal review request for the 2017 VM, we proposed the informal review submission periods for these groups and solo practitioners would occur during the 60 days following the release of the QRURs for the 2018 VM.

We requested comment on these proposals. We also proposed corresponding revisions to § 414.1210(b)(2).

The following is a summary of the comments we received regarding these proposals.

Comment: Commenters supported our proposals to use the PQRS data reported by EPs outside of the ACO for the CY 2017 and CY 2018 VM when the ACO does not successfully report quality data on behalf of its EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504. Several commenters requested that CMS consider holding these EPs harmless from VM adjustments for both the 2017 and 2018 payment adjustment years. Commenters stated EPs would not know if the ACO failed to report for PQRS until close to the end of the reporting period which would not allow sufficient time for them to report separately. In addition, commenters stated EPs are not in direct control of decisions made by the ACO, and therefore, should not be penalized if the ACO does not successfully report quality data. One commenter also stated that if the EPs had been aware of the option earlier in the 2016 reporting period, it would be a more viable proposal.

Response: As discussed in sections III.H. and III.K.1.e. of this final rule, we are finalizing our proposals to remove the prohibition on EPs who are part of a group or solo practitioner that participates in a Shared Savings Program ACO, for purposes of PQRS reporting for the CY 2017 and CY 2018 payment adjustments, to report outside the ACO. As discussed in section III.H. of this final rule, to allow affected EPs that participate in an ACO to report separately for the CY 2017 PQRS payment adjustment, we are finalizing our proposal to create a secondary PQRS reporting period for EPs that were in an ACO that did not successfully report quality data on behalf of the EPs in the group and those who are solo practitioners. Specifically, in section III.H. of this final rule, we are finalizing that affected individual EPs or groups, who report under an ACO, may separately report outside the ACO either as individual EPs (using the registry, QCDR, or EHR reporting option) or using one of the group registry, QCDR, or EHR reporting options (note these EPs and groups would not need to register for one of these group reporting options, but rather mark the data as group data in their submission) during a secondary PQRS reporting period for the CY 2017 PQRS payment adjustment if they were a participant in an ACO that did not successfully report quality data on their behalf during the established reporting period for the CY 2017 PQRS payment adjustment. We are also finalizing in section III.H. of this final rule that the secondary PQRS reporting period for the CY 2017 PQRS payment adjustment would coincide with the reporting period for the CY 2018 PQRS payment adjustment (that is, January 1, 2016, through December 31, 2016).

We appreciate the commenters' support of our proposal to use the PQRS data reported by EPs outside of the ACO for the CY 2017 and CY 2018 VM when the ACO does not successfully report quality data on behalf of its EPs and are finalizing the policies as proposed. We plan to communicate with the ACOs (and their participant TINs) that did not successfully report quality data on behalf of their EPs for purposes of PQRS for the CY 2017 PQRS payment adjustment to inform them about the reporting during the secondary PQRS reporting period. We encourage EPs to

communicate with their ACO and report quality data in the event the ACO does not successfully report quality data as required by the Shared Savings Program under § 425.504 for the CY 2018 PQRS payment adjustment.

For the CY 2018 payment adjustment period, we are finalizing that, if a Shared Savings Program ACO does not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504, then we will use the data reported to the PQRS by the EPs under the participant TIN (as a group (using one of the group registry, QCDR, or EHR reporting options) or as individuals (using the registry, QCDR, or EHR reporting option) outside of the ACO to determine whether the TIN would fall in Category 1 or Category 2 under the VM. We are also finalizing that we will apply the two-category approach finalized for the CY 2018 VM (80 FR 71280) 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. Thus, 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 using one of the group registry, QCDR, or EHR reporting options or have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option 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 using the registry, QCDR, or EHR reporting option, then they will also be included in Category 1. Category 2 will include those groups and solo practitioners subject to the CY 2018 VM that participate in a Shared Savings Program ACO and do not fall within Category 1.

For the CY 2017 payment adjustment period, we are finalizing that, if a Shared Savings Program ACO did not successfully report quality data on behalf of their EPs for purposes of PQRS as required by the Shared Savings Program under § 425.504 for the CY 2017 PQRS payment adjustment, then we will use the data reported to the PQRS by the EPs under the participant TIN (as a group using one of the group registry, QCDR, or EHR reporting options or as individuals using the registry, QCDR, or EHR reporting option) outside of the ACO during the secondary PQRS reporting period to determine whether the TIN would fall in Category 1 or Category 2 under the VM. We are also finalizing that we will apply the two-category approach finalized for the CY 2017 VM (79 FR 67938 to 67939 and as revised in 80 FR 71280 to 71281) 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. In section III.H. of this final rule, we finalized that 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, we are also finalizing that groups that meet the criteria to avoid PQRS payment adjustment for CY 2018 as a group practice participating in the PQRS GPRO (using one of the group registry, QCDR, or EHR reporting options) or have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals (using the registry, QCDR, or EHR reporting option), based on data submitted outside the ACO and during the secondary PQRS reporting period, will be included in Category 1 for the CY 2017 VM. We are also finalizing that solo practitioners that meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option, based on data submitted outside the ACO and during the secondary PQRS reporting period, will be included in Category 1 for the CY 2017 VM. 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.

Comment: Several commenters supported our proposal to classify the quality composite of TINs that report outside of the ACO as ''average quality'' for the CY 2017 VM so that these EPs are protected from downward adjustments under quality-tiering; however, few commenters stated that it would be appropriate to apply the quality-tiering methodology for the 2018 VM payment adjustment when TINs in the Shared Savings Program report separately from the ACO. One commenter stated that, for the 2018 VM, in cases where measures are submitted by both the EP and the ACO, the best performance be counted and the EP should be eligible for a payment adjustment based on performance; and in cases where the EP opts to report through an ACO, but the ACO fails to report, the EP should receive a neutral payment adjustment. One commenter supported our proposal to classify the quality composite of TINs that report outside of the ACO as ''average quality'' for the CY 2018 VM.

Response: As we stated previously, we continue to believe that it is appropriate to calculate a quality composite for groups and solo practitioners participating in the Shared Savings Program based on the ACO's quality data (79 FR 67944). Our proposed policies were not intended to encourage groups and solo practitioners that participate in a Shared Savings Program ACO to report to the PQRS outside the ACO, but in the event the ACO does not successfully report quality data on behalf of their EPs for purposes of PQRS, to provide them with a safeguard that would allow them to avoid the PQRS payment adjustment and the automatic downward adjustment under the VM. We encourage groups and solo practitioners to continue to report through the ACO in order to promote clinical and financial integration within the ACO and for the Medicare beneficiaries they treat.

Therefore, we are finalizing as proposed that, for groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data as required by the Shared Savings Program under § 425.504 and are in Category 1 as a result of reporting quality data to the PQRS outside of the ACO, we will classify their quality composite for the VM for the CY 2018 payment adjustment period as ''average quality.'' We are also finalizing that for groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data as required by the Shared Savings Program under § 425.504 and are in Category 1 as a result of reporting quality data to the PQRS outside of the ACO using the secondary PQRS reporting period, we will classify their quality composite for the VM for the CY 2017 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 will be

classified as ''average cost.'' We are also finalizing the corresponding revisions to § 414.1210(b)(2).

Since groups and solo practitioners taking advantage of the secondary PQRS reporting period for the CY 2017 PQRS payment adjustment will have missed the deadline for submitting an informal review request for the 2017 VM, we proposed the informal review submission periods for these groups and solo practitioners would occur during the 60 days following the release of the QRURs for the 2018 VM. We did not receive any comments on this proposal and are finalizing this policy as proposed.

M. Physician Self-referral Updates

1. Unit-based Compensation in Arrangements for the Rental of Office Space or Equipment

a. The Physician Self-referral Statute and Regulations

(1) Section 1877 of the Act

Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) (OBRA 1989), enacted on December 19, 1989, added section 1877 to the Act. Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. The statute establishes a number of specific exceptions, and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. Additionally, the statute mandates refunding any amount collected under a bill for an item or service furnished under a prohibited referral. Finally, the statute imposes reporting requirements and provides for sanctions, including civil monetary penalty provisions. Section 1877 of the Act became effective on January 1, 1992.

Section 4207(e) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) (OBRA 1990), enacted on November 5, 1990, amended certain provisions of section 1877 of the Act to clarify definitions and reporting requirements relating to physician ownership and referrals and to provide an additional exception to the prohibition. Several subsequent laws further changed section 1877 of the Act. Section 13562 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) (OBRA 1993), enacted on August 10, 1993, expanded the referral prohibition to cover certain other ''designated health services'' in addition to clinical laboratory services, modified some of the existing statutory exceptions, and added new exceptions. Section 152 of the Social Security Act Amendments of 1994 (SSA 1994) (Pub. L. 103–432), enacted on October 31, 1994, amended the list of designated health services, changed the reporting requirements at section 1877(f) of the Act, and modified some of the effective dates established by OBRA 1993. Some provisions relating to referrals for clinical laboratory services were effective retroactively to January 1, 1992, while other provisions became effective on January 1, 1995.

(2) Regulatory History

(a) General Background

The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law.

Following the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all DHS) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule), and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was published in the January 4, 2001 **Federal Register** (66 FR 856) as a final rule with comment period. The second final rulemaking (Phase II) was published in the March 26, 2004 **Federal Register** (69 FR 16054) as an interim final rule with comment period. Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published on April 6, 2004 (69 FR 17933). The third final rulemaking (Phase III) was published in the September 5, 2007 **Federal Register** (72 FR 51012) as a final rule. In addition to Phase I, Phase II, and Phase III, we issued final regulations on August 19, 2008 in the ''Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates'' final rule with comment period (73 FR 48434) (the FY 2009 IPPS final rule). That rulemaking made various revisions to the physician self-referral regulations, including provisions that prohibited certain per unit-of-service (often referred to as ''per-click'') and percentage-based compensation formulas for determining the rental charges for office space and equipment lease arrangements.

We issued additional final regulations after passage of the Affordable Care Act. In the CY 2011 PFS final rule with comment period (75 FR 73170), we codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception. We also issued regulations in the CY 2011 OPPS final rule with comment period (75 FR 71800), the CY 2012 OPPS final rule with comment period (76 FR 74122), and the CY 2015 OPPS final rule with comment period (79 FR 66770) that established or revised certain regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act. Finally, in the CY 2016 PFS final rule (80 FR 70886), we issued regulations to accommodate delivery and payment system reform, reduce burden, and to facilitate compliance. In that rulemaking, we established two new exceptions, clarified certain provisions of the physician self-referral law, updated regulations to reflect changes in terminology, and revised definitions related to physician-owned hospitals. One of the new exceptions, the exception for timeshare arrangements at § 411.357(y), includes a prohibition on certain per unit-of-service compensation formulas.

(b) Unit-based Compensation

We have addressed the issue of unit-based compensation in several rulemakings. Sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act provide that, for an arrangement for the rental of office space or equipment to satisfy the relevant exceptions to the physician self-referral law, the rental charges over the term of the lease must be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. Interpreting this ''volume or value'' standard in the 1998 proposed rule, we proposed that compensation could be based on units of service (for example, ''per-use'' equipment rentals) provided that the units of service did not include services provided to patients who were referred by the physician receiving the payment. For example, a physician who owned a lithotripter could rent it to a hospital on a per-procedure basis,

except for lithotripsies for patients referred by the physician owner. Instead, payments for the use of the lithotripter for those patients would have to use a methodology that did not vary with referrals. (63 FR 1714; *see also* 66 FR 876). We further proposed that arrangements in which a physician rents equipment to an entity that furnishes a designated health service, such as a hospital that rents an MRI machine, with the physician receiving rental payments on a ''per-use'' or ''per-click'' basis (that is, a rental payment is generated each time the machine is used) do not prohibit the physician from otherwise referring to the entity, provided that these kinds of arrangements are typical and comply with the fair market value and other standards that are included under the rental exception. However, because a physician's compensation under this exception cannot reflect the volume or value of the physician's own referrals, we proposed that the rental payments may not reflect ''per-use'' or ''per-click'' payments for patients who are referred for the service by the physician lessor (63 FR 1714).

After reviewing the public comments in response to the 1998 proposed rule, we finalized in Phase I significant revisions with respect to the scope of the volume or value standard. We revised our interpretation of the ''volume or value'' standard for purposes of section 1877 of the Act to permit, among other things, payments based on a unit of service, provided that the unit-based payment is fair market value and does not vary over time (66 FR 876 through 879). Importantly, we permitted unit-based compensation formulas, even when the physician receiving the payment has generated the payment through a DHS referral. To reach this position, we noted that page 814 of the House Conference Committee report (H. Rep. No. 213, 103rd Cong., 1st Sess. (1993)) stated, with respect to the statutory exceptions for the rental of office space and equipment in sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act, that the conferees ''intend[ed] that rental charges for [office] space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, so long as the amount of the time-based or units of service rates does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement.'' (66 FR 876). However, we stated our unequivocal belief that arrangements in which the lessor is compensated each time that the lessor refers a patient to the lessee for a service performed in the leased office space or using the leased equipment have an obvious potential for abuse and could incent overutilization (66 FR 878). We indicated that we would continue to monitor financial arrangements in the health care industry and would revisit particular regulatory decisions if we determine that there has been abuse or overutilization (66 FR 860).

In the CY 2008 PFS proposed rule (72 FR 38122), we stated that arrangements between a physician lessor and an entity lessee under which the physician lessor receives unit-of-service payments are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee. We proposed that space and equipment leases may not include per-click payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity (72 FR 38183). We also solicited comments on the question of whether we should prevent per-click payments in situations in which the physician is the lessee and a DHS entity is the lessor. The CY 2008 PFS proposed rule also included eight other significant proposed revisions to the physician self-referral regulations. Due to the large number of physician self-referral proposals, the significance of the provisions both individually and in concert with each other, and the volume of public comments received in response to the CY 2008 PFS proposed rule, we declined to finalize our proposals, including our proposal to prohibit certain per unit-of-service compensation formulas in arrangements for the rental of office space and equipment, in the CY 2008 PFS final rule (72 FR 66222).

After consideration of the public comments and our independent research, we finalized regulations prohibiting certain per-unit of service compensation formulas for determining office space and equipment rental charges in the FY 2009 IPPS final rule (73 FR 48434). Specifically, we revised § 411.357(a)(4) and (b)(4) to prohibit rental charges for the rental of office space or equipment that are determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. In doing so, we relied on our authority in section 1877(e)(1)(A)(vi) and (B)(vi) of the Act, which permits the secretary to impose by regulation other requirements needed to protect against program or patient abuse. We also revised the exceptions at §§ 411.357(l) and (p) for fair market value compensation and indirect compensation arrangements, respectively, to include similar limitations on the formula for determining office space and equipment rental charges, as applicable. We did so using our authority at section 1877(b)(4) of the Act, as those exceptions were established using that authority (*See* 73 FR 48713 through 48721). We determined it necessary to limit the type of per-click compensation formulas available for arrangements for the rental of office space and equipment because we believe that arrangements under which a lessor receives unit-of-service payments are inherently susceptible to abuse. Specifically, we believe that the lessor has an incentive to profit from referring a higher volume of patients to the lessee and from referring patients to the lessee that might otherwise go elsewhere for services.

b. Development of This Rulemaking

(1) Council for Urological Interests v. Burwell

On June 12, 2015, the D.C. Circuit (the Court) issued an opinion in *Council for Urological Interests* v. *Burwell,* 790 F.3d 212 (D.C. Cir. 2015), that addressed the prohibition on per-click rental charges for the lease of equipment found at § 411.357(b)(4)(ii)(B). In its ruling, the Court agreed with CMS that section 1877(e)(1)(B)(vi) of the Act provides the Secretary the authority to prohibit per-click leasing arrangements. The Court concluded that—

> The text of the statute does not unambiguously preclude the Secretary from using her authority to add a requirement that bans per-click leases. To the contrary, the statutory text of the exception clearly provides the Secretary with the discretion to impose any additional requirements that she deems necessary ''to protect against program or patient abuse.'' (*Council for Urological Interests,* 790 F.3d at 219.)

The Court further concluded that the relevant language in the House Conference Report merely interpreted section 1877(e)(1)(B)(iv) of the Act, and thus did not preclude CMS from imposing additional requirements under section 1877(e)(1)(B)(vi) of the Act. It stated that the legislative history ''simply indicates that, as written, the rental-charge clause [in section 1877(e)(1)(B)(iv) of the Act] does not preclude per-click leases'' and stated further that ''[n]othing in the legislative history suggests a limit on [the Secretary's] authority'' to prohibit per-click leases under section 1877(e)(1)(B)(vi) of the Act (*Id.* at 222.).

The Court also concluded, however, that CMS's discussion of the House

Conference Report in the FY 2009 IPPS final rule contained an unreasonable interpretation of the conferees' statements concerning sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act, and it remanded the case to the agency to permit a fuller consideration of the legislative history. This rulemaking addresses that decision.

(2) The FY 2009 IPPS Final Rule

As discussed above, in the FY 2009 IPPS final rule, we revised the exceptions for the rental of office space and equipment to include in each a requirement that the rental charges for the office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. We explained that our decision to add this requirement was ultimately based on our authority under section 1877(e)(1)(B)(vi) of the Act to promulgate ''other requirements'' needed to protect against program or patient abuse. However, we also discussed certain legislative history contained in the House Conference Report addressing sections 1877(e)(1)(A)(iv) and 1877(e)(1)(B)(iv) of the Act, which establish requirements that rental charges over the term of a lease for office space or rental equipment be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. With respect to those statutory conditions, the language in the House Conference Report states that—

> The conferees intend that charges for space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, so long as the amount of time-based or units of service rates does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement. (H.R. Rep. No. 103–213, at 814 (1993).)

In the FY 2009 IPPS final rule, we noted that CMS had previously concluded that this language indicated that Congress intended to permit leases that included per-click payments, even for patients referred by the physician lessor (66 FR 940), but stated that the language could also be interpreted as excluding from the office space and equipment lease exceptions those lease arrangements that include per-click payments for services provided to patients referred from one party to the other (73 FR 48716). Specifically, we stated that, where the total amount of rent (that is, the rental charges) over the term of the lease is directly affected by the number of patients referred by one party to the other, those rental charges can arguably be said to ''take into account'' or ''fluctuate during the contract period based on'' the volume or value of referrals between the parties. The Court found this revised interpretation to be an unreasonable reading of the language of the House Conference Report. The Court remanded § 411.357(b)(4)(ii)(B) to the Secretary for further proceedings consistent with its opinion, and directed that the Secretary should consider whether a ban on per-click equipment leases is consistent with the House Conference Report.

c. The CY 2017 PFS Proposed Rule: Re-proposal of Limitation on the Types of Per-unit of Service Compensation Formulas for Determining Office Space and Equipment Rental Charges

In the CY 2017 PFS proposed rule, we proposed certain requirements for arrangements involving the rental of office space or equipment. Specifically, using the same language in existing § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B), we proposed to include at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) a requirement that rental charges for the lease of office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. We used the authority granted to the Secretary in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to re-propose this requirement in the exceptions at § 411.357(a) and (b) for the rental of office space and equipment, respectively. We used the authority granted to the Secretary in section 1877(b)(4) of the Act to re-propose this requirement in the exceptions at § 411.357(l) and (p) for fair market value compensation and indirect compensation arrangements, respectively. For the reasons set forth below, we are finalizing without modification at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) a requirement that rental charges for the lease of office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

We emphasize that we did not propose and are not finalizing an absolute prohibition on rental charges based on units of service furnished. In general, per-unit of service rental charges for the rental of office space or equipment are permissible. We proposed to limit, and in this final rule are finalizing a limit on, the general rule by prohibiting per-unit of service rental charges where the lessor generates the payment from the lessee through a referral to the lessee for a service to be provided in the rented office space or using the rented equipment. Thus, under this final rule, per-unit of service rental charges for the rental of office space or equipment are permissible, but only in those instances where the referral for the service to be provided in the rented office space or using the rented equipment did not come from the lessor.

(1) Authority

In accordance with the Court's opinion in *Council for Urological Interests,* in the proposed rule, we set forth the Secretary's authority to include in the exceptions applicable to office space and equipment leases a requirement that rental charges are not determined using a formula based on per-unit of service rental charges that reflect services provided to patients referred by the lessor to the lessee. Our determination followed the Court's reasoning, excerpted below, in rejecting the Council for Urological Interests' assertion that the Secretary lacked the authority to impose a ban on ''per-click'' equipment—and by correlation—office space leases. We also described why limiting the types of per-click rental charges that would not violate the physician self-referral law's referral and claims submission prohibitions is consistent with the language of the House Conference Report.

As the Court stated, the physician self-referral law gives the Secretary power to add requirements as needed to protect against program or patient abuse, even if Congress did not anticipate such abuses at the time of enactment of the statute. Specifically, although Congress may not have originally included a ban on per-click rental charges in office space and equipment lease arrangements, it ''empowered the Secretary to make her own assessment of the needs of the Medicare program and regulate accordingly.'' (*Council for Urological Interests,* 790 F.3d at 220.) The statute explicitly permits the Secretary to impose additional conditions on arrangements for the rental of office space or equipment, and nowhere expressly states that per-click rates must always be permitted. Thus, as the Court confirmed, the Secretary's regulation limiting the use of per-click compensation formulas ''can properly be classified as an 'other' requirement expressly permitted by sections

1877(e)(1)(A)(vi) and (B)(vi) of the Act.'' (*Id.*)

The Secretary's authority to impose requirements regarding the type of compensation formulas upon which office space and equipment rental charges may be based is not constrained by the House Conference Report. In the proposed rule, we acknowledged that the language in the House Conference Report states Congress' intent at the time of enactment of the physician self-referral law that sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act not be interpreted as prohibiting charges for the rental of office space or equipment that are based on units of service furnished. We did not purport to interpret this language as implying anything other than the conferees' understanding—at the time of enactment of the statute—that the statute as written did not prohibit rental charges based on units of service rates. But Congress also gave the Secretary the authority in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose by regulation other requirements as needed to protect against program or patient abuse. Nowhere in the House Conference Report did Congress express an intent to limit the authority granted to the Secretary in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act (as enacted). In fact, the House Conference Report was completely silent regarding sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act, leaving the express words of the statute to speak for themselves. As the Court noted—

> The conference report . . . states only that rental charges ''may'' be based on units of service. The language is not obligatory. Instead, it simply indicates that, as written, the rental-charge clause [(section 1877(e)(1)(B)(iv) of the Act)] does not preclude per-click leases. But, as we have already explained, there is more to the statute than this clause, and to qualify for the exception, a rental agreement must comply with all six clauses, not merely the rental-charge clause alone. The final clause [(section 1877(e)(1)(B)(vi) of the Act)] gives the Secretary the authority to add further requirements. Nothing in the legislative history suggests a limit on this authority. We conclude that the statute does not unambiguously forbid the Secretary from banning per-click leases as she evaluates the needs of the Medicare system and its patients. (790 F.3d at 221–22 (*footnote omitted*).)

Moreover, as the Court further noted, a statement that unit of service-based rental charges are not precluded by sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act as they are written is not equivalent to a statement that the Secretary must continue to permit such charges as she reevaluates, in light of experience, the operation of the statute and the need to protect the Medicare program and its beneficiaries against abuse. (*Id.* at 222 n.7; *see also id.* at 222 n.6 (''Congress has expressly delegated to the Secretary the authority to promulgate additional requirements, as she has done here, and the legislative history does not clearly impose a constraint on that power.'').)

In the proposed rule, we discussed the Secretary's broad authority under sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose conditions on arrangements for the rental of office space or equipment in order to protect against program or patient abuse. That authority is not limited by the express words of the statute as it is in other provisions of section 1877 of the Act. In agreement, the Court in *Council for Urological Interests* explained—

> . . . Congress knew how to limit the Secretary's authority to impose additional requirements to the various exceptions [to the physician self-referral law]. In [section 1877(e)(2) of the Act], Congress excludes bona fide employment relationships from the definition of compensation arrangements. This provision states that the employment relationship must comply with various requirements, including that the pay not be determined ''in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.'' This employment exception also allows the Secretary to impose ''other requirements,'' just as the equipment rental exception. But the statute then goes on to say that the listed requirements ''shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician.'' This language shows that Congress knew how to cabin the Secretary's authority to impose ''other'' requirements and that it knew how to further clarify what it meant by compensation that does not take into account the volume of business generated between parties. That Congress employed neither of these tools with reference to the [exception for the rental of office space or equipment] again supports reading the statute as giving the Secretary broad discretion as she regulates in this area. (790 F.3d at 221 (citations omitted).)

The Secretary's authority to limit the use of per-unit of service rental charges in arrangements for the rental of office space or equipment is particularly clear when the exceptions for the rental of office space and equipment are compared to other provisions in section 1877 of the Act. According to the Court in *Council for Urological Interests*—

> [T]he statute elsewhere expressly permits charging per-click fees in other contexts, showing that Congress knew how to authorize such payment terms when it wanted to. In [section 1877(e)(7)(A) of the Act], Congress created an exception to the [physician self-referral law] that allows the continuation of certain group practice arrangements with a hospital. . . . The provision states that ''[a]n arrangement between a hospital and a group under which designated health services are provided by the group but are billed by the hospital'' is excepted from the ban on referrals if, among other things, ''the compensation paid over the term of the agreement is consistent with fair market value and the compensation *per unit of services* is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.'' Comparing this provision to the [exceptions for the rental of office space and equipment] shows that Congress knew how to permit per-click payments explicitly, suggesting that the omission in this particular context was deliberate. . . . In other words, Congress's decision not to include similar language in the [exceptions for the rental of office space and equipment] supports our conclusion that the statute is silent regarding the permissibility of per-click leases for equipment rentals. (790 F.3d at 220–21 (citations omitted).)

In the proposed rule, we stated in summary that, as we similarly stated in the FY 2009 IPPS final rule (73 FR 48716), the physician self-referral statute responds to the context of the times in which it was enacted (by addressing known risks of overutilization and, in particular, by creating exceptions for common business arrangements), and also incorporates sufficient flexibility to adapt to changing circumstances and developments in the health care industry. For example, in section 1877(b)(4) of the Act, Congress authorized the Secretary to protect additional beneficial arrangements by promulgating new regulatory exceptions. In addition, Congress included the means to address evolving fraud risks by inserting into many of the exceptions—and notably, for our purposes, in the lease exceptions—specific authority for the Secretary to add conditions as needed to protect against abuse. This design reflects a recognition that a fraud and abuse law with sweeping coverage over most of the health care industry could not achieve its purpose over the long term if it were frozen in time. In short, the statute evidences Congress' foresight in anticipating that the nature of fraud and abuse—and of beneficial industry arrangements—might change over time. (73 FR 48716 (citations omitted).)

As we did in 2007 when we first proposed to impose additional requirements for rental charges in arrangements for the rental of office space and equipment, and in 2008 when we finalized regulations incorporating

such additional requirements, we relied in making our proposal on the Secretary's clear authority in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose such other requirements needed to protect against program or patient abuse. With respect to our proposal to include the same requirements at § 411.357(l) and (p), we determined that the revisions to § 411.357(l) and (p) are necessary to meet the standard set forth in section 1877(b)(4) of the Act, which authorizes the Secretary to establish exceptions to the statute's referral and billing prohibitions only where the excepted financial relationships do not pose a risk of program or patient abuse.

(2) Rationale for Proposal

As we discussed in prior rulemakings, including the 1998 proposed rule, we stated in the proposed rule that a number of studies prior to the enactment of the physician self-referral law found that physicians who had financial relationships with entities to which they referred patients ordered more services than physicians without such financial relationships (63 FR 1661). We noted that studies conducted since that time, including recent studies by GAO, indicate that financial self-interest continues to affect physicians' medical decision making.

In the FY 2009 IPPS final rule, we discussed in detail our rationale for finalizing the limitation on per-unit of service rental charges in arrangements for the rental of office space or equipment. We noted primary concerns regarding the potential for overutilization, patient steering and other anti-competitive effects, and reduction in quality of care and patient outcomes, as well as concerns regarding the potential for increased costs to the Medicare program. For the reasons set forth in the FY 2009 IPPS final rule, some of which we restated in the proposed rule, we stated our belief that, in order to protect against program or patient abuse, it is necessary to impose additional requirements on arrangements for the rental of office space or equipment. Specifically, we stated that we believe that it is necessary to prohibit rental charges that are determined using a formula based on per-unit of service rental charges to the extent that such charges reflect services provided to patients referred by the lessor to the lessee of the office space or equipment.

In the CY 2017 PFS proposed rule, we noted that commenters responding to our proposal in the CY 2008 PFS proposed rule to impose additional requirements for office space and equipment lease arrangements provided compelling information regarding potential program or patient abuse. We were persuaded in 2008 to finalize requirements limiting per-unit of service rental charges in the exceptions applicable to the rental of office space or equipment, and stated our continued belief that these requirements continue to be necessary, due to our concerns that ''per-click'' lease arrangements in which the lessor makes referrals to the lessee that generate payments to the lessor—

- Create an incentive for overutilization of imaging services (as described by MedPAC in its comments to our proposal in the CY 2008 PFS proposed rule), as well as other services, including therapeutic services;
- Create an incentive for physicians to narrow their choice of treatment options to those for which they will realize a profit, even where the best course of action may be no treatment;
- Influence physicians to refer to the lessee instead of referring to another entity that utilizes the same or different (and perhaps more efficacious) technology to treat the patient's condition;
- Result in physicians steering patients to equipment they own, even if it means having the patient travel to a non-convenient site for services using the leased equipment; and
- Increase costs to the Medicare program when referring physicians pressure hospitals to use their leasing company despite not being the low cost provider.

We noted that, in the CY 2016 PFS final rule, we expressed our continued concern that, when physicians have a financial incentive to refer a patient to a particular entity, this incentive can affect utilization, patient choice, and competition. Physicians can overutilize by ordering items and services for patients that, absent a profit motive, they would not have ordered. A patient's choice is diminished when physicians steer patients to less convenient, lower quality, or more expensive providers of health care, just because the physicians are sharing profits with, or receiving remuneration from, the providers. And lastly, where referrals are controlled by those sharing profits or receiving remuneration, the medical marketplace suffers if new competitors cannot win business with superior quality, service, or price (80 FR 41926). We stated that, in establishing the exception at § 411.357(y) for timeshare arrangements, we determined it necessary to exclude from the exception any timeshare arrangements that incorporate compensation formulas based on: (1) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the timeshare; or (2) per-unit of service fees, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the timeshare to the party to which the permission is granted. We explained our belief that timeshare arrangements based on percentage compensation or per-unit of service compensation formulas present a risk of program or patient abuse because they may incentivize overutilization and patient steering. We noted in the CY 2016 PFS final rule, by way of example, that a per-patient compensation formula could incent the timeshare grantor to refer patients (potentially for unnecessary consultations or services) to the party using the timeshare because the grantor will receive a payment each time the premises, equipment, personnel, items, supplies, or services are used (80 FR 71331 through 71332). Similarly, we believe that arrangements utilizing rental charges for the rental of office space or equipment that are determined using a formula that rewards the lessor for each service the lessor refers to the lessee are susceptible to this and other abuse.

Finally, we noted in the CY 2017 PFS proposed rule that we are not alone in our concern regarding overutilization and steering of beneficiaries resulting from arrangements in which a physician's referral may provide future remuneration back to the physician. In two notable advisory opinions, OIG expressed its concern with per-unit of service compensation arrangements. Specifically, in Advisory Opinion 03–08, OIG stated that '''[p]er patient,' 'per click,' 'per order,' and similar payment arrangements with parties in a position, directly or indirectly, to refer or recommend an item or service payable by a federal health care program are disfavored under the anti-kickback statute. The principal concern is that such arrangements promote overutilization . . . .'' In Advisory Opinion 10–23, OIG noted that the arrangement that was the subject of the opinion ''involves a 'per-click' fee structure, which is inherently reflective of the volume or value of services ordered and provided . . . .''

The following is a summary of the comments we received regarding our re-proposal.

Comment: The majority of commenters that addressed the re-proposed regulations at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) supported the restriction on per-unit of service (or per-

click) compensation formulas for determining the rental charges for office space and equipment lease arrangements. Many of these commenters offered general support, while others noted appreciation for our continued monitoring of financial relationships in the health care industry, particularly with respect to per-click compensation arrangements and the ''misuses of physician-owned office space.'' One commenter commended us for continuing to recognize the ''perverse incentives created by compensation arrangements between physicians and other providers that are based on volume.'' Another commenter specifically agreed that overutilization and abuse can occur under these types of arrangements and agreed with our re-proposal to limit them.

One commenter commended us for keeping the integrity of the Medicare program in mind by re-proposing the per-click restrictions. This commenter and another noted that improper financial relationships risk wasting funds and could limit access to more appropriate treatment options. A third commenter encouraged us to ''keep in place the relevant restriction on per-unit arrangements when payments are made to referral sources.'' Another commenter acknowledged that a careful balance must be established between permitting physicians to lease office space or equipment to ensure access to patient care and avoiding potential risks of abuse of the Medicare program, and stated its appreciation that the restrictions we proposed on the formula for rental charges are reasonable and preserve the ability of physicians to lease office space and equipment from other physicians.

Response: We continue to believe, and agree with the commenters, that arrangements for the rental of office space or equipment utilizing rental charges that are determined using a formula that rewards the lessor for each service the lessor refers to the lessee are susceptible to abuse. As discussed in the CY 2017 PFS proposed rule, such abuse includes the potential for overutilization, patient steering and stifling patient choice, and the reduction in quality of care and patient outcomes, as well as the potential for increased costs to the Medicare program (81 FR 46452). For the reasons explained in detail in the proposed rule and elsewhere in this final rule, we believe that, in order to protect against program or patient abuse, it is necessary to impose additional requirements on arrangements for the rental of office space or equipment. Specifically, we believe that it is necessary to prohibit rental charges that are determined using a formula based on per-unit of service rental charges to the extent that such charges reflect services provided to patients referred by the lessor to the lessee of the office space or equipment. Therefore, using our using our authority at section 1877(e)(1)(A)(vi) and (B)(vi) of the Act, we are finalizing without modification the regulations re-proposed at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B).

Comment: One commenter welcomed what it referred to as a ''clarification'' that the restriction on per-unit of service compensation formulas applies only in instances where the referral that results in the payment for the use of the equipment comes from the lessor.

Response: The regulations at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) prohibit per-unit of service rental charges only to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. We discussed this limitation in the FY 2009 IPPS final rule, stating that the regulations do not prohibit per-click rental payments to physician lessors for services rendered to patients who were not referred to the lessee by the physician lessors, because such arrangements do not carry with them risk under the physician self-referral statute (73 FR 48719). We again discussed the provision in the CY 2017 PFS proposed rule, stating that per-unit of service rental charges for the rental of office space or equipment are permissible, but only in those instances where the referral for the service to be provided in the rented office space or using the rented equipment does not come from the lessor (81 FR 46450). The re-proposed language at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) is identical to the regulatory provisions finalized in the FY 2009 IPPS final rule.

Comment: We received one comment opposing our proposal to prohibit per-unit of service (''per-click'') rental charges where the lessor generates the payment from the lessee through a referral to the lessee for a service to be provided in the rented office space or using the rented equipment. The commenter asserted that, in its opinion, our re-proposal of the limitation on per-click rental charges does not comply with the Court's decision in *Council for Urological Interests* v. *Burwell.* The commenter asserted that, as a result, our re-proposal of the limitation on per-click rental charges is arbitrary and capricious.

The commenter premised its objection to our proposal in two ways. First, the commenter asserted that we lacked the authority to re-propose the regulations because our determination to prohibit certain per-click rental charges cannot be reconciled with the House Conference Report. The commenter asserted that we did ''not even try to reconcile a ban on per-click [compensation formulas] with the [House] Conference Report.'' At the same time, the commenter asserted that the Court rejected our explanation that, given the authority granted to the Secretary under sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act, the House Conference Report does not constrain her authority to impose requirements regarding the type of compensation formulas upon which office space and equipment rental charges may be based.

Second, the commenter rejected our justification for re-proposing the prohibition on certain per-click compensation formulas for determining rental charges in arrangements for the rental of office space and equipment. Specifically, the commenter claimed that we cited no ''industry developments'' since the enactment of the physician self-referral law or since our Phase I regulations that ''now warrant a prohibition on per-click [rental charge formulas]''; criticized our reliance on ''concerns'' and ''belief[s]'' informing our judgment that per-click rental charge arrangements create incentives for abuse and overutilization; and asserted that ''only empirical data or evidence'' can support a Secretarial determination under the physician self-referral law that additional conditions are needed to protect against program or patient abuse. The commenter acknowledged that the GAO studies and other studies, as well as an OIG advisory opinion, referenced in the CY 2017 PFS proposed rule ''stand . . . for the general proposition that physician financial interests can affect the utilization of medical tests and procedures.'' Nonetheless, the commenter asserted that the re-proposed regulations must be based on ''recent'' developments or ''recent'' studies showing abuse in per-click lease arrangements in order to stand.

Response: We disagree with the commenter. The Secretary's authority for the regulations re-proposed (and finalized here) at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B), which include a requirement that the rental charges for the lease of office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the

lessee, is found in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act, which we detail below. The Court in *Council for Urological Interests* v. *Burwell* expressly confirmed this authority. *See* 790 F.3d at 219–22. We specifically disagree with—and address below—the commenter's assertions that we lack the authority for this rulemaking because: (1) Our regulations cannot be reconciled with the House Conference Report; and (2) only recent empirical data or evidence can support a Secretarial determination under the physician self-referral law that additional conditions in the exceptions for the rental of office space and equipment are needed to protect against program or patient abuse.

We first address the commenter's assertion that a ban on per-click rental charges in arrangements for the lease of office space or equipment *cannot* be reconciled with the House Conference Report. The commenter is incorrect. In *Council for Urological Interests,* the Court itself explicitly reconciled such a ban with respect to per-click equipment leases, stating that the legislative history ''simply indicates that, as written, the rental-charge clause [in section 1877(e)(1)(B)(iv) of the Act] does not preclude per-click leases'' and emphasized that ''[n]othing in the legislative history suggests a limit on [the Secretary's] authority'' to prohibit per-click leases under section 1877(e)(1)(B)(vi) of the Act (790 F.3d at 222.). Here, in finalizing the re-proposed regulations at § 411.357(a)(5)(ii)(B) and (b)(4)(ii)(B), we are relying on the Secretary's authority under sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose such other requirements needed to protect against program or patient abuse. Thus, the House Conference Report can be reconciled with a ban on per-click rental charges in arrangements for the lease of office space or equipment.

We next address the commenter's assertion that our CY 2017 PFS rulemaking ''did not even try to reconcile a ban on per-click [compensation formulas] with the [House] Conference Report.'' The Court's directive to the Secretary was to ''consider—with more care than she exercised [in the FY 2009 IPPS final rule]—whether a per-click ban on equipment leases is consistent with the 1993 Conference Report.'' (*Id.* at 224.) The commenter implied that our explanation in the proposed rule as to why the Secretary's authority to impose requirements regarding the type of compensation formulas upon which office space and equipment rental charges may be based is not constrained by the House Conference Report should be disregarded on the theory that the Court rejected this explanation in *Council for Urological Interests.* As noted above, the Court did not reject this argument; rather, the Court set out in detail why the Secretary's authority to impose such regulatory restrictions is *not* constrained by the House Conference Report. (*Id.* at 222.) In the CY 2017 PFS proposed rule (81 FR 46452) and again in this final rule, we have complied with the Court's directive and set forth our analysis why a per-click ban on office space and equipment leases is consistent with the House Conference Report.

In accordance with the Court's opinion in *Council for Urological Interests* and in support of this final rule, we set forth below the Secretary's authority to include in the exceptions applicable to office space and equipment leases a requirement that rental charges are not determined using a formula based on per-unit of service rental charges that reflect services provided to patients referred by the lessor to the lessee. Our determination follows the Court's reasoning, which we excerpt below, in rejecting the Council for Urological Interests' assertion that the Secretary lacks the authority to impose a ban on certain ''per-click'' equipment—and by correlation—office space leases. We also further describe why limiting the types of per-click rental charges that would not violate the physician self-referral law's referral and claims submission prohibitions is consistent with the language of the House Conference Report.

As the Court stated, the physician self-referral law gives the Secretary power to add requirements as needed to protect against program or patient abuse, even if Congress did not anticipate such abuses at the time of enactment of the statute. Specifically, although Congress may not have originally included a ban on per-click rental charges in office space and equipment lease arrangements, it ''empowered the Secretary to make her own assessment of the needs of the Medicare program and regulate accordingly.'' (*Council for Urological Interests,* 790 F.3d at 220.) The statute explicitly permits the Secretary to impose additional conditions on arrangements for the rental of office space or equipment, and nowhere expressly states that per-click rates must always be permitted. As the Court confirmed, the Secretary's regulation ''can properly be classified as an 'other' requirement expressly permitted by sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act.'' (*Id.*)

The Secretary's authority to impose requirements regarding the type of compensation formulas upon which office space and equipment rental charges may be based is not constrained by the House Conference Report. Clause (iv) in each of the statutory exceptions for the rental of office space and equipment (sections 1877(e)(1)(A) and (B) of the Act) provide that a physician may only make use of either exception if the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. In the 1998 proposed rule, we proposed to interpret the ''volume or value'' standard, which is common in many of the exceptions to the physician self-referral law and included in the exceptions for the rental of office space and equipment at sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act, respectively, as permitting only those per-click compensation formulas where the units of service did not include services provided to patients who were referred by the physician receiving the payment (63 FR 1714). In our Phase I interim final rule with comment period, we stated that, after reviewing the comments on our proposed interpretation of the ''volume or value'' standard, we were substantially revising the regulation with respect to the scope of that standard (66 FR 876). Most importantly, under our revised interpretation of the ''volume or value'' standard, we would permit time-based or unit-based compensation formulas, even when the physician receiving the rental payment generated the payment through a DHS referral. We noted that we reviewed the legislative history with respect to the exceptions for office space and equipment lease arrangements and concluded that Congress intended that sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act not be interpreted to prohibit time-based or unit-of-service-based compensation formulas, so long as the payment per unit is fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals.

The passage in the House Conference Report relevant to sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act reads in full—

> The conferees intend that charges for space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, so long as the amount of the time-based or units of service rates does not fluctuate during the

contract period based on the volume or value of referrals between the parties to the lease agreement. (H.R. Rep. No. 103–213, at 814 (1993)).

In the CY 2017 PFS proposed rule, we again acknowledged that the language in the House Conference Report states Congress' intent at the time of enactment of the physician self-referral law that sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act (the clauses that contain the ''volume or value'' standard in the exceptions for the rental of office space and equipment, respectively) not be interpreted as prohibiting charges for the rental of office space or equipment that are based on units of service furnished (81 FR 46451). Even so, the House Conference Report in no way limits any other provision, including clause (vi) of the exceptions for the rental of office space and equipment.

As in the proposed rule, we do not purport here to interpret this language as implying anything other than the conferees' understanding—at the time of enactment of the statute—that the statute as written did not prohibit rental charges based on unit-of-service rates. But Congress also gave the Secretary the authority in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose by regulation other requirements as needed to protect against program or patient abuse, which could only happen *after* the enactment of the statute. Nowhere in the House Conference Report did Congress express an intent to limit the authority granted to the Secretary in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act (as enacted). In fact, the House Conference Report was completely silent regarding sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act, leaving the express words of the statute to speak for themselves. As the Court noted—

> The conference report . . . states only that rental charges ''may'' be based on units of service. The language is not obligatory. Instead, it simply indicates that, as written, the rental-charge clause [(section 1877(e)(1)(B)(iv) of the Act)] does not preclude per-click leases. But, as we have already explained, there is more to the statute than this clause, and to qualify for the exception, a rental agreement must comply with all six clauses, not merely the rental-charge clause alone. The final clause [(section 1877(e)(1)(B)(vi) of the Act)] gives the Secretary the authority to add further requirements. Nothing in the legislative history suggests a limit on this authority. We conclude that the statute does not unambiguously forbid the Secretary from banning per-click leases as she evaluates the needs of the Medicare system and its patients. (790 F.3d at 221–22 (*footnote omitted*).)

Moreover, as the Court further noted, a statement that unit of service-based rental charges are not precluded by sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act as they are written is not equivalent to a statement that the Secretary must continue to permit such charges as she reevaluates, in light of experience, the operation of the statute and the need to protect the Medicare program and its beneficiaries against abuse. (*Id.* at 222 n.7; *see also id.* at 222 n.6 (''Congress has expressly delegated to the Secretary the authority to promulgate additional requirements, as she has done here, and the legislative history does not clearly impose a constraint on that power.'').)

The Secretary has broad authority under sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose conditions on arrangements for the rental of office space or equipment in order to protect against program or patient abuse. That authority is not limited by the express words of the statute as it is in other provisions of section 1877 of the Act. In agreement, the Court in *Council for Urological Interests* explained—

> . . . Congress knew how to limit the Secretary's authority to impose additional requirements to the various exceptions [to the physician self-referral law]. In [section 1877(e)(2) of the Act], Congress excludes bona fide employment relationships from the definition of compensation arrangements. This provision states that the employment relationship must comply with various requirements, including that the pay not be determined ''in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.'' This employment exception also allows the Secretary to impose ''other requirements,'' just as the equipment rental exception. But the statute then goes on to say that the listed requirements ''shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician.'' This language shows that Congress knew how to cabin the Secretary's authority to impose ''other'' requirements and that it knew how to further clarify what it meant by compensation that does not take into account the volume of business generated between parties. That Congress employed neither of these tools with reference to the [exceptions for the rental of office space or equipment] again supports reading the statute as giving the Secretary broad discretion as she regulates in this area. (790 F.3d at 221 (citations omitted).)

The Secretary's authority to limit the use of per-unit of service rental charges in arrangements for the rental of office space or equipment is particularly clear when the exceptions for the rental of office space and equipment are compared to other provisions in section 1877 of the Act. According to the Court in *Council for Urological Interests*—

> [T]he statute elsewhere expressly permits charging per-click fees in other contexts, showing that Congress knew how to authorize such payment terms when it wanted to. In [section 1877(e)(7)(A) of the Act], Congress created an exception to the [physician self-referral law] that allows the continuation of certain group practice arrangements with a hospital. . . . The provision states that ''[a]n arrangement between a hospital and a group under which designated health services are provided by the group but are billed by the hospital'' is excepted from the ban on referrals if, among other things, ''the compensation paid over the term of the agreement is consistent with fair market value and the compensation *per unit of services* is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.'' Comparing this provision to the [exceptions for the rental of office space and equipment] shows that Congress knew how to permit per-click payments explicitly, suggesting that the omission in this particular context was deliberate. . . . In other words, Congress's decision not to include similar language in the [exceptions for the rental of office space and equipment] supports our conclusion that the statute is silent regarding the permissibility of per-click leases for equipment rentals. (790 F.3d at 220–21 (citations omitted).)

In summary, as we stated in the FY 2009 IPPS final rule (73 FR 48716), the physician self-referral statute responds to the context of the times in which it was enacted (by addressing known risks of overutilization and, in particular, by creating exceptions for common business arrangements), and also incorporates sufficient flexibility to adapt to changing circumstances and developments in the health care industry. For example, in section 1877(b)(4) of the Act, Congress authorized the Secretary to protect additional beneficial arrangements by promulgating new regulatory exceptions. In addition, Congress included the means to address other fraud risks by inserting into many of the exceptions—and notably, for our purposes, in the lease exceptions—specific authority for the Secretary to add conditions as needed to protect against abuse. This design reflects a recognition that a fraud and abuse law with sweeping coverage over most of the health care industry could not achieve its purpose over the long term if it were frozen in time (73 FR 48716). It also demonstrates Congress' respect for regulatory expertise of the Secretary. The Secretary administers and oversees numerous federal health care programs, including Medicare and Medicaid, and interacts with numerous participants in

the health care industry. Aware of the Secretary's expertise in this area, Congress expressly allowed the Secretary to impose further restrictions upon compensation arrangements that the Secretary, in her judgment, finds to present risks of overutilization and abuse. (*Accord, e.g., Council for Urological Interests,* 790 F.3d at 220 (''While Congress may not have originally intended the ban of per-click leases, it empowered the Secretary to make her own assessment of the needs of the Medicare program and regulate accordingly.'').)

As we did in 2007 when we first proposed to impose additional requirements for rental charges in arrangements for the rental of office space and equipment, and in 2008 when we finalized regulations incorporating such additional requirements, we are relying in this final rule on the Secretary's clear authority in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to finalize such other requirements needed to protect against program or patient abuse. With respect to our determination to include the same requirements at §§ 411.357(l) and (p), we have determined that the revisions to §§ 411.357(l) and (p) that we are finalizing here are necessary to meet the standard set forth in section 1877(b)(4) of the Act, which authorizes the Secretary to establish exceptions to the statute's referral and billing prohibitions only where the excepted financial relationships do not pose a risk of program or patient abuse.

We intend and believe that the reasoning set forth in this final rule fully addresses the basis for the D.C. Circuit's conclusion that the prior regulation of per-click compensation arrangements contained in the FY 2009 IPPS final rule was arbitrary and capricious. In *Council for Urological Interests,* the Court remanded the rule because it disagreed with our statement in the FY 2009 IPPS final rule that ''both the statutory language [of section 1877(e)(1)(A)(iv) and (B)(iv)] and the Conference Report'' could ''reasonably be interpreted to exclude'' the relevant per-click payments even without reliance on the Secretary's separate authority under sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act (73 FR 48716). The Court concluded that this statement undermined the reasonableness of the regulation as a whole because the agency had ''treate[d] the Conference Report as a key interpretive roadblock,'' and thus may have relied on an erroneous interpretation as a basis for the regulation. (*Council for Urological Interests,* 790 F.3d at 224.) By contrast, in re-proposing and now finalizing this rule here, we rely exclusively on the Secretary's authority under sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to impose such other requirements as needed to protect against program or patient abuse. We do not rely on the interpretation that the Court in *Council for Urological Interests* found to be arbitrary and capricious, and we note that the House Conference Report does not present any ''interpretive roadblock'' to invoking our authority under sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act.

We next address the commenter's assertion that only recent empirical data or evidence can support a Secretarial determination under the physician self-referral law that additional conditions in the exceptions for the rental of office space and equipment are needed to protect against program or patient abuse, and that the agency may not rely on its concerns and beliefs when issuing regulations. As a preliminary matter, section 1877 of the Act does not require the agency to ''clear a specific evidentiary hurdle prior to imposing additional restrictions for lease exceptions.'' (*Council for Urological Interests* v. *Sebelius,* 946 F. Supp. 2d 91, 110 n.15 (D.D.C. 2013), *aff'd in part, rev'd in part sub nom. Council of Urological Interests* v. *Burwell,* 790 F.3d 212 (D.C. Cir. 2015)). Specifically, the provisions upon which we rely for finalizing the re-proposed regulations, sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act, impose no such precondition on the Secretary's ability to regulate, and it is reasonable to infer that ''[i]f Congress had wanted the Secretary to meet a specific evidentiary burden of proof, it would have said so.'' *Id.* Moreover, the Administrative Procedure Act itself does not impose any ''general obligation on agencies to produce empirical evidence.'' (*Stilwell* v. *Office of Thrift Supervision,* 569 F.3d 514, 519 (D.C. Cir. 2009).) An agency's reasoned assessment of the potential for abuse inherent in a particular business arrangement—particularly in circumstances where, as here, that assessment is corroborated by numerous comments in the rulemaking—justifies the issuance of a prophylactic rule. (*Stilwell,* 569 F.3d at 519 (''[A]gencies can, of course, adopt prophylactic rules to prevent potential problems before they arise. An agency need not suffer the flood before building the levee.''); *see also Ethyl Corp.* v. *Envtl. Prot. Agency,* 541 F.2d 1, 25 (D.C. Cir. 1976) (''Awaiting certainty will often allow for only reactive, not preventive, regulation.'').)

As we discussed in prior rulemakings, including the 1998 proposed rule, a number of studies prior to the enactment of the physician self-referral law found that physicians who had financial relationships with entities to which they referred patients ordered more services than physicians without such financial relationships (63 FR 1661). Studies conducted since that time, including recent studies by GAO, indicate that financial self-interest continues to affect physicians' medical decision making. We note that the commenter agreed that, as a general matter, ''physician financial interests can affect the utilization of medical tests and procedures.'' Nonetheless, the regulations finalized in this rulemaking at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) are based not merely on general propositions regarding financial self-interest, but on input from stakeholders and public comments to proposed rulemaking, as well as our own conclusions and those of our law enforcement partners regarding the risks of per-click compensation arrangements. Contrary to the commenter's contention that we cited ''no industry developments since the [physician self-referral] law was enacted—or since the 2001 [Phase I] regulations,'' we stated in the CY 2017 PFS proposed rule and repeat here that commenters responding to our proposal in the CY 2008 PFS proposed rule to impose additional requirements for office space and equipment lease arrangements provided compelling information regarding potential program or patient abuse. In addition, commenters responding to our proposal in the CY 2017 PFS proposed rule supported the continuation of the per-click bans finalized in the FY 2009 IPPS final rule. We note that, even in the absence of the information upon which we relied in the FY 2009 IPPS final rule and in this final rule (all of which was developed after the publication of the Phase I interim final rule with comment period), the commenter is incorrect that we are now prohibited from determining that additional conditions on certain per-click compensation formulas are needed to protect against program or patient abuse. It is axiomatic that ''agencies are entitled to alter their policies '*with or without* a change in circumstances,' so long as they satisfactorily explain why they have done so.'' (*Nat'l Audubon Soc'y* v. *Hester,* 801 F.2d 405, 408 (D.C. Cir. 1986) (per curiam) (quoting *State Farm,* 463 U.S. at 57).)

In the FY 2009 IPPS final rule and the CY 2017 PFS proposed rule, we discussed in detail our rationale for the limitation on per-unit of service rental

charges in arrangements for the rental of office space or equipment. We explained that under a per-unit of service rental arrangement, the more referrals that a physician lessor makes, the more revenue he or she earns. (73 FR 48715 and 48718; 81 FR 46452–46453). We noted primary concerns regarding the potential for overutilization, patient steering, and reduction in quality of care and patient outcomes, as well as concerns regarding the potential for increased costs to the Medicare program. In summarizing the comments to our proposals in the CY 2008 PFS proposed rule and explaining our rationale for finalizing those proposals, we stated in the FY 2009 IPPS final rule that numerous commenters—including physicians, physician groups, and others—specifically agreed that these risks were raised by per-click leasing arrangements. For example, we noted that one commenter, a radiation oncologist, said that some leasing arrangements are abusive and provide incentives to physicians to narrow their choice of treatment options to those for which they will realize a profit (73 FR 48714). We further noted that another commenter, an association of radiologists, stated that it strongly supports banning use-of-service based leases because such leases fuel an incentive to order unnecessary examinations. (*Id.*) Other commenters expressed similar concerns. We also emphasized in the FY 2009 IPPS final rule that, even with respect to referrals for therapeutic (as opposed to diagnostic) services, the risks of overutilization and abuse may be substantial (73 FR 48718). Regardless of the use for the equipment at issue, there remains the potential for a physician lessor, in order to protect his or her investment or gain additional profits, to refer patients to the lessee of that equipment. (*Id.*) As an example of overutilized therapeutic treatments, we noted that a large hospital system had settled a case involving several of their physicians who were accused of performing unnecessary cardiac surgeries. In that case, federal officials alleged that the physicians had entered into a scheme to cause patients to undergo unneeded, invasive cardiac procedures such as artery bypass and heart valve replacement surgeries in order to generate additional revenue. We noted that the hospital system agreed to pay $54 million to settle the federal case. (*Id.*)

For the reasons set forth in the FY 2009 IPPS final rule and the CY 2017 PFS proposed rule, some of which are restated below, we continue to believe that, in order to protect against program or patient abuse, it is necessary to impose additional requirements on arrangements for the rental of office space or equipment. Specifically, we believe that it is necessary to prohibit rental charges that are determined using a formula based on per-unit of service rental charges to the extent that such charges reflect services provided to patients referred by the lessor to the lessee of the office space or equipment.

We were persuaded to finalize in the FY 2009 IPPS final rule requirements limiting per-unit of service rental charges in the exceptions applicable to the rental of office space or equipment, and agree with the commenters to the CY 2017 PFS proposed rule that these requirements continue to be necessary, due to our concerns that ''per-click'' lease arrangements in which the lessor makes referrals to the lessee that generate payments to the lessor—

- Create an incentive for overutilization of imaging services (as described by MedPAC in its comments to our proposal in the CY 2008 PFS proposed rule), as well as other services, including therapeutic services;
- Create an incentive for physicians to narrow their choice of treatment options to those for which they will realize a profit, even where the best course of action may be no treatment;
- Influence physicians to refer to the lessee instead of referring to another entity that utilizes the same or different (and perhaps more efficacious) technology to treat the patient's condition;
- Result in physicians steering patients to equipment they own, even if it means having the patient travel to a non-convenient site for services using the leased equipment; and
- Increase costs to the Medicare program when referring physicians pressure hospitals to use their leasing company despite not being the low cost provider. (*See* 73 FR 48715–48718).

We note also that, in the CY 2016 PFS final rule, we expressed our continued concern that, when physicians have a financial incentive to refer a patient to a particular entity, this incentive can affect utilization, patient choice, and competition. Physicians can overutilize by ordering items and services for patients that, absent a profit motive, they would not have ordered. A patient's choice is diminished when physicians steer patients to less convenient, lower quality, or more expensive providers of health care, just because the physicians are sharing profits with, or receiving remuneration from, the providers. And lastly, where referrals are controlled by those sharing profits or receiving remuneration, the medical marketplace suffers if new competitors cannot win business with superior quality, service, or price (80 FR 41926). In that rule, in establishing the exception at § 411.357(y) for timeshare arrangements, we determined it necessary to exclude from the exception any timeshare arrangements that incorporate compensation formulas based on: (1) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the timeshare; or (2) per-unit of service fees, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the timeshare to the party to which the permission is granted. We explained our belief that timeshare arrangements based on percentage compensation or per-unit of service compensation formulas present a risk of program or patient abuse because they may incentivize overutilization and patient steering. We noted, by way of example, that a per-patient compensation formula could incent the timeshare grantor to refer patients (potentially for unnecessary consultations or services) to the party using the timeshare because the grantor will receive a payment each time the premises, equipment, personnel, items, supplies, or services are used (80 FR 71331 through 71332). Similarly, we believe that arrangements utilizing rental charges for the rental of office space or equipment that are determined using a formula that rewards the lessor for each service the lessor refers to the lessee are susceptible to this and other abuse. Simply put, per-click lease arrangements create an incentive for overutilization because the physician knows that the more referrals he or she makes to the lessee, the more revenue that that physician will earn.

For all of these reasons, and because we believe that there is a continued need to protect the program and its beneficiaries against the potential abuses of per-click office space and equipment leases, we are finalizing without modification the re-proposed regulations at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B), which include a requirement that the rental charges for the lease of office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

Comment: Although not commenting specifically on our actual proposals, two commenters suggested that we analyze

the physician self-referral law regulations and any revisions to the regulations to consider the impact on stakeholders' work to develop beneficial arrangements that advance health care payment and delivery reforms.

Response: We note that the restrictions on per-unit of service compensation formulas have been in place since October 1, 2009. Although we are cognizant of the impact of the physician self-referral law on health care payment and delivery reform efforts, we must balance concerns about impeding such efforts against protecting the Medicare program and its beneficiaries. For the reasons stated in the FY 2009 IPPS final rule, the CY 2017 PFS proposed rule, and in this final rule, we believe these restrictions are necessary to protect the Medicare program and its beneficiaries against abuse.

Comment: Two commenters requested that we confirm that FAQ 9780 regarding lithotripsy services provided ''under arrangements'' to a hospital by a physician-owned lithotripsy vendor remains CMS policy despite our re-proposal of the regulations at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B). One of the commenters indicated it would oppose re-proposed § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) if the intent of the re-proposed regulations is to reverse the policy set forth in FAQ 9780. This commenter requested that, if we are indeed reversing the policy set forth in FAQ 9780, we do so by proposing regulatory language and offering the opportunity for public comment.

Response: The policy established in FAQ 9780 remains our policy regarding lithotripsy service arrangements between physician-owned lithotripsy vendors and hospitals. FAQ 9780 is available on the CMS Web site at *https://questions.cms.gov/faq.php?id=5005&faqId=9780* and states that, provided that a lithotripsy vendor is actually furnishing a service (or a package of services) to the hospital, and not merely leasing equipment over which the hospital would have dominion and control, the hospital may compensate the lithotripsy vendor using a per-unit or percentage-based compensation formula, as long as all of the requirements of a relevant exception are satisfied.

Comment: Many commenters requested that we revise our regulations in ways other than as re-proposed in the CY 2017 PFS proposed rule. These comments suggested variously that we ''modernize'' the definitions and exceptions in the regulations to (1) keep pace with the rapidly evolving provider landscape and efforts to integrate medical professionals into accountable networks of integrated providers or (2) permit hospitals to subsidize the start-up costs needed to meet the objectives of value-based purchasing, MIPS, and participation in alternative payment models; modify the in-office ancillary services exception at § 411.355(b) to exclude certain designated health services from the coverage of the exception; revise the definition of ''entity'' and our policy regarding services furnished ''under arrangements'' to an entity furnishing designated health services; revise the requirements for ''group practices'' to remove the requirement at § 411.352(g) prohibiting compensation to group practice physicians that takes into account the volume or value of referrals; and establish exceptions to or grant waivers of the physician self-referral law's referral and billing prohibitions similar to those for ACOs participating in the MSSP and certain CMMI models that would enable physicians to participate in alternative payment modes and earn incentives through MIPS.

Response: Although we appreciate the commenters' thoughtful consideration of the impact of the physician self-referral law on physicians and entities furnishing designated health services, our proposals in the CY 2017 PFS proposed rule relate only to the per-click compensation formula restrictions at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) and our advisory opinion regulations at § 411.372. Therefore, the suggested revisions are outside the scope of this rulemaking.

After considering the comments, for the reasons set forth above and in the CY 2017 proposed rule (81 FR 46448), we are finalizing without modification our proposal to include at § 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) a requirement that the rental charges for the lease of office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

2. Technical Correction: Advisory Opinions Relating to Physician Referrals, Procedure for Submitting a Request

We proposed to revise § 411.372(a) by making a minor technical correction to change the instructions for submitting a request for an advisory opinion relating to physician referrals. We noted that the current language in this subsection directs a requesting party to submit its request to a physical address that is out of date. In an effort to expedite the receipt and processing of these requests, and to account for any future changes, we proposed to revise paragraph (a) to state that a party or parties must submit a request for an advisory opinion to CMS according to the instructions specified on the CMS Web site.

We noted that, at the time of the proposed rule, the correct address for such advisory opinion requests was: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Office of Financial Management, Division of Premium Billing and Collections, Mail Stop C3–09–27, Attention: Advisory Opinions, 7500 Security Boulevard, Baltimore, MD 21244–1850. However, we noted that this address is subject to change, per this technical correction, and that parties seeking to submit a request for an advisory opinion relating to physician referrals would need to refer to the instructions on the CMS Web site.

We received no comments regarding this technical correction and are finalizing it without modification.

N. Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes

1. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Outpatient speech-language pathology services.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

2. Annual Update to the Code List

a. Background

In § 411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The DHS categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs furnished in or by an ESRD facility (§ 411.355(g)).
- Preventive screening tests, immunizations, or vaccines (§ 411.355(h)).

The definition of DHS at § 411.351 excludes services for which payment is made by Medicare as part of a composite rate (unless the services are specifically identified as DHS and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not DHS and are not listed among the drugs that could qualify for the exception at § 411.355(g) for EPO and other dialysis-related drugs furnished by an ESRD facility.

Drugs for which there are no injectable equivalents or other forms of administration were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, there have been several delays of the implementation of payment of these drugs under ESRD PPS. Most recently, on December 19, 2014, section 204 of the Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) was enacted and delayed the inclusion of these drugs under the ESRD PPS until 2025. Until that time, such drugs furnished in or by an ESRD facility are not paid as part of a composite rate and thus, are DHS. For purposes of the exception at § 411.355(g), only those drugs that are required for the efficacy of dialysis may be identified on the List of CPT/HCPCS Codes as eligible for the exception. As we have explained previously in the CY 2010 PFS final rule with comment period (75 FR 73583), we do not believe any of these drugs are required for the efficacy of dialysis. Therefore, we have not included any such drugs on the list of drugs that can qualify for the exception.

The Code List was last updated in Tables 50 and 51 of the CY 2016 PFS final rule with comment period (80 FR 71342).

b. Response to Comments

We received one public comment relating to the Code List that became effective January 1, 2016.

Comment: One commenter asked that the screening breast tomosynthesis code 77063 be added to the list of ''Preventive Screening Tests, Immunizations and Vaccines'' to which the physician self-referral law does not apply. The commenter indicated that adding this code is necessary to conform with various CMS policy statements and noted that the other screening mammography services codes payable by Medicare are on this list.

Response: We agree and have added code 77063 to the list of ''Preventive Screening Tests, Immunizations and Vaccines'' to which the physician self-referral law does not apply.

c. Revisions Effective for CY 2017

The updated, comprehensive Code List effective January 1, 2017, is available on our Web site at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html*.

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II and to changes in Medicare coverage policy and payment status.

Tables 45 and 46 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2017. Tables 45 and 46 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

TABLE 45—ADDITIONS TO THE PHYSICIAN SELF-REFERRAL LIST OF CPT 1/ HCPCS CODES

Clinical Laboratory Services	
0008M	Onc breast risk score
Physical Therapy, Occupational Therapy, and Outpatient Speech–Language Pathology Services	
97161	Pt eval low complex 20 min
97162	Pt eval mod complex 30 min
97163	Pt eval high complex 45 min
97164	Pt re-eval est plan care
97165	Ot eval low complex 30 min
97166	Ot eval mod complex 45 min
97167	Ot eval high complex 60 min
97168	Ot re-eval est plan care
Radiology and Certain Other Imaging Services	
0422T	Tactile breast img uni/bi
76706	Us abdl aorta screen aaa
77065	Dx mammo incl cad uni
77066	Dx mammo incl cad bi
77067	Scr mammo bi incl cad
A9515	Choline c–11
A9587	Gallium Ga–68
A9588	Fluciclovine F–18
A9597	Pet, dx, for tumor id, noc
A9598	Pet dx for non-tumor id, noc
C9461	Choline C 11, diagnostic
C9744	Abd us w/contrast
Q9982	Flutemetamol f18 diagnostic
Q9983	Florbetaben f18 diagnostic
Radiation Therapy Services and Supplies	
{No additions}	
Drugs Used by Patients Undergoing Dialysis	
{No additions}	
Preventive Screening Tests, Immunizations and Vaccines	
77063	Breast tomosynthesis bi
77067	Scr mammo bi incl cad
90674	CCIIV4 vac no prsv 0.5 ml im
90687	IIV4 vacc splt 0.25 ml im
G0499	HepB screen high risk indiv

[1] CPT codes and descriptions only are copyright 2016 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 46—DELETIONS FROM THE PHYSICIAN SELF-REFERRAL LIST OF CPT 1/ HCPCS CODES

Clinical Laboratory Services	
{No deletions}	
Physical Therapy, Occupational Therapy, and Outpatient Speech–Language Pathology Services	
97001	Pt evaluation
97002	Pt re-evaluation
97003	Ot evaluation
97004	Ot re-evaluation
Radiology and Certain Other Imaging Services	
77051	Computer dx mammogram add-on
77052	Comp screen mammogram add-on
77055	Mammogram one breast
77056	Mammogram both breasts
77057	Mammogram screening
A9544	I131 tositumomab, dx

TABLE 46—DELETIONS FROM THE PHYSICIAN SELF-REFERRAL LIST OF CPT [1/] HCPCS CODES—Continued

C9458	Florbetaben f18
C9459	Flutemetamol f18
Radiation Therapy Services and Supplies	
0019T	Extracorp shock wv tx ms nos
A9545	I131 tositumomab, rx
Drugs Used by Patients Undergoing Dialysis	
{No deletions}	
Preventive Screening Tests, Immunizations and Vaccines	
77052	Comp screen mammogram add-on
77057	Mammogram screening

[1] CPT codes and descriptions only are copyright 2016 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

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 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, 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.

In the CY 2017 PFS proposed rule (81 FR 46456–46457) we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements. PRA-related comments were received as indicated below under section IV.B.2.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates. In this regard, Table 47 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 47—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Compliance Officer	13–1041	33.26	33.26	66.52
Epidemiologist	19–1040	36.97	36.97	73.94
Medical Scientist	19–1042	45.06	45.06	90.12
Medical Secretary	43–6013	16.50	16.50	33.00
Non-Physician Practitioner (Health Diagnosing and Treating Practitioners)	29–1000	46.65	46.65	93.90
Office and Administrative Support Operations	43–0000	17.47	17.47	34.94
Physicians and Surgeons	29–1060	97.33	97.33	194.66
Physicians and Surgeons, All Other	29–1069	95.05	95.05	190.10
Statistician	15–2041	40.60	40.60	81.20

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. Information Collection Requirements (ICRs) and Burden Estimates

1. ICRs Regarding the Physician Quality Reporting System (PQRS) (§ 414.90)

For individual EPs or group practices, who choose to separately report quality measures during the secondary PQRS reporting period for the 2017 PQRS payment adjustment, who bill under the TIN of an ACO participant if the ACO failed to report on behalf of such EPs or group practices during the previously established reporting period for the 2017 PQRS payment adjustment, we do not believe the individual EP or group practice incurs any additional burden. The associated reporting burden which is currently approved by OMB under control number 0938–1059 (CMS–10276) explains that the PQRS annual burden estimate was calculated separately for (1) individual eligible professionals and group practices using the claims (for eligible professionals only), (2) qualified registry and QCDR, (3) EHR-based reporting mechanisms, and (4) group practices using the GPRO. We estimated that ALL 1.25 million eligible professionals will participate in the PQRS in 2016 for purposes of meeting the criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2018 PQRS payment adjustment. This is a high estimate according to the 2014 PQRS Reporting Experience and Trends Report which found approximately 822,000 EPs participated in PQRS in 2014. Therefore, the additional EPs who choose to report separately from the ACOs have already been accounted for in the PQRS burden. We estimate there were approximately 1,947 EPs that are part of the 218 participant TINs that are under the 8 ACOs that failed to successfully report their 2015 quality data. There is no change in the reporting mechanisms or reporting criteria for PQRS. It is important to note that if the ACO fails to report on behalf of an EP or group practice and the EP or group practice does not utilize this secondary reporting period they may be subject to a downward adjustment.

We did not receive any comments pertaining to our position that the proposed rule would not set out any additional requirements or burden. Consequently, we are restating our position without change.

2. ICRs Regarding Appropriate Use Criteria for Advanced Diagnostic Imaging Services (§ 414.94)

Consistent with section 1834(q) of the Act (as amended by section 218(b) of the PAMA), we have established specific requirements for clinical decision support mechanisms (CDSMs) that can be qualified CDSMs under § 414.94 as

part of the Medicare appropriate use criteria (AUC) program. CDSMs that believe they meet the requirements to be qualified CDSMs (for the purpose of this section) may apply to CMS to be specified as a qualified CDSM.

Applications must be submitted electronically and demonstrate how the CDSM meets the requirements under § 414.94(g)(1). Specifically, applications must demonstrate how the CDSM: (1) Makes available specified applicable AUC and its related supporting documentation; (2) identifies the appropriate use criterion consulted if the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario; (3) makes available, at a minimum, specified applicable AUC that reasonably address common and important clinical scenarios within all priority clinical areas identified in § 414.94(e)(5); (4) is able to incorporate specified applicable AUC from more than one qualified PLE; (5) determines, for each consultation, the extent to which the applicable imaging service is consistent with a specified applicable AUC; (6) generates and provides a certification or documentation at the time of order each time an ordering professional consults a qualified CDSM that includes a unique consultation identifier that documents: Which qualified CDSM was consulted, the name and national provider identifier (NPI) of the ordering professional that consulted the CDSM, whether the service ordered would adhere to specified applicable AUC, whether the service ordered would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; (7) updates AUC content within 12 months from the date the qualified PLE updates AUC; (8) has a protocol in place to expeditiously remove AUC determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed; (9) makes available specified applicable AUC that reasonably address common and important clinical scenarios within any new priority clinical area for consultation through the qualified CDSM within 12 months of the priority clinical area being finalized by CMS; (10) meets privacy and security standards under applicable provisions of law; (11) provides the ordering professional aggregate feedback regarding their consultations with specified applicable AUC in the form of an electronic report on at least an annual basis; (12) maintains electronic storage of clinical, administrative, and demographic information of each unique consultation for a minimum of 6 years; (13) complies with modification(s) to any requirements under § 414.94(g)(1) made through rulemaking within 12 months of the effective date of the modification; and (14) notifies ordering professionals upon de-qualification.

To be specified as a qualified CDSM by CMS, applicants must document adherence to the requirements in their application for CMS review and use the application process identified in § 414.94(g)(2) which includes: (1) Applications submitted by CDSMs documenting adherence to each requirement outlined in § 414.94(g)(1) must be received annually by January 1 except for the first round of applications following publication of the CY 2017 PFS Final Rule which will be due by March 1, 2017; (2) CDSMs with applications that document adherence to all requirements under § 414.94(g)(1) may receive full qualification and CDSMs with applications that cannot document adherence to each requirement must document how and when each requirement is reasonably expected to be met and may receive preliminary qualification; (3) the preliminary qualification period begins June 30, 2017 and ends when CMS implements sections 1834(q)(4)(A) and 1834(q)(4)(B) of the Act; (4) CDSMs with preliminary qualification that fail to meet all requirements by the end of the preliminary qualification period will not be automatically converted to qualified status; (5) all qualified CDSMs specified by CMS in each year will be included on the list of specified qualified CDSMs posted to the CMS Web site by June 30 of that year; (6) qualified CDSMs are specified by CMS as such for a period of 5 years; and (7) qualified CDSMs are required to re-apply during the 5th year after they are specified by CMS to maintain their status as qualified CDSMs and the applications must be received by CMS by January 1 of the 5th year after the most recent approval date. If a qualified CDSM is found to be non-adherent to the requirements identified above, CMS may terminate its qualified status or may consider this information during re-qualification.

The one-time burden associated with the requirements under § 414.94(g)(2) is the time and effort it will take each of the approximately 30 CDSM developers (as estimated by CMS, the Office of the National Coordinator (ONC), and the Agency for Healthcare Research and Quality (AHRQ)) that have interests in incorporating AUC consultation into their mechanisms' functionality to compile, review and submit documentation demonstrating adherence to the CDSM requirements. We anticipate 30 respondents based on the number of existing CDSMs that have expressed an interest in incorporating AUC for advanced diagnostic imaging, as well as our estimation of the number of CDSM developers that may be interested in incorporating AUC for advanced diagnostic imaging in the future as their mechanisms develop and evolve. Each respondent will voluntarily compile, review and submit documentation that demonstrates their adherence to the CDSM requirements listed above.

We estimate it will take 10 hours at $68.18/hr for a business operations specialist to compile, prepare and submit the required information, 2.5 hours at $86.72/hr for a computer system analyst to review and approve the submission, 2.5 hours at $135.58/hr for a computer and information systems manager to review and approve the submission, and 5 hours at $131.02/hr for a lawyer to review and approve the submission. In this regard, we estimate 20 hours per submission at a cost of $1,892.65. In aggregate, we estimate 600 hours (20 hr × 30 submissions) at $56,779.50 ($1,892.65 × 30 submissions).

After the anticipated initial 30 respondents, we expect less than 10 applicants to apply to become qualified CDSMs annually. Since we estimate fewer than 10 respondents, the information collection requirements and burden are exempt (5 CFR 1320.2(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Given that qualified CDSMs must re-apply every 5 years, in years 6–10, we expect the initial 30 entities will re-apply. The ongoing burden for re-applying is expected to be half the burden of the initial application process. The CDSM developers will be able to make modifications to their original application which should result in a burden of 5 hours at $68.18/hr for a business operations specialist to compile, prepare and submit the required information, 1.25 hours at $86.72/hr for a computer system analyst to review and approve the submission, 1.25 hours at $135.58/hr for a computer and information systems manager to review and approve the submission, and 2.5 hours at $131.02/hr for a lawyer to review and approve the submission. Annually, we estimate 10 hours per submission at a cost of $946.33 per CDSM developer. In aggregate, we estimate 300 hours (10 hr × 30

submissions) at $28,389.90 ($946.33 × 30 submissions).

In response to public comments, we added a new requirement under § 414.94(g)(1)(xii) whereby CDSMs are required to notify ordering professionals upon de-qualification. We estimate that 1 CDSM will be de-qualified each year. Because this disclosure is required of less than 10 entities, the PRA is not applicable.

The aforementioned requirements and burden will be submitted to OMB under control number 0938–1315 (CMS–10624).

As regulatory requirements become more complex, we will look to innovative technologies that minimize the burden on an organizations' budget and manpower. To this end, the CDSM functionality requirements identified in § 414.94(g)(1) will help practitioners meet the requirements of the AUC program. While the CDSM application process in § 414.94(g)(2) is a new burden under this program, the CDSM functionality requirements in § 414.94(g)(1) do not add burden as they are functions of the CDSM. These mechanisms function consistently with their voluntary and individualized design so the requirements in § 414.94(g)(1) are either part of a mechanism's functionality or not. If CDSM developers wish their CDSMs to become qualified under this program, they may choose to develop the functionality of their mechanisms consistent with these requirements to be qualified, but all CDSMs are not required to participate in this program. For example, a CDSM that does not incorporate AUC for any advanced diagnostic imaging services would likely choose not to seek to become qualified under this Medicare AUC program. As such, only CDSMs that wish to participate in the Medicare AUC for advanced diagnostic imaging services program are required to apply for qualification and, in choosing to seek qualification, CDSM developers would also choose to incorporate the requirements into their mechanism's functionality.

We received public comments (see below) regarding our proposed requirements and burden estimates. We considered the comments and are largely adopting the proposed provisions with minimal changes to improve clarity. Three areas where we have made more significant changes include: (1) Revising the proposed requirement for CDSMs to ''reasonably encompass the entire clinical scope of all priority clinical areas'' to now ''reasonably address common and important clinical scenarios within all priority clinical areas;'' (2) a new requirement that qualified CDSMs notify ordering professionals upon de-qualification; and (3) a new preliminary qualification period for CDSMs that apply for qualification during the first application period but do not fully meet all requirements under § 414.94(g)(1).

Comment: The majority of commenters addressed the proposal to require CDSMs to contain, at a minimum, AUC that encompass the entire clinical scope of priority clinical areas. Commenters were split regarding the proposed requirement. Some commenters suggested that CDSMs requiring minimum AUC content would add cost and be unnecessary for CDSMs that serve specialists. They favored CDSMs determining, along with the ordering practitioners they serve, what AUC content would be made available. Other commenters favored requiring every CDSM to contain comprehensive AUC. Those commenters said this was the intent of the PAMA since ordering professionals must consult for every advanced diagnostic imaging order and takes into account the lessons learned from the MID to avoid ordering practitioners from consulting for imaging services and not finding relevant AUC within their CDSM. Other commenters agreed with a minimum floor of AUC but expressed concerned about the way CMS proposed that the priority clinical areas must be addressed stating that encompassing the entire clinical scope of priority clinical areas is not preferred and would draw in AUC without a strong evidence base.

Response: We understand the significance of this aspect of the proposal, as well as the statements made by the commenters both for and against the requirement of an AUC floor related to priority clinical areas. We reiterate that, in alignment with statute, ordering professionals must consult for each advanced diagnostic imaging service ordered. Therefore, we believe many professionals will choose a qualified CDSM that best fits their ordering patterns and clinical practice. Those ordering a wide array of imaging services or perhaps infrequently ordering imaging services across a spectrum will align themselves with a mechanism that fits their needs and contains comprehensive specified applicable AUC so when the qualified CDSM is consulted they will lessen their chances of the qualified CDSM identifying no applicable AUC as this was a major frustration of the MID.

Specialists may seek to align themselves with a qualified CDSM that contains AUC more exhaustive in one area of medicine to reflect the imaging services that they order most often.

We continue to believe that all tools should contain the specified applicable AUC needed by the ordering professionals they serve, as well as contain specified applicable AUC related to the priority clinical areas to ensure that if the professional needs to order an imaging service then they will not have to go outside their regular qualified CDSM for the consultation. We reiterate that we envision having a given qualified CDSM allow efficient access to ordering professionals of one or more specialty-focused specified applicable AUC sets along with more comprehensive specified applicable AUC sets. We believe the determination of which AUC sets are made accessible through a given CDSM should be demand-driven by ordering professionals, who would be choosing from a marketplace of options for both CDSMs and AUC, all of which meet basic CMS qualifications to ensure implementation of the PAMA statutory requirements.

To balance the requirement for the minimum floor, we believe it is important to reconsider the extent to which specified applicable AUC encompass the entire clinical scope of priority clinical areas. We agree that requiring the entire clinical scope may not yield consultation of the highest quality specified applicable AUC and that ordering professionals, particularly specialists, may not require specified applicable AUC addressing the entire clinical scope of a priority clinical area. Therefore, we agree with commenters who suggested we keep the AUC floor but allow the requirement to be fulfilled if specified applicable AUC address less than the entire scope of the priority clinical areas and instead reasonably address the common and important clinical scenarios within each priority clinical area.

Comment: Some commenters expressed concerns regarding CDSMs that either fail to requalify after the first 5-year qualification period or are found to no longer be adherent to CDSM requirements during the 5-year qualification period. One commenter recommended that CDSMs be temporarily suspended before being disqualified. Other commenters recommended that CMS ensure providers using these mechanisms not be penalized while they seek a new mechanism for consultation. Another commenter suggested that the CDSM be required to notify ordering professionals of such a disqualification. Other commenters requested that qualification of CDSMs not be disrupted due to

standard technical updates to CDSMs made during the 5-year qualification period.

Response: We agree and do not foresee penalties under these circumstances or disqualification of a CDSM due to a standard update assuming no changes are made to functionality that result in non-adherence to the CDSM requirements in § 414.94(g)(1). We agree that qualified CDSMs be required to notify ordering professionals in the event of disqualification and have added this requirement under § 414.94(g)(1).

Comment: Some commenters cited insufficient time for CDSMs to incorporate requirements between the release of the final CDSM requirements, on or around November 1, 2016, and the January 1, 2017 due date for qualified CDSM applications. These commenters requested that CMS delay the deadline and accept applications later into the year for this first round of applicants. Due to the limited time between finalization of CDSM requirements and the application deadline, another commenter recommended that CDSMs be qualified based on their commitment to support required functionality, rather than an attestation that the existing functionality is fully implemented in a CDSM.

Response: We recognize the challenge CDSM developers may have submitting applications by January 1, 2017, and have extended the deadline only for the first round of applications to March 1, 2017. To this end, all CDSMs qualified in this round only, receive preliminary qualification to conclude at such time as we implement the consultation and reporting requirements of this AUC program.

3. ICRs Regarding the Enrollment of MA Providers, Suppliers, and First-Tier, Downstream, and Related Entities (FDRs) (§ 422.222)

There are approximately 1.9 million providers and suppliers nationwide that are enrolled in Medicare. Through our analysis of currently available encounter data provided by MA organizations, we have found that some providers and suppliers that furnish items or services to MA organization enrollees are not enrolled in Medicare in an approved status. Based on preliminary data, we estimate that 64,000 MA providers and suppliers will have to enroll in Medicare under § 422.222 in order to treat enrollees.

About half of the approximately 64,000 unenrolled providers and suppliers, or 32,000, are individuals and the other half are organizations. We do not have data at this point to confirm the number of unenrolled individuals who are physicians as opposed to non-physician practitioners. For purposes of fulfilling the requirements of the PRA, we will project that one-half (16,000) are physicians and the other half (16,000) are practitioners.

Consistent with our prior time (per respondent) estimates, we project that it will take 3 hours at $194.66/hr for a physician and $93.30/hr for a non-physician practitioner to complete their individual enrollments. For organizations (office and administrative support personnel), we estimate it will take 6 hours at $34.94/hr, since organizational enrollees typically must submit more data than individual enrollees. For physicians, we estimate a total burden of 48,000 hours (16,000 applicants × 3 hours) at a cost of $9,343,680 (48,000 hr × $194.66/hr). For non-physician practitioners, we estimate 48,000 hours (16,000 applicants × 3 hours) at a cost of $4,478,400 (48,000 hr × $93.30/hr). For organizations, we estimate 192,000 hours (32,000 applicants × 6 hours) at a cost of $6,708,480 (192,000 hr × $34.94). In aggregate, we estimate 288,000 hours at $20,530,560.

When projected annually over OMB's maximum 3-year approval period, we estimate 96,000 hours at a cost of $6,843,520.

For physicians and non-physician practitioners, the requirements and annualized burden (32,000 hours) will be submitted to OMB under control number 0938–0685 (Form CMS–855I) because physicians and non-physician practitioners enroll via the Form CMS–855I. For organizations, the requirements and annualized burden of 64,000 hours (192,000 hours/3 years) will be submitted to OMB under control number 0938–0685 (21,333.3 hours for Form CMS–855A and 21,333.3 hours for Form CMS–855B) and control number 0938–1056 (21,333.3 hours for Form CMS–855S). The specific form to be completed will depend upon the provider or supplier type at issue. For instance, and consistent with current enrollment policy, certified providers and certain certified suppliers will complete the Form CMS–855A; group practices, ambulance suppliers, and certain other supplier types will complete the Form CMS–855B; suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) will complete the Form CMS–855S.

Please note that breakout of the organization burden (dividing 64,000 hours by 3 forms) is an estimate. Logistically, this is necessary for the purposes of submitting burden for approval. We have no way of estimating the number of providers/suppliers that will complete the individual forms. We welcomed comments on this issue to help us derive a more reliable breakout but received none. Nor did we receive comments pertaining to any other aspects of the proposed requirements or burden. Consequently, we are adopting our proposed requirements and burden estimates without change.

TABLE 48—CMS–855 BURDEN IMPLICATIONS

	Individuals (32,000 total respondents) (3 hours/application)	Organizations (32,000 total respondents) (6 hours/application)
CMS–855–I (32,000)	32,000 respondents, 96,000 hours.	
Physicians (16,000) $194.66/hour	16,000 physicians × 3 hours = 48,000 hours @$194.66 = $9,343,680.00.	
Non-physician Practitioners (16,000) $93.30/hour.	16,000 non-physician practitioners × 3 hours = 48,000 hours @$93.30 = $4,478,400.00.	
CMS–855–A (10,666) $34.94/hour		10,666 respondents × 6 hours = 63,996 hours 10,666 respondents × 6 hours = 63,996 hours @$34.94 = $2,236,020.24
CMS–855–B (10,666)		10,666 respondents × 6 hours = 63,996 hours 10,666 respondents × 6 hours = 63,996 hours @$34.94 = $2,236,020.24

TABLE 48—CMS–855 BURDEN IMPLICATIONS—Continued

	Individuals (32,000 total respondents) (3 hours/application)	Organizations (32,000 total respondents) (6 hours/application)
CMS–855–S (10,666)		10,666 respondents × 6 hours = 63,996 hours 10,666 respondents × 6 hours = 63,996 hours @$34.94 = $2,236,020.24
Sub-total respondents	32,000 respondents	32,000 respondents
Sub-total hours	96,000 hours	192,000 hours
Sub-total cost	$13,822,080.00	$6,708,060.72
Total	64,000 respondents, 288,000 hours, $20,530,140.72	

4. ICRs Regarding the Release of Medicare Advantage Bid Pricing Data (§ 422.272) and the Release of Part C and Part D Medical Loss Ratio (MLR) Data (§§ 422.2490 and 423.2490)

In the proposed rule, new § 422.272 proposed an annual public release of MA bid pricing data (with specified exceptions from release), which would occur after the first Monday in October and would contain MA bid pricing data that was approved by CMS for a contract year at least 5 years prior to the upcoming calendar year. Under Part C, MA organizations (MAOs) are required to submit bid data to CMS each year for MA plans they wish to offer in the upcoming contract year (calendar year), under current authority at § 422.254.

Proposed §§ 422.2490 (for Part C) and 423.2490 (for Part D) also provided for the public release of Part C and Part D MLR data for each contract year, which would occur no sooner than 18 months after the end of the contract year for which the MLR Report was submitted. Starting with contract year 2014, if an MAO or Part D sponsor fails to spend at least 85 percent of the revenue received under an MA or Part D contract on incurred claims and quality improvement activities, the MAO or Part D sponsor must remit to the Secretary the product of: (1) The contract's total revenue; and (2) the difference between 85 percent and the contract's MLR. For each contract year, each MAO and Part D sponsor must submit an MLR Report to CMS which includes the data needed by the MAO or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract. The proposed rule provided for the release of the Part C and Part D MLR data contained in the MLR Reports that we receive from MAOs and Part D sponsors, with specified exceptions to release.

We determined for the proposed rule that the proposed provisions on the release of MA bid pricing data and the release of Part C and Part D MLR data did not change any of the existing requirements regarding submission of bid data and MLR data by MAOs or Part D plan sponsors, nor did the proposed rule propose any new or revised reporting, recordkeeping, or third-party disclosure requirements. We noted that although the proposed provisions have no impact on respondent requirements or burden, the changes have been submitted to OMB for approval under control number 0938–0944 (CMS–10142) for MA bid pricing data and 0938–1232 (CMS–10476) for Part C and Part D MLR data.

We did not receive any comments on the proposed requirements or burden and are finalizing them without change.

5. ICRs Regarding Application Requirements (§ 422.501) and Termination of Contract by CMS (§ 422.510)

Changes to §§ 422.501 and 422.510 involve only CMS contract changes and will not result in any external charges or operational costs to MA organizations. Many MA organizations already require Medicare enrollment for all their network providers and suppliers. So there will be no additional costs to most MA and MA–PD plans. The only tangible costs will be to those providers or suppliers that are not enrolled and those costs are estimated in section IV.B.3. of this final rule.

6. ICRs Regarding Payment to Organizations That Provide Medicare Diabetes Prevention Program Services (§ 424.59)

Section 1115A(d)(3) of the Social Security Act exempts the Center for Medicare and Medicaid Innovation (CMMI) model tests and expansions, including the Medicare Diabetes Prevention Program expansion, from the PRA. The section provides that Chapter 35 of title 44, United States Code, which includes such provisions as the PRA, shall not apply to the testing and evaluation of CMMI models or expansion of such models.

7. 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 any information collection activities under the Shared Savings Program.

C. Summary of Annual Burden Estimates

TABLE 49—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s) under title 42 of the CFR	OMB control No.	Respondents	Total responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)	Total cost ($) *
§ 414.94(g)(2)	0938–1315	30	30	20	600	varies	56,780
§ 414.94(g)(2) (reapply).			30	10	300	varies	28,390
§ 422.222 (physicians and non-physician practitioners).	0938–0685	32,000	10,666.6 (32,000 responses annualized over 3 years).	3	32,000	varies	4,607,360

TABLE 49—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS—Continued

Regulation section(s) under title 42 of the CFR	OMB control No.	Respondents	Total responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)	Total cost ($) *
§ 422.222 (organizations).	0938–0685	32,000	7,111.1 for two CMS–855 forms (21,333.3 responses annualized over 3 years).	6	42,666.6	34.94	1,490,771
§ 422.222 (organizations).	0938–1056	.....	3,555.6 for one CMS–855 form.	6	21,333.3	34.94	745,386
Total	.....	64,030	21,393	.....	96,900	varies	6,928,687

* This rule does not set out any non-labor costs.

D. Associated Information Collections Not Specified in Regulatory Text

This rule references three information collection requirements that do not pertain to the amendments in the regulatory text. While the activities meet the PRA's definition of an information collection requirement, section 220 of the Protecting Access to Medicare Act (PAMA) of 2014 (Pub. L. 113–93) provides that the activities are exempt from the requirements of under the PRA. The exemption applies to information collected to ensure the accurate valuation of services under the Physician Fee Schedule which includes but is not limited to surveys of physicians, other suppliers, providers of services, manufacturers, and vendors; surgical logs, billing systems, or other practice or facility records; electronic health records; and, any other mechanism deemed appropriate by the Secretary.

The activities consist of the following:

1. Global Surgical Services

Section II.D.2. of this final rule details our plans for a claims-based reporting program for global surgical services. Our claims-based data collection is applicable to 10- and 90-day global services furnished on or after January 1, 2017, which will set out: Who will be required to report, what they will be required to report, and how the reports will be submitted.

2. Survey of Practitioners

As discussed earlier in section II.D.6.e.(1) through (2) of this final rule, we intend to conduct a survey of practitioners to help us explore options and collect data with respect to assessing and revaluing the global surgery services.

3. Data Collection for Accountable Care Organizations

In section II. D.6.e.(3) of this final rule, we intend to conduct a survey of ACOs on a number of issues surrounding pre- and post-operative surgical services. In addition to the PRA exemption as described above under PAMA, the survey is also exempt from the PRA under section 3022 of the Affordable Care Act which exempts collections associated with the Medicare Shared Savings Program.

E. Submission of PRA-Related Comments

We have submitted a copy of this rule's information collection and recordkeeping requirements to OMB for review and approval. The requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed above, please visit CMS' Web site at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please identify the rule (CMS–1654–F) and submit your comments to the OMB desk officer via one of the following transmissions:

Mail: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer,

Fax Number: 202–395–5806 OR,

Email: OIRA_submission@omb.eop.gov.

PRA-related comments must be received on/by December 2, 2016.

V. Regulatory Impact Analysis

A. Statement of Need

This final 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) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate, as discussed in this section, that the PFS provisions included in this final rule 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.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule 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 2016, that threshold is approximately $146 million. This final 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.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this final rule, 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 final rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this final rule. The relevant sections of this final 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 2016 with proposed payment rates for CY 2017 using CY 2015 Medicare utilization. The payment impacts in this final 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 Lab Fee Schedule.

The annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). 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 2017, 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 2017 net reduction in expenditures resulting from adjustments to relative values of misvalued codes to be 0.32 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 2017 target

recapture amount will produce a reduction to the conversion factor of −0.18 percent.

Effective January 1, 2012, we implemented an MPPR of 25 percent on the professional component (PC) of advanced imaging services. Section 502(a)(2)(A) of Division O, Title V of the Consolidated Appropriations Act of 2016 (Pub. L 114–113, enacted on December 18, 2015) added a new section 1848(b)(10) of the Act, which revises the MPPR on the professional component of imaging services from 25 percent to 5 percent, effective January 1, 2017. Section 502(a)(2)(B) of Division O, Title V of the Consolidated Appropriations Act of 2016 added a new subclause at section 1848(c)(2)(B)(v)(XI) which exempts the MPPR reductions attributable to the new 5 percent MPPR on the PC of imaging from the PFS budget neutrality provision. However, the provision does not exempt the change attributable to the 25 percent MPPR from PFS budget neutrality. Therefore, for CY 2017 we must calculate PFS rates in a manner that exempts the 5 percent MPPR from budget neutrality but ensures that the elimination of the 25 percent MPPR is included in PFS budget neutrality. We note that the application of the 25 percent MPPR has been applied in a budget neutral fashion to date.

The CY 2017 final PFS rates exclude the 5 percent MPPR for the professional component of imaging services by calculating the rates as if the discount does not occur, consistent with our approach to other discounts that occur outside of PFS budget neutrality. In order to implement the change from the 25 percent discount in 2016 to the 5 percent discount in 2017 within PFS budget neutrality, we measured the difference in total RVUs for the relevant services, assuming an MPPR of 25 percent and the total RVUs for the same services without an MPPR, and then applied that difference as an adjustment to the conversion factor to account for the increased expenditures attributable to the change, within PFS budget neutrality. This approach is consistent with the statutory provision that requires the 5 percent MPPR to be implemented outside of PFS budget neutrality.

To calculate the final 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, the budget neutrality adjustment and the imaging MPPR adjustment described in the preceding paragraphs. We estimate the CY 2017 PFS conversion factor to be 35.8887, which reflects the budget neutrality adjustment, the 0.5 percent update adjustment factor specified under section 1848(d)(18) of the Act, the adjustment due to the non-budget neutral 5 percent MPPR for the professional component of imaging services, and the −0.18 percent target recapture amount required under section 1848(c)(2)(O)(iv) of the Act and described above. We estimate the CY 2017 anesthesia conversion factor to be 22.0454, which reflects the same overall PFS adjustments.

We note that the proposed RVU budget neutrality adjustment was negative, due to the estimated overall increases in proposed RVUs relative to 2016. However, because we did not finalize the proposed changes to make separate payment for the additional resource costs involved in mobility impairment services, we are finalizing an overall decrease in RVUs relative to 2016. This results in an RVU budget neutrality adjustment that is positive.

TABLE 50—CALCULATION OF THE FINAL CY 2017 PFS CONVERSION FACTOR

Conversion factor in effect in CY 2016		35.8043
Update Factor	0.50 percent (1.0050).	
CY 2017 RVU Budget Neutrality Adjustment	−0.013 percent (0.99987).	
CY 2017 Target Recapture Amount	−0.18 percent (0.9982).	
CY 2017 Imaging MPPR Adjustment	−0.07 percent (0.9993).	
CY 2017 Conversion Factor		35.8887

TABLE 51—CALCULATION OF THE FINAL CY 2017 ANESTHESIA CONVERSION FACTOR (CM ESTIMATE)

CY 2016 National Average Anesthesia Conversion Factor		21.9935
Update Factor	0.50 percent (1.0050).	
CY 2017 RVU Budget Neutrality Adjustment	0.013 percent (0.99987).	
CY 2017 Target Recapture Amount	−0.18 percent (0.9982).	
CY 2017 Imaging MPPR Adjustment	−0.07 percent (0.9993).	
CY 2017 Conversion Factor		22.0454

Table 52 shows the payment impact on PFS services of the proposals contained in this final 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 52 (CY 2017 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 52.

- *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 2015 utilization and CY 2016 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 2017 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 2017 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 2017 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 2017 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 52—CY 2017 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *

(A) Specialty	(B) Allowed charges (mil)	(C) Impact of work RVU changes (%)	(D) Impact of PE RVU changes (%)	(E) Impact of MP RVU changes (%)	(F) Combined impact ** (%)
TOTAL	$89,866	0	0	0	0
ALLERGY/IMMUNOLOGY	231	0	1	0	1
ANESTHESIOLOGY	1,982	0	0	0	0
AUDIOLOGIST	61	0	0	0	0
CARDIAC SURGERY	324	0	0	0	0
CARDIOLOGY	6,485	0	0	0	0
CHIROPRACTOR	784	0	0	0	0
CLINICAL PSYCHOLOGIST	734	0	0	0	0
CLINICAL SOCIAL WORKER	606	0	0	0	0
COLON AND RECTAL SURGERY	161	0	0	0	0
CRITICAL CARE	311	0	0	0	0
DERMATOLOGY	3,308	0	0	0	0
DIAGNOSTIC TESTING FACILITY	754	0	−1	0	−1
EMERGENCY MEDICINE	3,145	0	0	0	0
ENDOCRINOLOGY	460	0	0	0	0
FAMILY PRACTICE	6,110	0	1	0	1
GASTROENTEROLOGY	1,747	−1	0	0	−1
GENERAL PRACTICE	456	0	0	0	1
GENERAL SURGERY	2,172	0	0	0	0
GERIATRICS	213	0	1	0	1
HAND SURGERY	182	0	0	0	0
HEMATOLOGY/ONCOLOGY	1,751	0	0	0	0
INDEPENDENT LABORATORY	706	0	−5	0	−5
INFECTIOUS DISEASE	656	0	0	0	0
INTERNAL MEDICINE	10,915	0	1	0	1
INTERVENTIONAL PAIN MGMT	769	0	−1	0	0
INTERVENTIONAL RADIOLOGY	317	−1	0	0	−1
MULTISPECIALTY CLINIC/OTHER PHYS	129	0	0	0	1
NEPHROLOGY	2,210	0	0	0	0
NEUROLOGY	1,521	0	0	0	0
NEUROSURGERY	789	−1	0	0	−1
NUCLEAR MEDICINE	47	0	0	0	0
NURSE ANES/ANES ASST	1,214	0	0	0	0
NURSE PRACTITIONER	2,988	0	0	0	0
OBSTETRICS/GYNECOLOGY	651	0	0	0	0
OPHTHALMOLOGY	5,492	−1	−2	0	−2
OPTOMETRY	1,219	0	−1	0	−1
ORAL/MAXILLOFACIAL SURGERY	49	0	−1	0	−1
ORTHOPEDIC SURGERY	3,695	0	0	0	0
OTHER	27	0	0	0	0
OTOLARNGOLOGY	1,210	0	0	0	−1
PATHOLOGY	1,135	0	−2	0	−1
PEDIATRICS	61	0	0	0	0
PHYSICAL MEDICINE	1,068	0	0	0	0
PHYSICAL/OCCUPATIONAL THERAPY	3,407	0	1	0	1
PHYSICIAN ASSISTANT	1,964	0	0	0	0
PLASTIC SURGERY	378	0	0	0	0
PODIATRY	1,972	0	0	0	0
PORTABLE X-RAY SUPPLIER	106	0	0	0	0
PSYCHIATRY	1,265	0	0	0	0
PULMONARY DISEASE	1,765	0	0	0	0
RADIATION ONCOLOGY	1,726	0	0	0	0
RADIATION THERAPY CENTERS	44	0	0	0	0
RADIOLOGY	4,683	0	0	0	−1
RHEUMATOLOGY	537	0	0	0	0
THORACIC SURGERY	357	0	0	0	0
UROLOGY	1,772	−1	0	0	−2
VASCULAR SURGERY	1,046	0	0	0	−1

** Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2017 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. Several specialties, including interventional radiology and independent labs, would experience significant decreases to overall payments for services that they frequently furnish as a result of revisions to the coding structure or the final inputs used to develop RVUs for the codes that describe particular services. Other specialties, including endocrinology and family practice, would experience significant increases to payments for similar reasons.

We note that the positive impact for CY 2017 several specialties is lower than it was in the proposed rule, especially for certain specialties disproportionately likely to have reported the proposed code related to mobility impairment services. Because we did not finalize that proposal, we do not anticipate that shift in payment for CY 2017. However, we note that we believe that many practitioners of those same specialties will likely report the several other new codes described in section F of this final rule. Based on the history with other, similar codes, we would anticipate significant changes in allowed charges for these specialties over a longer period of time thanis shown by the single year comparison that we believe is more generally relevant in displaying the impacts of changes in payment under the PFS.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table, including comments received in response to the proposed rates for the current year. 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 52 displays the estimated CY 2017 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 2017 PFS final 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.I. of this final rule, we added several new codes to the list of Medicare telehealth services. Although we expect these changes to increase access to care in rural areas, based on recent utilization of similar services already on the telehealth list, we estimate no significant impact on PFS expenditures from the additions relative to overall PFS expenditures.

E. Geographic Practice Cost Indices (GPCIs)

Based upon statutory requirements, we proposed new GPCIs for each Medicare payment locality. The final GPCIs incorporate updated data and cost share weights as discussed in section II.I. The Act requires that updated GPCIs be phased in over two years. Addendum D shows the estimated effects of the revised GPCIs on area GAFs for the transition year (CY 2017) and the fully implemented year (CY 2018). The GAFs reflect the use of the updated underlying GPCI data, and the cost share weights remain unchanged from the previous (seventh) GPCI update. The GAFs are a weighted composite of each area's work, PE and malpractice expense GPCIs using the national GPCI cost share weights. Although we do not actually use the GAFs in computing the PFS payment for a specific service, they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service will deviate from the GAF to the extent that the proportions of work, PE and malpractice expense RVUs for the service differ from those of the GAF.

The most significant changes occur in 19 non-California payment localities, where the fully implemented (CY 2018) GAF moves up by more than 1 percent (14 payment localities) or down by more than 2 percent (5 payment localities). These changes, required by section 1848(e)(6) of the Act, are discussed in section II.I. of this final rule.

F. Other Provisions of the Proposed Regulation

1. Impact of Changing the Direct Supervision Requirement to General Supervision for CCM Services Furnished Incident to RHCs and FQHCs, and Impact of Revising the CCM Requirements for RHCs and FQHCs

We are finalizing our proposal to revise § 405.2413(a)(5) and § 405.2415(a)(5) to state that services and supplies furnished incident to TCM and CCM services can be furnished under general supervision of a RHC or FQHC practitioner. This regulatory change was already made for CCM services furnished by practitioners billing the PFS, and changes to RHC and FQHC regulations have no impact on regulations for practitioners billing under the PFS. The impact of this change on RHCs and FQHCs in 2017 is negligible, as estimates are rounded to the nearest 5 million and 2017 was too small of an impact to have a notable effect on the estimate.

We are also finalizing our proposal to revise the CCM requirements for RHCs and FQHCs to be consistent with the proposed revisions to the CCM requirements for practitioners billing under the PFS. These revisions will allow RHCs and FQHCs to provide TCM and CCM services at the level that was projected when the programs were authorized, and therefore, no impact on spending is expected.

2. FQHC-Specific Market Basket

As discussed in section III.B of this final rule, we are finalizing our proposal to create a 2013-based FQHC market basket to update the FQHC PPS base payment rate. Table 53 shows the 5-year and 10-year fiscal cost estimates from switching from a MEI-adjusted base payment rate to a FQHC PPS market basket-adjusted base payment rate. This was determined by compiling data on historical FQHC spending, projecting it forward, and creating two separate baselines. The first baseline assumed an MEI price update and the second baseline assumed an FQHC specific market basket price update which was created by the Office of the Actuary within CMS. The utilization of services was held constant between the two

baselines, and therefore, the impact table specifically captures the change in price from now growing at an FQHC MB update relative to how it was growing at the MEI updates. We estimate that this will cost approximately 210 million dollars over 10 years from FY 2017–2026, 45 million of which would be paid for through beneficiary premiums and the remaining 165 million would be paid for through Part B.

TABLE 53—5-YEAR AND 10-YEAR FISCAL COST ESTIMATES FROM SWITCHING FROM AN MEI-ADJUSTED BASE PAYMENT RATE TO A FQHC PPS MARKET BASKET-ADJUSTED BASE PAYMENT RATE

Estimate (in millions)	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	5-year impact 2017–2021	10-year impact 2017–2026
FY Cash Impact (with MC)													
Part B													
Benefits	.....	5	10	10	15	16	20	25	30	35	45	55	210
Premium Offset	.....	.....	.....	.....	(5)	(5)	(5)	(5)	(5)	(10)	(10)	(10)	(45)
Total Part B	.....	5	10	10	10	10	15	20	25	25	35	45	165

3. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The clinical decision support mechanism (CDSM) requirements, as well as the application process that CDSM developers must comply with for their mechanisms to be specified as qualified under this program do not impact CY 2017 physician payments under the PFS.

4. Reports of Payments or Other Transfers of Value to Covered Recipients

We solicited comments to inform future rulemaking. We do not intend to finalize any requirements directly as a result of this final rule; so there is no impact to CY 2017 physician payments under the PFS.

5. Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D Medical Loss Ratio (MLR) Data

Under section III.E. of the preamble of this final rule, we describe our proposal to revise the existing regulations by adding § 422.272 to provide for an annual public release of MA bid pricing data (with specified exceptions from release). We proposed that the annual release would occur after the first Monday in October and would contain MA bid pricing data that was accepted or approved by CMS for a contract year at least 5 years prior to the upcoming calendar year. We noted that under current authority at § 422.254, MA organizations (MAOs) are required to submit bid pricing data to CMS each year for MA plans they wish to offer in the upcoming contract year (calendar year).

In addition, we proposed to add § 422.2490 for Part C and § 423.2490 for Part D to provide for an annual public release of Part C and Part D medical loss ratio (MLR) data (with specified exceptions from release). This annual release would occur no sooner than 18 months after the end of the contract year for which MLR data was reported to us. Starting with contract year 2014, each MAO or Part D sponsor that fails to spend at least 85 percent of revenue received under an MA or Part D contract on incurred claims and quality improving activities must remit the difference to the government. Under current authority at § 422.2460 and § 423.2460, each year MAOs and Part D sponsors must submit an MLR Report to us, which includes the data needed by the MAO or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract.

We proposed to add regulatory language to permit our release of such data to the public. In the proposed rule, we determined that the proposed regulatory amendments do not impose any mandatory costs on the public or entities that seek to download and use the released data. We expect that this data will be available to the public from the CMS Web site (*https://www.cms.gov/*). The public may elect to download the data files, which will not impose mandatory costs on any user. Therefore, we determined that there were not any significant effects of the proposed provisions. We also determined that the proposed regulatory amendments would not impose a burden on the entity requesting or downloading the data files. We did not receive any public comments on our proposed regulatory impact analysis and are finalizing our language as proposed.

6. Prohibition on Billing Qualified Medicare Beneficiary Individuals for Medicare Cost-Sharing

We are restating information to inform providers to take steps to educate themselves and their staff about QMB billing prohibitions and to exempt QMB individuals from Medicare cost-sharing billing and related collection efforts. Therefore, there is no impact to CY 2017 physician payments under the PFS.

7. Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number

This final rule implements section 1866(j) of the Act which grants the Secretary the authority to make any necessary adjustments to the payments of an applicable provider of services or supplier who shares a TIN with an obligated provider of services or supplier that has an outstanding Medicare overpayment. The Secretary is authorized to adjust the payments of such applicable provider, regardless of whether that applicable provider is assigned a different Medicare billing number or National Provider Identifier (NPI) number from the obligated provider with the outstanding Medicare overpayment. The concept of offsetting or recouping payments of providers sharing a TIN to satisfy a Medicare overpayment is analogous to Treasury's current practice of offsetting against entities that share a TIN to collect Medicare overpayments. This final rule will help support our efforts to safeguard the Medicare Trust Funds by collecting its own overpayments more quickly and reducing the accounts receivable delinquency rates reported in the Treasury Report on Receivables. This final rule also helps the obligated provider because we will collect the overpayments more quickly; thus reducing the additional interest assessments that would continue on the provider's outstanding delinquent balance until paid in full. Therefore, there is no impact to CY 2017 physician payments under the PFS.

8. Medicare Advantage Provider Enrollment

This final rule will require that providers and suppliers must be enrolled in Medicare in approved status

in order to render services to beneficiaries in the Medicare Advantage program. This final rule will not have a significant economic impact on a substantial number of small businesses because the total number of non-enrolled providers and suppliers required to enroll in Medicare to comply with this rule appears to be small in comparison to the general population of providers and suppliers. The completion of the Form CMS–855 (as explained in section III.) will be required very infrequently, in many cases either only one time or once every several years. Also, the hour and cost burden per provider or supplier will not pose a significant burden on a provider and supplier, especially when considering the overall revenue that providers and suppliers receive per year. We thus do not believe our proposal will impact a substantial number of small businesses.

Virtually all of the quantifiable costs associated with this final rule involve the paperwork burden to providers and suppliers (see section IV. of this final rule). The estimates presented in this section do not address the potential financial benefits of this final rule from the standpoint of the rule's effectiveness in preventing or deterring certain providers from enrolling in or maintaining their enrollment in Medicare. We simply have no means of quantifying these benefits in monetary terms.

There are three main uncertainties associated with this final rule. First, we are uncertain as to the number of providers and suppliers that will be required to enroll in Medicare under § 422.222. Second, we cannot estimate the savings in fraud and abuse prevention that will accrue from this rule. Third, since we have no systematic method to know how many FDRs may be used by MA or MA–PD organizations to deliver services to Medicare beneficiaries, therefore, we cannot estimate the possible impact to FDRs.

9. Expansion of the Diabetes Prevention Program (DPP) Model

We proposed to expand the Diabetes Prevention Program (DPP) Model in accordance with section 1115A(c) of the Act, and we proposed to refer to this expanded model as the Medicare Diabetes Prevention Program (MDPP). We proposed that MDPP would become effective January 1, 2018, and we would continue to test and evaluate MDPP as finalized. In the future, we will assess whether the nationwide implementation of the MDPP is continuing to either reduce Medicare spending without reducing quality of care or improve the quality of patient care without increasing spending, and could modify the nationwide MDPP as appropriate. In this final rule, we are finalizing the framework for expansion and finalizing details of the MDPP benefit, beneficiary eligibility criteria, and MDPP supplier eligibility criteria and enrollment policies. We will engage in additional rulemaking within the next year to address payment, delivery of virtual MDPP services, the preliminary recognition standard, use of coach information during enrollment and monitoring, and other program integrity safeguards. MDPP policies finalized in this rule and those proposed in future rulemaking will result in changes to our current financial projections and therefore affect economic impact estimates of MDPP. For these reasons, it is premature to provide an impact statement at this time. We intend to provide an impact statement in future rulemaking.

10. Medicare Shared Savings Program

We are finalizing certain rules having to do with ACO quality reporting: (1) We are finalizing conforming changes to align with the policies adopted for the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) in the QPP final rule with comment period including changes to the quality measure set; (2) we are finalizing a policy to streamline the quality validation audit process and, absent unusual circumstances, to use the results to modify an ACO's overall quality score; (3) we are finalizing revisions to references to the Quality Performance Standard and Minimum Attainment Level; (4) we are revising our policies regarding the application of flat percentages to provide that measures calculated as ratios are excluded from use of flat percentages when such benchmarks appear ''clustered'' or ''topped out''; and (5) we are modifying our PQRS alignment rules to permit flexibility for EPs to report quality data to PQRS to avoid the PQRS and VM downward adjustments for 2017 and 2018 in cases where an ACO fails to report on their behalf. (The rule can be accessed at *https://qpp.cms.gov/education*.) In addition, we are updating the assignment methodology to include beneficiaries who identify ACO professionals as being responsible for coordinating their overall care.

We are also finalizing additional beneficiary protections when ACOs in Track 3 make use of the SNF 3-day rule waiver under the Shared Savings Program. Finally, we are finalizing certain technical changes and clarifications related to financial reconciliation for ACOs that fall below 5,000 assigned beneficiaries and related to our policies for consideration of claims billed by merged and acquired TINs.

Because the final policies are not expected to substantially change the quality reporting burden for ACOs participating in the Shared Savings Program and their ACO participants or financial calculations under the Shared Savings Program, we do not anticipate any impact for these final policies.

11. Value-Based Payment Modifier and the Physician Feedback Program

Section 1848(p) of the Act requires that we establish a value-based payment modifier (VM) and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015 and to all physicians and groups of physicians by January 1, 2017. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. Budget-neutrality means that, in aggregate, the increased payments to high performing physicians and groups of physicians equal the reduced payments to low performing physicians and groups of physicians, as well as those physicians and groups of physicians that failed to avoid the PQRS payment adjustment as a group or as individuals.

In the CY 2015 PFS final rule with comment period (79 FR 67936 and 67941 through 67942), we established that, beginning with the CY 2017 payment adjustment period, the VM will apply to physicians in groups with two or more EPs and to physicians who are solo practitioners based on the applicable performance period, including physicians that participate in an ACO under the Shared Savings Program. In the CY 2014 PFS final rule with comment period (78 FR 74771 through 74772), we established CY 2015 as the performance period for the VM that will be applied to payments during CY 2017. In CY 2017, 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 2015 participated in the Pioneer ACO Model or the Comprehensive Primary Care initiative in 2015 (80 FR 71288).

In the CY 2015 PFS final rule with comment period (79 FR 67938 through 67939), we adopted a two-category approach for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners. Category 1 will include those groups that meet the criteria to avoid the PQRS payment adjustment for CY 2017 as a group

practice participating in the PQRS GPRO in CY 2015. We finalized in the CY 2016 PFS final rule with comment period (80 FR 71280 through 71281) that, for the CY 2017 VM, Category 1 will also include groups that have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2017 as individuals. In determining whether a group will be included in Category 1, we will consider whether the 50 percent threshold has been met regardless of whether the group registered to participate in the PQRS GPRO in CY 2015. Lastly, Category 1 will include those solo practitioners that meet the criteria to avoid the PQRS payment adjustment for CY 2017 as individuals.

For groups and solo practitioners that participated in an ACO under the Shared Savings Program in CY 2015, they are considered to be Category 1 for the CY 2017 VM if the ACO in which they participated successfully reported on quality measures via the GPRO Web Interface in CY 2015 (79 FR 67946). As discussed in sections III.H. and III.K.1.e. of this final rule, we are finalizing our proposal to remove the prohibition on EPs who are part of a group or solo practitioner that participates in a Shared Savings Program ACO, for purposes of PQRS reporting for the CY 2017 and CY 2018 payment adjustments, to report outside the ACO. In section III.L.3.b. of this final rule, we are finalizing that for the CY 2017 payment adjustment period, if a Shared Savings Program ACO did not successfully report quality data as required by the Shared Savings Program under § 425.504 for the CY 2017 PQRS payment adjustment, then we will use the data reported to the PQRS by the EPs (as a group using one of the group registry, QCDR, or EHR reporting options or as individuals using the registry, QCDR, or EHR reporting option) under the participant TIN) outside of the ACO during the secondary PQRS reporting period to determine whether the TIN will fall in Category 1 or Category 2 under the VM. We are finalizing that groups that meet the criteria to avoid PQRS payment adjustment for CY 2018 as a group practice participating in the PQRS GPRO (using one of the group registry, QCDR, or EHR reporting options) or have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals (using the registry, QCDR, or EHR reporting option), based on data submitted outside the ACO and during the secondary PQRS reporting period, will be included in Category 1 for the CY 2017 VM. We are also finalizing that solo practitioners that meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals using the registry, QCDR, or EHR reporting option, based on data submitted outside the ACO and during the secondary PQRS reporting period, will be included in Category 1 for the CY 2017 VM and be classified as ''average quality'' and ''average cost'' under the quality-tiering methodology. 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.

The CY 2017 VM payment adjustment amount for groups and solo practitioners in Category 2 is −4.0 percent for groups of physicians with 10 or more EPs and −2.0 percent for groups of physicians with between 2 to 9 EPs and physician solo practitioners.

In the CY 2015 PFS final rule with comment period (79 FR 67939 through 67941), we finalized that quality-tiering, which is the methodology for evaluating performance on quality and cost measures for the VM, will apply to all groups of physicians and physician solo practitioners in Category 1 for the VM for CY 2017. However, groups of physicians with between 2 to 9 EPs and physician solo practitioners will be subject only to upward or neutral adjustments derived under quality-tiering, while groups of physicians with 10 or more EPs will be subject to upward, neutral, or downward adjustments derived under quality-tiering. That is, groups of physicians with between 2 to 9 EPs and physician solo practitioners in Category 1 will be held harmless from any downward adjustments derived under quality-tiering for the CY 2017 VM.

Under the quality-tiering methodology, each group and solo practitioner's quality and cost composites will 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 2017 payment adjustment period according to the amounts in Tables 54 and 55.

TABLE 54—CY 2017 VM PAYMENT ADJUSTMENT AMOUNTS UNDER QUALITY-TIERING FOR GROUPS OF PHYSICIANS WITH TWO TO NINE EPS AND PHYSICIAN 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.

TABLE 55—CY 2017 VM PAYMENT ADJUSTMENT AMOUNTS UNDER QUALITY-TIERING FOR GROUPS OF PHYSICIANS WITH TEN OR MORE EPS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	+2.0x*	+4.0x*
Average cost	−2.0%	+0.0%	+2.0x*
High cost	−4.0%	−2.0%	+0.0%

* Groups eligible for an additional +1.0x if reporting 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 2015, the cost composite will be classified as

''Average'' and the quality of care composite will 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 2017 payment adjustment period according to the amounts in Tables 54 and 55.

We are finalizing in section III.L.3.b. of this final rule, for groups and solo practitioners that participate in a Shared Savings Program ACO that did not successfully report quality data for CY 2015 and are in Category 1 as a result of reporting quality data to the PQRS outside of the ACO using the secondary PQRS reporting period, our proposal to classify their quality composite for the VM for the CY 2017 payment adjustment period as ''average quality.'' Their cost composite will be classified as ''average cost'' (79 FR 67943).

To ensure budget neutrality, we first aggregate the downward payment adjustments in Tables 54 and 55 for those groups and solo practitioners in Category 1 with the automatic downward payment adjustments of −2.0 percent or −4.0 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). We plan to incorporate assumptions about the number of physicians in groups and physician solo practitioners in the ACOs that did not successfully report their CY 2015 quality data whose status could potentially change from Category 2 to Category 1 if the group or solo practitioner satisfactorily report their 2016 data during the secondary PQRS reporting period. Additionally, as we had done when calculating the upward payment adjustment factor for the 2016 VM, we will also incorporate adjustments made for estimated changes in physician behavior (*i.e.,* 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.

On September 26, 2016, we made the 2015 Annual QRURs available to all groups and solo practitioners based on their performance in CY 2015. We also completed a preliminary analysis (based on results included in the 2015 Annual QRURs and prior to accounting for the informal review process) of the impact of the VM in CY 2017 on physicians in groups with 2 or more EPs and physician solo practitioners based on their performance in CY 2015. A summary of the results for groups and solo practitioners subject to the 2017 VM is presented below.

There are 208,832 groups and physician solo practitioners (as identified by their Taxpayer Identification Number (TIN)) consisting of 885,108 physicians whose physicians' payments under the Medicare PFS will be subject to the VM in the CY 2017 payment adjustment period. These counts include both TINs that participated in a Shared Savings Program ACO in CY 2015 and TINs that did not. Of all the physicians subject to the CY 2017 VM, approximately 65 percent of the physicians (577,959 physicians) are in TINs that met the criteria for inclusion in Category 1 and are subject to the quality-tiering methodology in order to calculate their CY 2017 VM; and approximately 35 percent of the physicians (307,149 physicians) are in TINs that are Category 2. Physicians in Category 2 TINs with between 1 to 9 EPs will be subject to an automatic −2.0 percent payment adjustment, while physicians in Category 2 TINs with 10 or more EPs will be subject to an automatic −4.0 percent payment adjustment under the VM during the CY 2017 payment adjustment period for failing to meet quality reporting requirements.

For physicians (428,461) that are in Category 1 TINs that did not participate in a Shared Savings Program ACO (61,445) in CY 2015, Tables 56 and 57 show the distribution of these physicians and TINs with between 1 to 9 EPs and 10 or more EPs, respectively, into the various quality and cost tiers. The results show that 2,351 TINs consisting of 12,026 physicians will receive an upward payment adjustment; 58,099 TINs consisting of 384,922 physicians will receive a neutral payment adjustment; and 995 TINs consisting of 31,513 physicians will receive a downward payment adjustment under the VM in CY 2017.

TABLE 56—PRELIMINARY DISTRIBUTION OF CATEGORY 1 NON-SHARED SAVINGS PROGRAM TINS WITH BETWEEN 1 TO 9 EPS (AND PHYSICIANS IN THE TINS) UNDER THE CY 2017 VM

[53,119 TINs; 101,168 physicians]

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0% (6 TINs; 7 physicians)	+1.0x (36 TINs; 72 physicians) +2.0x* (36 TINs; 75 physicians)	+2.0x (8 TINs; 28 physicians). +3.0x* (11 TINs; 32 physicians).
Average Cost	+0.0% (4,632 TINs; 9,009 physicians)	+0.0% (44,895 TINs; 85,466 physicians).	+1.0x (1,478 TINs; 2,480 physicians) +2.0x* (531 TINs; 1,104 physicians).
High Cost	+0.0% (516 TINs; 943 physicians)	+0.0% (948 TINs; 1,889 physicians)	+0.0% (22 TINs; 63 physicians).

*These TINs were eligible for an additional +1.0x for reporting measures and having an average beneficiary risk score in the top 25 percent of all beneficiary risk scores.

TABLE 57—PRELIMINARY DISTRIBUTION OF CATEGORY 1 NON-SHARED SAVINGS PROGRAM TINS WITH 10 OR MORE EPS (AND PHYSICIANS IN THE TINS) UNDER THE CY 2017 VM

[8,326 TINs; 327,293 physicians]

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0% (3 TINs; 149 physicians)	+2.0x (11 TINs; 383 physicians) +3.0x* (24 TINs; 2,414 physicians)	+4.0x (0 TINs; 0 physicians). +5.0x* (3 TINs; 69 physicians).
Average Cost	−2.0% (612 TINs; 17,272 physicians)	+0.0% (7,069 TINs; 287,111 physicians).	+2.0x (95 TINs; 2,439 physicians) +3.0x* (118 TINs; 2,930 physicians).

TABLE 57—PRELIMINARY DISTRIBUTION OF CATEGORY 1 NON-SHARED SAVINGS PROGRAM TINS WITH 10 OR MORE EPS (AND PHYSICIANS IN THE TINS) UNDER THE CY 2017 VM—Continued

[8,326 TINs; 327,293 physicians]

Cost/quality	Low quality	Average quality	High quality
High Cost	−4.0% (122 TINs; 4,051 physicians) ...	−2.0% (261 TINs; 10,190 physicians)	+0.0% (8 TINs; 285 physicians)

*These TINs were eligible for an additional +1.0x for reporting measures and having an average beneficiary risk score in the top 25 percent of all beneficiary risk scores.

For physicians (149,498) that are in Category 1 TINs that participated in a Shared Savings Program ACO (12,500) in CY 2015, Table 58 shows the distribution of the 389 ACOs into the various quality tiers along with the number of physicians in the ACOs. The results show that physicians in participant TINs in 3 ACOs will receive an upward payment adjustment; physicians in participant TINs in 382 ACOs will receive a neutral payment adjustment; and physicians in participant TINS with 10 or more EPs in 4 ACOs will receive a downward payment adjustment under the VM in CY 2017. Physicians in ACO TINs are more likely to be in a Category 1 TIN compared to those in non-ACO TINs and are less likely to get the downward adjustment based on performance compared to those in Category 1 non-ACO TINs. Physicians in ACOs are also more likely to get either an average or upward adjustment under the VM compared to physicians overall. The VM is applied at the TIN-level, and the amount of the upward or downward adjustment will vary based on the size of the ACO's participant TIN.

TABLE 58—PRELIMINARY DISTRIBUTION OF CATEGORY 1 SHARED SAVINGS PROGRAM ACOS (AND PHYSICIANS IN THE ACOS' PARTICIPANT TINS) UNDER THE CY 2017 VM

[389 ACOs; 149,498 physicians]

Cost/quality	Low quality	Average quality	High quality
Low Cost	Does not apply	Does not apply	Does not apply.
Average Cost	4 ACOs	382 ACOs	3 ACOs.
High Cost	Does not apply	Does not apply	Does not apply.

*These TINs were eligible for an additional +1.0x for reporting measures and having an average beneficiary risk score in the top 25 percent of all beneficiary risk scores.

The numbers presented above are preliminary numbers and may be subject to change as a result of the informal review process. In late 2016, after the conclusion of the informal review period, we will release updates to the number of TINs receiving upward, neutral, and downward adjustments, along with the adjustment factor for the CY 2017 VM on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/2015-QRUR.html.* We note that in the 2015 QRUR Experience Report, which we intend to release in early 2017, we will provide a detailed analysis of the impact of the 2017 VM policies on physicians in groups of 2 or more EPs and physician solo practitioners subject to the VM in CY 2017, including findings based on the data contained in the 2015 Annual QRURs for all groups and solo practitioners.

12. Physician Self-Referral Updates

The physician self-referral update provisions are discussed in section III.M of this final rule. We re-issued regulatory provisions prohibiting certain per-unit of service compensation formulas for determining rental charges in the exceptions for the rental of office space, rental of equipment, fair market value compensation, and indirect compensation arrangements. These provisions are necessary to protect against potential abuses such as overutilization and stifling patient choice. We believe that most parties comply with these regulatory provisions since they originally became effective on October 1, 2009, and the re-issued regulations text is identical to the existing regulations text. Therefore, we do not believe that the provisions will have a significant burden.

G. Alternatives Considered

This final 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 final 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 final payment rates, and therefore, result in different estimates than those shown in Table 52 (CY 2017 PFS Estimated Impact on Total Allowed Charges by Specialty). For example, the estimated increases to primary care specialties would be lessened without the revised payment policies for certain care management and patient-specific services as described in section II.E. of this final rule with comment period. However, because PFS rates are based on relative value units, the final rates reflect all of the final changes and eliminate some of the proposed changes that might have multi-faceted impacts on the payment rates for other services.

H. Impact on Beneficiaries

There are a number of changes in this final 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. In particular, we believe that improving payment for primary care and care management services based on more accurate assessment of patient needs and the resources involved in caring for them will benefit beneficiaries by improving care coordination and

providing more effective treatment, particularly to those beneficiaries with behavioral health conditions.

Most of the aforementioned final 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 2016 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $108.85, which means that in CY 2016, a beneficiary would be responsible for 20 percent of this amount, or $21.77. Based on this final rule, using the CY 2017 CF, the CY 2017 national payment amount in the nonfacility setting for CPT code 99203, as shown in the Impact on Payment for Selected Procedures table, is $109.46, which means that, in CY 2017, the final beneficiary coinsurance for this service would be $21.89.

As discussed in section III.B of this final rule, we proposed that beginning on January 1, 2017, the FQHC base rate would be updated using a FQHC-specific market basket instead of using the MEI to more accurately reflect changes in the cost of furnishing FQHC services. This would result in a higher payment to FQHCs, and since coinsurance is 20 percent of the lesser of the FQHC's charge for the specific payment code or the PPS rate, beneficiary coinsurance would also increase. The FQHC market basket cost estimates in Table 53 include a premium offset line which is the amount of cost that would be offset by the beneficiaries. The beneficiaries would pay approximately $5 million and $35 million over the 5 and 10 year projection windows.

I. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 59 and 60 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2016 to CY 2017 based on the FY 2017 President's Budget baseline.

TABLE 59—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2017 Annualized Monetized Transfers	Estimated increase in expenditures of $0.2 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 60—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2017 Annualized Monetized Transfers of beneficiary cost coinsurance	$0.0 billion.
From Whom to Whom?	Federal Government to Beneficiaries.

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 411

Kidney diseases, Medicare, Physician Referral, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, 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.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.373 is amended by—

■ a. Revising paragraphs (a) introductory text and (b).

■ b. Adding paragraph (f).

The revisions and addition read as follows:

§ 405.373 Proceeding for offset or recoupment.

(a) *General rule.* Except as specified in paragraphs (b) and (f) of this section, if

the Medicare Administrative Contractor or CMS has determined that an offset or recoupment of payments under § 405.371(a)(3) should be put into effect, the Medicare Administrative Contractor must—

* * * * *

(b) *Exception to recouping payment.* Paragraph (a) of this section does not apply if the Medicare Administrative Contractor, after furnishing a provider a written notice of the amount of program reimbursement in accordance with § 405.1803, recoups payment under paragraph (c) of § 405.1803. (For provider rights in this circumstance, see §§ 405.1809, 405.1811, 405.1815, 405.1835, and 405.1843.)

* * * * *

(f) *Exception to offset or recoupment of payments for shared Taxpayer Identification Number.* Paragraph (a) of this section does not apply in instances where the Medicare Administrative Contractor intends to offset or recoup payments to the applicable provider of services or supplier to satisfy an amount due from an obligated provider of services or supplier when the applicable and obligated provider of services or supplier share the same Taxpayer Identification Number.

■ 3. 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 and chronic care management services 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.

* * * * *

■ 4. 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 and chronic care management services 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

■ 5. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd).

■ 6. Section 410.26 is amended by—

■ a. Redesignating paragraphs (a)(3) through (7) as paragraphs (a)(4) through (8), respectively.

■ b. Adding new paragraph (a)(3).

■ c. Revising paragraph (b)(5).

The addition and revision reads as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) * * *

(3) *General supervision* means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service.

* * * * *

(b) * * *

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Designated care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services.

* * * * *

■ 7. Section 410.79 is added to subpart B to 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 January 1, 2018.

(b) *Definitions.* For purposes of this section, the following definitions apply:

Baseline weight refers to the eligible beneficiary's body weight recorded during that beneficiary's first core session.

CDC-approved DPP curriculum refers to the content of the core sessions, core maintenance sessions, and ongoing maintenance sessions. The curriculum may be either the CDC-preferred curriculum as designated by the CDC DPRP Standards or an alternative curriculum approved for use in DPP by the CDC.

Coach refers to an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer.

Core maintenance sessions refer to at least 6 monthly sessions furnished over the MDPP core benefit's months 6–12 and furnished after the core sessions, regardless of weight loss.

Core sessions refer to at least 16 weekly sessions that are furnished over the MDPP core benefit's months 1–6.

Diabetes Prevention Recognition Program (DPRP) refers to a program administered by the Centers for Disease Control and Prevention (CDC) that recognizes organizations that are able to furnish diabetes prevention program (DPP) services, follow a CDC-approved DPP curriculum, and meet CDC's performance standards and reporting requirements.

Evaluation weight refers to the beneficiary's body weight updated from the first core session and recorded before or during that beneficiary's final core session.

Full CDC DPRP recognition refers to the designation from the CDC that an organization has consistently furnished CDC-approved DPP sessions, met CDC-performance standards and met CDC reporting requirements for at least 24–36 months following the organization's application to participate in the DPRP.

Maintenance of weight loss refers to achieving the required minimum weight loss from baseline weight at any point during each 3-month core maintenance or ongoing maintenance session bundle.

Maintenance session bundle refers to each 3-month interval of core maintenance or ongoing maintenance sessions. They must include at least one maintenance session furnished in each of the 3 months, for a minimum of three sessions in each bundle.

MDPP core benefit refers to a 12-month intensive behavioral change program that applies a CDC-approved curriculum. The core benefit consists of at least 16 weekly core sessions over the first 6 months and at least 6 monthly core maintenance sessions over the second 6 months, furnished regardless of weight loss.

MDPP eligible beneficiary refers to an individual who satisfies the criteria defined in paragraph (c)(1) of this section.

MDPP services refer to structural health behavior change sessions with the goal of preventing diabetes among individuals with pre-diabetes. MDPP services consist of core sessions, core maintenance sessions, and ongoing maintenance sessions 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 supplier refers to an entity that has enrolled in Medicare, furnishes MDPP services, and has either preliminary or full CDC DPRP recognition.

Medicare Diabetes Prevention Program (MDPP) refers to an expanded model test under section 1115A(c) of the Act that makes MDPP services available to MDPP eligible beneficiaries.

National Diabetes Prevention Program (DPP) refers to an evidence-based intervention targeted to individuals with pre-diabetes that is furnished in community and health care settings and administered by the Centers for Disease Control and Prevention (CDC).

Ongoing maintenance sessions refer to monthly sessions furnished after the 12-month core benefit has been completed and that teach a CDC-approved curriculum.

Required minimum weight loss refers to the percentage by which the beneficiary's evaluation weight is less than the baseline weight. The required minimum weight loss percentage is 5 percent.

(c) *Program requirements*—(1) *Beneficiary eligibility.* Medicare beneficiaries are eligible for MDPP services if they meet all of the following criteria:

(i) Are enrolled in Medicare Part B.

(ii) 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 and a BMI of at least 23 if self-identified as Asian.

(iii) 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).

(iv) Have no previous diagnosis of type 1 or type 2 diabetes.

(v) Do not have end-stage renal disease (ESRD).

(2) *MDPP services*—(i) *Core sessions and core maintenance sessions.* MDPP suppliers must furnish to MDPP beneficiaries the MDPP core benefit. 16 core sessions must be furnished at least a week apart over a period of at least 16 weeks to 26 weeks. At least one core maintenance session must be furnished in each of the second 6 months. All core sessions and core maintenance sessions must have a duration of approximately one hour. MDPP suppliers must address at least 16 different curriculum topics in the core sessions and at least 6 different curriculum topics in the core maintenance sessions.

(ii) *Ongoing maintenance sessions.* MDPP suppliers must furnish each ongoing maintenance session bundle after the core benefit to MDPP eligible beneficiaries who have achieved maintenance of weight loss during the previous maintenance session bundle. All ongoing maintenance sessions must have a duration of approximately one hour. All curriculum topics may be offered except for the introductory sessions.

(d) *Limitations on coverage of MDPP services.* (1) The MDPP core benefit is available only once per lifetime per MDPP eligible beneficiary.

(2) Ongoing maintenance sessions are available only if the MDPP eligible beneficiary has achieved maintenance of weight loss.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 8. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn).

■ 9. Section 411.357 is amended by revising paragraphs (a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(a) * * *

(5) * * *

(ii) * * *

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

* * * * *

(l) * * *

(3) * * *

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

* * * * *

(p) * * *

(1) * * *

(ii) * * *

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

* * * * *

■ 10. Section 411.372 is amended by revising paragraph (a) to read as follows:

§ 411.372 Procedure for submitting a request.

(a) *Format for a request.* A party or parties must submit a request for an advisory opinion to CMS according to the instructions specified on the CMS Web site.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 11. 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)).

■ 12. Section 414.22 is amended by revising paragraphs (b)(5) introductory text and (b)(5)(i)(A) and (B) to read as follows:

§ 414.22 Relative value units (RVUs).

* * * * *

(b) * * *

(5) For services furnished in 2002 and subsequent years, the practice expense RVUs are based entirely on relative practice expense resources.

(i) * * *

(A) *Facility practice expense RVUs.* The facility practice expense RVUs apply to services furnished to patients in a hospital, a skilled nursing facility, a community mental health center, a hospice, or an ambulatory surgical center, or in a wholly owned or wholly operated entity providing preadmission services under § 412.2(c)(5) of this chapter, or via telehealth under § 410.78 of this chapter.

(B) *Nonfacility practice expense RVUs.* The nonfacility practice expense RVUs apply to services furnished to patients in all locations other than those listed in paragraph (b)(5)(i)(A) of this section, but not limited to, a physician's office, the patient's home, a nursing facility, or a comprehensive outpatient rehabilitation facility (CORF).

* * * * *

§ 414.32 [Removed]

■ 13. Section 414.32 is removed.

■ 14. Section 414.90 is amended by adding paragraphs (j)(1)(ii), (j)(4)(v), (j)(7)(viii) and (k)(4)(ii) to read as follows:

§ 414.90 Physician Quality Reporting System (PQRS).

* * * * *

(j) * * *

(1) * * *

(ii) Secondary Reporting Period for the 2017 PQRS payment adjustment for certain eligible professionals or group practices– Individual eligible professionals or group practices, who bill under the TIN of an ACO participant if the ACO failed to report data on behalf of such EPs or group practices during the previously established reporting period for the 2017 PQRS payment adjustment, may separately report during a secondary reporting period for the 2017 PQRS payment adjustment. The secondary reporting period for the 2017 PQRS payment adjustment for the affected individual eligible professionals or group practices is January 1, 2016 through December 31, 2016.

* * * * *

(4) * * *

(v) Paragraphs (j)(8)(ii), (iii), and (iv) of this section apply to individuals reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

* * * * *

(7) * * *

(viii) Paragraphs (j)(9)(ii), (iii), and (iv) of this section apply to group practices reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

* * * * *

(k) * * *

(4) * * *

(ii) Section 414.90(k)(5) applies to individuals and group practices reporting using the secondary reporting period established under paragraph (j)(1)(ii) of this section for the 2017 PQRS payment adjustment.

* * * * *

■ 15. Section 414.94 is amended by—

■ a. Amending paragraph (b) to add the definitions of ''Applicable payment system'' and ''Clinical decision support mechanism'' in alphabetical order.

■ b. Adding paragraphs (e)(5), (g), (h), and (i).

The additions read as follows:

§ 414.94 Appropriate use criteria for advanced diagnostic imaging services.

* * * * *

(b) * * *

Applicable payment system means the following:

(i) The physician fee schedule established under section 1848(b) of the Act;

(ii) The prospective payment system for hospital outpatient department services under section 1833(t) of the Act; and

(iii) The ambulatory surgical center payment systems under section 1833(i) of the Act.

* * * * *

Clinical decision support mechanism (CDSM) means the following: 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.

* * * * *

(e) * * *

(5) Priority clinical areas include the following:

(i) Coronary artery disease (suspected or diagnosed).

(ii) Suspected pulmonary embolism.

(iii) Headache (traumatic and non-traumatic).

(iv) Hip pain.

(v) Low back pain.

(vi) Shoulder pain (to include suspected rotator cuff injury).

(vii) Cancer of the lung (primary or metastatic, suspected or diagnosed).

(viii) Cervical or neck pain.

* * * * *

(g) *Qualified clinical decision support mechanisms (CDSMs).* Qualified CDSMs are those specified as such by CMS. Qualified CDSMs must adhere to the requirements described in paragraph (g)(1) of this section.

(1) *Requirements for qualification of CDSMs.* A CDSM must meet all of the following requirements:

(i) Make available specified applicable AUC and its related supporting documentation.

(ii) Identify the appropriate use criterion consulted if the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario.

(iii) Make available, at a minimum, specified applicable AUC that reasonably address common and important clinical scenarios within all priority clinical areas identified in paragraph (e)(5) of this section.

(iv) Be able to incorporate specified applicable AUC from more than one qualified PLE.

(v) Determines, for each consultation, the extent to which the applicable imaging service is consistent with specified applicable AUC.

(vi) Generate and provide a certification or documentation at the time of order that documents which qualified CDSM was consulted; the name and national provider identifier (NPI) of the ordering professional that consulted the CDSM; whether the service ordered would adhere to specified applicable AUC; whether the service ordered would not adhere to specified applicable AUC; or whether the specified applicable AUC consulted was not applicable to the service ordered. Certification or documentation must:

(A) Be generated each time an ordering professional consults a qualified CDSM.

(B) Include a unique consultation identifier generated by the CDSM.

(vii) Modifications to AUC within the CDSM must comply with the following timeline requirements:

(A) Make available updated AUC content within 12 months from the date the qualified PLE updates AUC.

(B) A protocol must be in place to expeditiously remove AUC determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed.

(C) Specified applicable AUC that reasonably address common and important clinical scenarios within any new priority clinical area must be made available for consultation through the qualified CDSM within 12 months of the priority clinical area being finalized by CMS.

(viii) Meet privacy and security standards under applicable provisions of law.

(ix) Provide to the ordering professional aggregate feedback regarding their consultations with specified applicable AUC in the form of an electronic report on at least an annual basis.

(x) Maintain electronic storage of clinical, administrative, and demographic information of each unique consultation for a minimum of 6 years.

(xi) Comply with modification(s) to any requirements under paragraph (g)(1) of this section made through rulemaking within 12 months of the effective date of the modification.

(xii) Notify ordering professionals upon de-qualification.

(2) *Process to specify qualified CDSMs.* (i) The CDSM developer must

submit an application to CMS for review that documents adherence to each of the CDSM requirements outlined in paragraph (g)(1) of this section;

(ii) *Receipt of applications.* (A) Applications must be received by CMS annually by January 1 (except as stated in paragraph (g)(2)(ii)(B) of this section).

(B) For CDSM applicants seeking qualification in CY 2017, applications must be submitted by March 1, 2017; and

(*1*) Applications that document current adherence to qualified CDSM requirements will receive full qualification.

(*2*) Applications that do not document current adherence to each qualified CDSM requirement, but that document how and when each requirement is reasonably expected to be met, will receive preliminary qualification.

(*3*) A preliminary qualification period begins under paragraph (2) on June 30, 2017 and ends on the effective date of the requirements under sections 1834(q)(4)(A) and 1834(q)(4)(B) of the Act.

(*4*) A CDSM with preliminary qualification will become fully qualified by the end of the preliminary qualification period, or earlier if CMS determines that the CDSM has demonstrated adherence to each qualified CDSM requirement, unless we determine that the CDSM fails to meet all requirements (including those requirements they expected to meet in paragraph (g)(2)(ii)(B)(*2*) of this section) by the end of the preliminary qualification period.

(iii) All qualified CDSMs specified by CMS in each year will be included on the list of specified qualified CDSMs posted to the CMS Web site by June 30 of that year; and

(iv) Qualified CDSMs are specified by CMS as such for a period of 5 years.

(v) Qualified CDSMs are required to re-apply during the fifth year after they are specified by CMS in order to maintain their status as qualified CDSMs. This application must be received by CMS by January 1 of the 5th year after the most recent approval date.

(h) *Identification of non-adherence to requirements for qualified CDSMs.* (1) If a qualified CDSM is found non-adherent to the requirements in paragraph (g)(1) of this section, CMS may terminate its qualified status or may consider this information during requalification.

(i) *Exceptions.* Consulting and reporting requirements are not required for orders for applicable imaging services made by ordering professionals under the following circumstances:

(1) 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.

(3) Ordering professionals who are granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment for that year under § 495.102(d)(4) of this chapter, except for those granted such an exception under § 495.102(d)(4)(iv)(C) of this chapter.

■ 16. Section 414.1210 is amended by revising paragraphs (b)(2)(i)(B), (C), (D), and (F) to read as follows:

§ 414.1210 Application of the value-based payment modifier.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(B) For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data as required by the Shared Savings Program under § 425.504 of this chapter, the quality composite score is calculated under § 414.1260(a) using quality data reported by the ACO for the performance period through the ACO GPRO Web interface as required under § 425.504(a)(1) of this chapter or another mechanism specified by CMS and the ACO all-cause readmission measure. Groups and solo practitioners that participate in two or more ACOs during the applicable performance period receive the quality composite score of the ACO that has the highest numerical quality composite score. For the CY 2018 payment adjustment period, the CAHPS for ACOs survey also will be included in the quality composite score. For the CY 2017 and 2018 payment adjustment periods, for groups and solo practitioners who participate in a Shared Savings Program ACO that does not successfully report quality data as required by the Shared Savings Program under § 425.504 and who meet the requirements to avoid the PQRS payment adjustment for CY 2018 by reporting to the PQRS outside the ACO, the quality composite is classified as ''average'' under § 414.1275(b).

(C) For the CY 2017 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275 for the payment adjustment period, except that if the ACO (or groups and solo practitioners that participate in the ACO) does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to –4% for groups of physicians with 10 or more eligible professionals and equal to –2% for groups of physicians with two to nine eligible professionals and for physician solo practitioners. If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group of physician or physician solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2017 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3 × (rather than +2 ×) if the group has 10 or more eligible professionals or +2 × (rather than +1 ×) for a solo practitioner or the group has two to nine eligible professionals.

(D) For the CY 2018 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275 for the payment adjustment period, except that if the ACO (or groups and solo practitioners that participate in the ACO) does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to the downward payment adjustment amounts described at § 414.1270(d)(1). If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group or solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2018 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3 × (rather than +2 ×) if the group of physicians has 10 or more eligible professionals, +2 × (rather than +1 ×) for a physician solo practitioner or if the group of physicians has two to nine eligible professionals, or +2 × (rather than +1 ×) for a solo practitioner who is a nonphysician eligible professional or if the group consists of nonphysician eligible professionals.

* * * * *

(F) For groups and solo practitioners that participate in a Shared Savings Program ACO that successfully reports quality data as required by the Shared Savings Program under § 425.504 of this chapter, the same value-based payment modifier adjustment will be applied in the payment adjustment period to all groups based on size as specified under § 414.1275 and solo practitioners that

participated in the ACO during the performance period.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 17. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

■ 18. Section 417.478 is amended by adding paragraph (e) to read as follows:

§ 417.478 Requirements of other laws and regulations.

* * * * *

(e) Sections 422.222 and 422.224 of this chapter which requires all providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, to be enrolled in Medicare in an approved status and prohibits payment to providers and suppliers that are excluded or revoked. This includes locum tenens suppliers and, if applicable, incident-to suppliers.

■ 19. Section 417.484 is amended by adding paragraph (b)(3) to read as follows:

§ 417.484 Requirement applicable to related entities.

* * * * *

(b) * * *

(3) All providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, are enrolled in Medicare in an approved status.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 20. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 21. Section 422.1 is amended by redesignating paragraphs (a)(1)(i) through (x) as paragraphs (a)(1)(ii) through (xi) and adding new paragraph (a)(1)(i) to read as follows:

§ 422.1 Basis and scope.

(a) * * *

(1) * * *

(i) 1106—Disclosure of information in possession of agency.

* * * * *

■ 22. Section 422.204 is amended by adding paragraph (b)(5) to read as follows:

§ 422.204 Provider selection and credentialing.

* * * * *

(b) * * *

(5) Ensures compliance with the provider and supplier enrollment requirements at § 422.222.

■ 23. Section 422.222 is added to subpart E to read as follows:

§ 422.222 Enrollment of MA organization network providers and suppliers; first-tier, downstream, and related entities (FDRs); cost HMO or CMP, and demonstration and pilot programs.

(a) Providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. This requirement applies to all of the following providers and suppliers:

(1) Network providers and suppliers.

(2) First-tier, downstream, and related entities (FDR).

(3) Providers and suppliers in Cost HMOs or CMPs, as defined in 42 CFR part 417.

(4) Providers and suppliers participating in demonstration programs.

(5) Providers and suppliers in pilot programs.

(6) Locum tenens suppliers.

(7) Incident-to suppliers.

(b) MA organizations that do not ensure that providers and suppliers comply with paragraph (a) of this section, may be subject to sanctions under § 422.750 and termination under § 422.510.

■ 24. Section 422.224 is added to subpart E to read as follows:

§ 422.224 Payment to providers or suppliers excluded or revoked.

(a) An MA organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency and urgently needed services as defined in § 422.113) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is revoked from the Medicare program except as provided.

(b) If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is revoked in the Medicare program, the MA organization must notify the enrollee and the excluded or revoked individual or entity in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is revoked in the Medicare program.

■ 25. Section 422.250 is revised to read as follows:

§ 422.250 Basis and scope.

This subpart is based largely on section 1854 of the Act, but also includes provisions from sections 1853 and 1858 of the Act, and is also based on section 1106 of the Act. It sets forth the requirements for the Medicare Advantage bidding payment methodology, including CMS' calculation of benchmarks, submission of plan bids by Medicare Advantage (MA) organizations, establishment of beneficiary premiums and rebates through comparison of plan bids and benchmarks, negotiation and approval of bids by CMS, and the release of MA bid submission data.

■ 26. Section 422.272 is added to subpart F to read as follows:

§ 422.272 Release of MA bid pricing data.

(a) *Terminology.* For purposes of this section, the term ''MA bid pricing data'' means the following information that MA organizations must submit for each MA plan bid for the annual bid submission:

(1) The pricing-related information described at § 422.254(a)(1); and

(2) The information required for MSA plans, described at § 422.254(e).

(b) *Release of MA bid pricing data.* Subject to paragraph (c) of this section and to the annual timing identified in paragraph (d) of this section, CMS will release to the public MA bid pricing data for MA plan bids accepted or approved by CMS for a contract year under § 422.256. The annual release will contain MA bid pricing data from the final list of MA plan bids accepted or approved by CMS for a contract year that is at least 5 years prior to the upcoming calendar year.

(c) *Exclusions from release of MA bid pricing data.* For the purpose of this section, the following information is excluded from the data released under paragraph (b) of this section:

(1) For an MA plan bid that includes Part D benefits, the information described at § 422.254(b)(1)(ii), (c)(3)(ii), and (c)(7).

(2) Additional information that CMS requires to verify the actuarial bases of

the bids for MA plans for the annual bid submission, as follows:

(i) Narrative information on base period factors, manual rates, cost-sharing methodology, optional supplement benefits, and other required narratives.

(ii) Supporting documentation.

(3) Any information that could be used to identify Medicare beneficiaries or other individuals.

(4) Bid review correspondence and reports.

(d) *Timing of data release.* CMS will release MA bid pricing data as provided in paragraph (b) of this section on an annual basis after the first Monday in October.

■ 27. Section 422.501 is amended by adding paragraph (c)(1)(iv) and revising paragraph (c)(2) to read as follows:

§ 422.501 Application requirements.

* * * * *

(c) * * *

(1) * * *

(iv) Documentation that all providers or suppliers in the MA or MA–PD plan that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, are enrolled in an approved status.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation that all providers and suppliers referenced in § 422.222 are enrolled in Medicare in an approved status.

* * * * *

■ 28. Section 422.504 is amended by—

■ a. Revising paragraph (a)(6).

■ b. Adding paragraph (i)(2)(v).

■ c. Revising paragraph (n).

The revisions and addition read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(6) To comply with all applicable provider and supplier requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, limits on physician incentive plans, and Medicare provider and supplier enrollment requirements.

* * * * *

(i) * * *

(2) * * *

(v) They will require all of their providers and suppliers to be enrolled in Medicare in an approved status consistent with § 422.222.

* * * * *

(n) *Acknowledgements of CMS release of data*—(1) *Summary CMS payment data.* The contract must provide that the MA organization acknowledges that CMS releases to the public summary reconciled CMS payment data after the reconciliation of Part C and Part D payments for the contract year as follows:

(i) For Part C, the following data—

(A) Average per member per month CMS payment amount for A/B (original Medicare) benefits for each MA plan offered, standardized to the 1.0 (average risk score) beneficiary.

(B) Average per member per month CMS rebate payment amount for each MA plan offered (or, in the case of MSA plans, the monthly MSA deposit amount).

(C) Average Part C risk score for each MA plan offered.

(D) County level average per member per month CMS payment amount for each plan type in that county, weighted by enrollment and standardized to the 1.0 (average risk score) beneficiary in that county.

(ii) For Part D plan sponsors, plan payment data in accordance with § 423.505(o) of this subchapter.

(2) *MA bid pricing data and Part C MLR data.* The contract must provide that the MA organization acknowledges that CMS releases to the public data as described at §§ 422.272 and 422.2490.

* * * * *

■ 29. Section 422.510 is amended by adding paragraph (a)(4)(xiii) to read as follows:

§ 422.510 Termination of contract by CMS.

(a) * * *

(4) * * *

(xiii) Fails to meet provider and supplier enrollment requirements in accordance with §§ 422.222 and 422.224.

* * * * *

■ 30. Section 422.752 is amended by adding paragraph (a)(13) to read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) * * *

(13) Fails to comply with §§ 422.222 and 422.224, that requires the MA organization to ensure providers and suppliers are enrolled in Medicare and not make payment to excluded or revoked individuals or entities.

* * * * *

■ 31. Section 422.2400 is revised to read as follows:

§ 422.2400 Basis and scope.

This subpart is based on sections 1857(e)(4), 1860D–12(b)(3)(D), and 1106 of the Act, and sets forth medical loss ratio requirements for Medicare Advantage organizations, financial penalties and sanctions against MA organizations when minimum medical loss ratios are not achieved by MA organizations, and release of medical loss ratio data to entities outside of CMS.

■ 32. Section 422.2490 is added to subpart X to read as follows:

§ 422.2490 Release of Part C MLR data.

(a) *Terminology.* Subject to the exclusions in paragraph (b) of this section, Part C MLR data consists of the information contained in reports submitted under § 422.2460.

(b) *Exclusions from Part C MLR data.* For the purpose of this section, the following items are excluded from Part C MLR data:

(1) Narrative descriptions that MA organizations submit to support the information reported to CMS pursuant to the reporting requirements at § 422.2460, such as descriptions of expense allocation methods.

(2) Information that is reported at the plan level, such as the number of member months associated with each plan under a contract, including information submitted for a contract consisting of only one plan.

(3) Any information that could be used to identify Medicare beneficiaries or other individuals.

(4) MLR review correspondence.

(5) Any information for a contract for those contract years for which the contract is determined to be non-credible, as defined in accordance with § 422.2440(d).

(c) *Data release.* CMS releases to the public Part C MLR data, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 33. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 34. Section 423.505 is amended by revising paragraph (o) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(o) *Acknowledgements of CMS release of data*—(1) *Summary CMS payment data.* The contract must provide that the

Part D sponsor acknowledges that CMS releases to the public summary reconciled Part D payment data after the reconciliation of Part D payments for the contract year as follows:

(i) The average per member per month Part D direct subsidy standardized to the 1.0 (average risk score) beneficiary for each Part D plan offered.

(ii) The average Part D risk score for each Part D plan offered.

(iii) The average per member per month Part D plan low-income cost sharing subsidy for each Part D plan offered.

(iv) The average per member per month Part D Federal reinsurance subsidy for each Part D plan offered.

(v) The actual Part D reconciliation payment data summarized at the Parent Organization level including breakouts of risk sharing, reinsurance, and low income cost sharing reconciliation amounts.

(2) *Part D MLR data.* The contract must provide that the Part D sponsor acknowledges that CMS releases to the public data as described at § 423.2490.

* * * * *

■ 35. Section 423.2400 is revised to read as follows:

§ 423.2400 Basis and scope.

This subpart is based on sections 1857(e)(4), 1860D–12(b)(3)(D), and 1106 of the Act, and sets forth medical loss ratio requirements for Part D sponsors, financial penalties and sanctions against Part D sponsors when minimum medical loss ratios are not achieved by Part D sponsors and release of medical loss ratio data to entities outside of CMS.

■ 36. Section 423.2490 is added to subpart X to read as follows:

§ 423.2490 Release of Part D MLR data.

(a) *Terminology.* Subject to the exclusions in paragraph (b) of this section, Part D MLR data consists of the information contained in reports submitted under § 423.2460.

(b) *Exclusions from Part D MLR data.* For the purpose of this section, the following items are excluded from Part D MLR data:

(1) Narrative descriptions that Part D sponsors submit to support the information reported to CMS pursuant to the reporting requirements at § 423.2460, such as descriptions of expense allocation methods.

(2) Information that is reported at the plan level, such as the number of member months associated with each plan under a contract, including information submitted for a contract consisting of only one plan.

(3) Any information that could be used to identify Medicare beneficiaries or other individuals.

(4) MLR review correspondence.

(5) Any information for a contract for those contract years for which the contract is determined to be non-credible, as defined in accordance with § 423.2440(d).

(c) *Data release.* CMS releases to the public Part D MLR data, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 37. 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).

■ 38. Section 424.59 is added to subpart D to read as follows:

§ 424.59 Requirements for Medicare diabetes prevention program suppliers.

(a) *Conditions for enrollment.* An entity may enroll as an MDPP supplier if it satisfies all of the following criteria and meets all other applicable Medicare enrollment requirements:

(1) At the time of enrollment has either preliminary or full CDC DPRP recognition.

(2) Has obtained and maintains an active and valid TIN and NPI at the organizational level.

(3) Has passed application screening at a high categorical risk level per § 424.518(c).

(4) All coaches who will be furnishing MDPP services on the entity's behalf have obtained and maintain active and valid NPIs.

(5) Submits a roster of all coaches who will be furnishing MDPP services on the entity's behalf that includes the coaches' first and last names, date of birth, SSN, and NPI.

(b) *Documentation retention and provision requirements.* An MDPP supplier must maintain all documentation in accordance with § 424.516(f) and all other federal and state laws. The MDPP supplier must submit any documentation requested by the government or a contractor to substantiate the attestations or claims submitted for payment under the Medicare program.

(1) The records must contain documentation of the services furnished including evidence of 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.

(2) MDPP suppliers are required to maintain and handle any beneficiary PII and PHI in compliance with HIPAA, other applicable privacy laws and CMS standards.

(3) The MDPP supplier must maintain a crosswalk between the beneficiary identifiers submitted to CMS for billing and the beneficiary identifiers submitted to CDC for beneficiary level-clinical data.

(4) The records must include an attestation from the supplier that the MDPP eligible beneficiary for which it is submitting a claim:

(i) Has attended 1, 4 or 9 core sessions, or

(ii) Has achieved the required minimum weight loss percentage specified in § 410.79 of this chapter, or

(iii) Has achieved maintenance of weight loss and attended core maintenance sessions, or

(iv) Has achieved maintenance of weight loss and attended ongoing maintenance sessions.

(c) *Conditions for payment of claims for MDPP services furnished.* An MDPP supplier must meet all of the following requirements in order to receive payment for claims made for MDPP services furnished:

(1) Establishes and maintains all enrollment and program requirements under Title 42.

(2) Submits attestation as specified in paragraph (b) of this section.

(d) *Revocation of MDPP supplier enrollment.* An MDPP supplier is subject to revocation of its MDPP supplier enrollment if:

(1) It loses its CDC DPRP recognition or withdraws from seeking CDC DPRP recognition.

(2) One of the revocation reasons specified in § 424.535 applies.

(e) *Procedures for revoking or denying MDPP supplier enrollment.* (1) MDPP suppliers are subject to the enrollment regulations set forth in subpart P of this part.

(2) An MDPP supplier that has had its MDPP supplier enrollment revoked may:

(i) Become eligible to bill for MDPP services again if it reapplies for CDC DPRP recognition, successfully achieves preliminary CDC DPRP recognition, and enrolls again Medicare as an MDPP supplier subject to paragraph (a) of this section.

(ii) Appeal in accordance with the procedures specified in 42 CFR part 405, subpart H, 42 CFR part 424, and 42 CFR part 498. References to suppliers in these sections apply to MDPP suppliers.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 39. **AUTHORITY:** Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302, 1306, 1395hh, and 1395jjj).

■ 40. Section 425.110 is amended by revising paragraph (b)(1) to read as follows:

§ 425.110 Number of ACO professionals and beneficiaries.

* * * * *

(b) * * *

(1) While under the CAP, the ACO remains eligible for shared savings and losses.

(i) For ACOs with a variable MSR and MLR (if applicable), the MSR and MLR (if applicable) will be set at a level consistent with the number of assigned beneficiaries.

(ii) For ACOs with a fixed MSR/MLR, the MSR/MLR will remain fixed at the level consistent with the choice of MSR and MLR that the ACO made at the start of the agreement period.

* * * * *

§ 425.204 [Amended]

■ 41. § 425.204 is amended by—

■ a. Amending paragraph (g) heading to remove the phrase ''and acquired Medicare-enrolled TINs'' and adding in its place the phrase ''and acquired entities' TINs''.

■ b. Amending paragraph (g) introductory text to remove the phrase ''claims billed by Medicare-enrolled entities' TINs that'' and adding in its place the phrase ''claims billed under the TINs of entities that''.

■ c. Amending paragraph (g)(1) introductory text to remove the phrase ''an acquired Medicare-enrolled entity's TIN'' and adding in its place the phrase ''an acquired entity's TIN''.

■ d. Amending paragraph (g)(1)(i) to remove the phrase ''the acquired entity's Medicare-enrolled TIN'' and adding in its place the phrase ''the acquired entity's TIN''

■ e. Amending paragraph (g)(2)(i)(A) to remove the phrase ''Identifies by Medicare-enrolled TIN'' and adding in its place the phrase ''Identifies by TIN''.

§ 425.316 [Amended]

■ 42. Amend 425.316—

■ a. In paragraph (c)(1), by removing the phrase ''minimum attainment level in one or more domains as determined under § 425.502 and may be subject to a CAP. CMS, may forgo the issuance'' and adding in its place the phrase ''minimum attainment level on at least 70 percent of the measures, as determined under § 425.502, in one or more domains and may be subject to a CAP. CMS may forgo the issuance''.

■ b. In paragraph (c)(2) by removing the phrase ''quality performance standards'' and adding in its place the phrase ''quality performance standard''.

■ 43. Section 425.402 is amended by—

■ a. In paragraph (b) introductory text, removing the phrase ''beneficiaries to an ACO:'' and adding in its place the phrase ''beneficiaries to an ACO based on available claims information:''

■ b. Adding paragraph (e).

The addition reads as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(e) For performance year 2018 and subsequent performance years, if a system is available to allow a beneficiary to designate a provider or supplier as responsible for coordinating their overall care and for CMS to process the designation electronically, CMS will supplement the claims-based assignment methodology described in this section with information provided by beneficiaries regarding the provider or supplier they consider responsible for coordinating their overall care. Such designations must be made in the form and manner and by a deadline determined by CMS.

(1) Notwithstanding the assignment methodology under paragraph (b) of this section, beneficiaries who designate an ACO professional participating in an ACO as responsible for coordinating their overall care are prospectively assigned to that ACO, regardless of track, annually at the beginning of each benchmark and performance year based on available data at the time assignment lists are determined for the benchmark and performance year.

(2) Beneficiaries will be added to the ACO's list of assigned beneficiaries if all of the following conditions are satisfied:

(i) The beneficiary must have had at least one primary care service during the assignment window as defined under § 425.20 with a physician who is an ACO professional in the ACO who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

(ii) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to ACOs under all tracks based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section.

(iii) The beneficiary must have designated an ACO professional who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for coordinating their overall care.

(iv) If a beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year under the assignment methodology in paragraph (b) of this section.

(3) The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities are prohibited from providing or offering gifts or other remuneration to Medicare beneficiaries as inducements for influencing a Medicare beneficiary's decision to designate or not to designate an ACO professional under paragraph (e) of this section. The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities must not, directly or indirectly, commit any act or omission, nor adopt any policy that coerces or otherwise influences a Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, including but not limited to the following:

(i) Offering anything of value to the Medicare beneficiary as an inducement to influence the Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section. Any items or services provided in violation of paragraph (e)(3) will not be considered to have a reasonable connection to the medical care of the beneficiary, as required under § 425.304(a)(2).

(ii) Withholding or threatening to withhold medical services or limiting or threatening to limit access to care.

■ 44. Section 425.500 is amended by revising paragraphs (e)(2) and (3) to read as follows:

§ 425.500 Measures to assess the quality of care furnished by an ACO.

* * * * *

(e) * * *

(2) If, at the conclusion of the audit process the overall audit match rate between the quality data reported and the medical records provided under paragraph (e)(1) of this section is less than 90 percent, absent unusual circumstances, CMS will adjust the ACO's overall quality score proportional to the ACO's audit performance.

(3) If, at the conclusion of the audit process CMS determines there is an audit match rate of less than 90 percent, the ACO may be required to submit a CAP under § 425.216 for CMS approval.

* * * * *

■ 45. Section 425.502 is amended by—

■ a. Revising paragraph (a) introductory text.

■ b. In paragraph (a)(1), removing the phrase ''period, CMS, CMS defines'' and adding in its place the phrase ''period, CMS defines''.

■ c. In paragraphs (a)(2) and (3), removing the phrase ''level of certain measures'' and adding in its place ''level of all measures''.

■ d. In paragraph (a)(4), removing the phrases ''The quality performance standard for a newly'' and ''periods, the quality performance standard for the measure'' and adding in their place the phrases ''A newly'' and ''periods, the measure'', respectively.

■ e. In paragraph (b)(2)(ii), removing the phrase ''95 percentt'' and adding in its place the phrase ''95 percent''.

■ f. Revising paragraph (b)(3).

■ g. In paragraph (c)(2), removing the phrase ''level for a measure'' and adding in its place the phrase ''level for a pay-for-performance measure''.

■ h. Adding paragraph (c)(5).

■ i. In paragraph (d) heading, removing the phrase ''quality performance requirements'' and adding in its place the phrase ''quality requirements''.

■ j. In paragraph (d)(1) introductory text, removing the phrase ''individual quality performance standard measures'' and adding in its place the phrase ''individual measures''.

■ k. In paragraph (d)(2) introductory text, removing the phrase ''quality performance requirements'' and adding in its place the phrase ''quality requirements''.

■ l. Revising paragraph (d)(2)(ii).

The revisions and addition read as follows:

§ 425.502 Calculating the ACO quality performance score.

(a) *Establishing a quality performance standard.* CMS designates the quality performance standard in each performance year. The quality performance standard is the overall standard the ACO must meet in order to be eligible for shared savings.

* * * * *

(b) * * *

(3) The minimum attainment level for pay for performance measures is set at 30 percent or the 30th percentile of the performance benchmark. The minimum attainment level for pay for reporting measures is set at the level of complete and accurate reporting.

* * * * *

(c) * * *

(5) Performance equal to or greater than the minimum attainment level for pay-for-reporting measures will receive the maximum available points.

(d) * * *

(2) * * *

(ii) CMS may take the compliance actions described in § 425.216 for ACOs exhibiting poor performance on a domain, as determined by CMS under § 425.316.

* * * * *

■ 46. Section 425.504 is amended by—

■ a. Amending paragraph (c) to remove the phrase ''for 2016 and subsequent years'' everywhere it appears and adding in its place the phrase ''for 2016''.

■ b. Redesignating paragraph (d) as paragraph (c)(5).

■ c. Adding new paragraph (d).

The addition reads as follows:

§ 425.504 Incorporating reporting requirements related to the Physician Quality Reporting System Incentive and Payment Adjustment.

* * * * *

(d) *Physician Quality Reporting System payment adjustment for 2017 and 2018.* (1) ACOs, on behalf of eligible professionals who bill under the TIN of an ACO participant, must submit all of the ACO GPRO measures determined under § 425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2017 and 2018.

(2) Eligible professionals who bill under the TIN of an ACO participant within an ACO participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2017 and 2018.

(3) If an ACO, on behalf of eligible professionals who bill under the TIN of an ACO participant, does not satisfactorily report for purposes of the Physician Quality Reporting System payment adjustment for 2017 or 2018, each eligible professional who bills under the TIN of an ACO participant will receive a payment adjustment, as described in § 414.90(e) of this chapter, unless such eligible professionals have reported quality measures apart from the ACO in the form and manner required by the Physician Quality Reporting System.

(4) For eligible professionals subject to the Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program for 2017 or 2018, the Medicare Part B Physician Fee Schedule amount for covered professional services furnished during the program year is equal to the applicable percent of the Medicare Part B Physician Fee Schedule amount that would otherwise apply to such services under section 1848 of the Act, as described in § 414.90(e) of this chapter.

(5) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied, unless otherwise specified by CMS under the Physician Quality Reporting System.

■ 47. Section 425.506 is amended by—

■ a. Revising the section heading.

■ b. Amending paragraph (d) introductory text to remove the phrase ''Eligible professionals participating in an ACO'' and adding in its place the phrase ''Through reporting period 2016, eligible professionals participating in an ACO''

■ c. Adding paragraph (e).

The revision and addition read as follows:

§ 425.506 Incorporating reporting requirements related to adoption of certified electronic health record technology.

* * * * *

(e) For 2017 and subsequent years, CMS will annually assess the degree of use of certified EHR technology by eligible clinicians billing through the TINs of ACO participants for purposes of meeting the CEHRT criterion necessary for Advanced Alternative Payment Models under the Quality Payment Program.

(1) During years in which the measure is designated as pay for reporting, in order to demonstrate complete and accurate reporting, at least one eligible clinician billing through the TIN of an ACO participant must meet the reporting requirements under the Advancing Clinical Information category under the Quality Payment Program.

(2) During years in which the measure is designated as pay for performance, the quality measure regarding EHR adoption will be measured based on a sliding scale.

■ 48. Section 425.508 is added to subpart F to read as follows:

§ 425.508 Incorporating quality reporting requirements related to the Quality Payment Program.

(a) *For 2017 and subsequent reporting years.* ACOs, on behalf of eligible clinicians who bill under the TIN of an ACO participant, must submit all of the CMS web interface measures determined under § 425.500 to satisfactorily report on behalf of their eligible clinicians for purposes of the quality performance category of the Quality Payment Program.

(b) [Reserved]

■ 49. Section 425.612 is amended by—

■ a. Amending paragraph (a)(1) introductory text to remove the phrase ''ACOs participating in Track 3 that receive otherwise'' and adding in its place the phrase ''ACOs participating in Track 3, and as provided in paragraph (a)(1)(iv) of this section during a grace period for beneficiaries excluded from prospective assignment to a Track 3 ACO, who receive otherwise''.

■ b. Adding paragraphs (a)(1)(iv), (a)(1)(v), and (d)(4).

The additions read as follows:

§ 425.612 Waivers of payment rules or other Medicare requirements.

(a) * * *

(1) * * *

(iv) For a beneficiary who was included on the prospective assignment list under § 425.400(a)(3) for a performance year for a Track 3 ACO for which a waiver of the SNF 3-day rule has been approved under paragraph (a)(1) of this section, but who was subsequently excluded from the ACO's prospective assignment list, CMS makes payment for SNF services furnished to the beneficiary by a SNF affiliate if the following conditions are met:

(A) The beneficiary was prospectively assigned to the ACO at the beginning of the applicable performance year but was excluded in the most recent quarterly update to the prospective assignment list under § 425.401(b).

(B) The SNF services are furnished to a beneficiary who was admitted to a SNF affiliate within 90 days following the date that CMS delivers the quarterly exclusion list to the ACO.

(C) But for the beneficiary's exclusion from the ACO's prospective assignment list, CMS would have made payment to the SNF affiliate for such services under the waiver under paragraph (a)(1) of this section.

(v) The following beneficiary protections apply when a beneficiary receives SNF services without a prior 3-day inpatient hospital stay from a SNF affiliate that intended to provide services pursuant to a SNF 3-day rule waiver under paragraph (a)(1) of this section, but the beneficiary was not prospectively assigned to the ACO and was not in the 90 day grace period under paragraph (a)(1)(iv) of this section. The SNF affiliate services must be non-covered only because the SNF affiliate stay was not preceded by a qualifying hospital stay under section 1861(i) of the Act.

(A) A SNF is presumed to intend to provide services pursuant to the SNF 3-day rule waiver under paragraph (a)(1) of this section if the SNF submitting the claim is a SNF affiliate of an ACO for which such a waiver has been approved.

(B) CMS makes no payments for SNF services to a SNF affiliate of an ACO for which a waiver of the SNF 3-day rule has been approved when the SNF affiliate admits a FFS beneficiary who was never prospectively assigned to the ACO or was prospectively assigned but was later excluded and the 90 day grace period under paragraph (a)(1)(iv) of this section has lapsed.

(C) In the event that CMS makes no payment for SNF services furnished by a SNF affiliate as a result of paragraph (a)(1)(v)(B) of this section and the only reason the claim was non-covered is due to the lack of a qualifying inpatient stay, the following beneficiary protections will apply:

(1) The SNF must not charge the beneficiary for the expenses incurred for such services; and

(2) The SNF must return to the beneficiary any monies collected for such services; and

(3) The ACO may be required to submit a corrective action plan under § 425.216(b) for CMS approval. If after being given an opportunity to act upon the corrective action plan the ACO fails to come into compliance with the requirements of paragraph (a)(1), approval for the SNF 3-day rule waiver under this section will be terminated as provided under paragraph (d) of this section.

* * * * *

(d) * * *

(4) CMS reserves the right to take compliance action, including termination, against an ACO for noncompliance with program rules, including misuse of a waiver under this section, as specified at §§ 425.216 and 425.218.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 50. The authority citation for part 460 continues to read as follows:

Authority: Secs. 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f)).

■ 51. Section 460.40 is amended by adding paragraph (j) to read as follows:

§ 460.40 Violations for which CMS may impose sanctions.

* * * * *

(j) Employs or contracts with any provider or supplier that is a type of individual or entity that can enroll in Medicare in accordance with section 1861 of the Act, that is not enrolled in Medicare in an approved status.

■ 52. Section 460.50 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 460.50 Termination of PACE program agreement.

* * * * *

(b) * * *

(1) * * *

(ii) The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement, including employing or contracting with any provider or supplier that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, that is not enrolled in Medicare in an approved status.

* * * * *

■ 53. Section 460.68 is amended by adding paragraph (a)(4) to read as follows:

§ 460.68 Program integrity.

(a) * * *

(4) That are not enrolled in Medicare in an approved status, if the providers or suppliers are of the types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act.

* * * * *

■ 54. Section 460.70 is amended by adding paragraph (b)(1)(iv) to read as follows:

§ 460.70 Contracted services.

* * * * *

(b) * * *

(1) * * *

(iv) Providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an

approved status in Medicare in order to provide health care items or services to a PACE participant who receives his or her Medicare benefit through a PACE organization.

* * * * *

■ 58. Section 460.71 is amended by adding paragraph (b)(7) to read as follows:

§ 460.71 Oversight of direct participant care.

* * * * *

(b) * * *

(7) Providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a PACE participant who receives his or her Medicare benefit through a PACE organization.

■ 59. Section 460.86 is added to subpart E to read as follows:

§ 460.86 Payment to providers or suppliers excluded or revoked.

(a) A PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is revoked from the Medicare program.

(b) If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is revoked in the Medicare program, the PACE organization must notify the enrollee and the excluded or revoked individual or entity in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is exclude by the OIG or is revoked in the Medicare program.

Dated: October 24, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: October 27, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–26668 Filed 11–2–16; 4:15 pm]

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