

**Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program
[CMS-1693-P]**

Summary of Proposed Rule

On July 12, 2018¹, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule relating to the Medicare physician fee schedule (PFS) for CY 2019² and other revisions to Medicare Part B policies. The proposed rule is scheduled to be published in the July 27, 2018 issue of the *Federal Register*. If finalized, policies in the proposed rule generally would take effect on January 1, 2019. **The 60-day comment period ends at close of business on September 10, 2018.**

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¹ This summary was prepared from the July 12th display copy of the proposed rule. On July 18th, the *Federal Register* posted a revised version of the proposed rule with an editorial note indicating that due to technical issues, it had changed the document. The nature of those changes was not described, and the revised version was one page shorter in length. HPA did a preliminary review of the revised version which did not reveal any changes to the policy discussion or to the language of the proposed regulation text. Formatting and a graph (Figure A) were corrected. We are continuing to identify whether there are other differences and will notify clients if we learn of any substantive changes.

² Henceforth in this document, a year is a calendar year unless otherwise indicated.

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I. Introduction and Background

The proposed rule would update the PFS payment policies that apply to services furnished by physicians and other practitioners in all sites of services. In addition to physicians, the PFS is used to pay a variety of practitioners and entities including nurse practitioners, physician assistants, physical therapists, radiation therapy centers, and independent diagnostic testing facilities. The proposed rule includes a proposal related to office/outpatient E/M codes; CMS proposes alternatives for documenting the appropriate level of E/M visit and a single payment rate for established E/M visits. CMS also proposes to pay separately for two newly defined physicians' services using communication technologies. In addition, CMS proposes to systematically update the prices of over 1,300 supplies and 750 equipment items used in the calculation of practice expense.

Prior to 2015, the annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula (the Sustainable Growth Rate methodology that was largely overridden each year by Congressional action). The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the update for calendar years 2015 through 2025. For 2019, the specified update is 0.5 percent, before applying additional adjustments. Section 53106 of the Bipartisan Budget Act (BBA) of 2018 requires for 2019 an update of 0.25 percent before applying any other adjustments. In addition to the update factor, the CF for 2019 takes into account an RVU budget neutrality adjustment.

The proposed CF for 2019 is \$36.0463, which reflects the 0.25 percent update adjustment factor specified under BBA of 2018 and a budget neutrality adjustment of -0.12 percent (2018 conversion factor is $\$35.9996 \times 1.025 \times 0.9988$). The 2019 proposed anesthesia conversion factor is \$22.2986, which reflects the same adjustments and an additional adjustment due to an update to the malpractice risk factor for the anesthesia specialty. Table 92 from the proposed rule, is reproduced below.

TABLE 92: Calculation of the Proposed 2019 PFS Conversion Factor

Conversion Factor in effect in 2018		\$35.9996
Statutory Update Factor	0.25 percent (1.0025)	
2019 RVU Budget Neutrality Adjustment	-0.12 percent (0.9988)	
2019 Conversion Factor		\$36.0463

The most widespread specialty impacts of the proposed RVU changes are generally related to changes for specific services resulting from the Misvalued Code Initiatives, including the establishment of proposed RVUs for new and revised codes. CMS states that the specialty level impacts in this proposed rule are being driven by CMS’ proposal related to office/outpatient E/M codes, which comprise a large volume of services in the PFS. In addition, CMS also proposes to systematically update prices of over 1,300 supplies and 750 equipment items used in the calculation of practice expense, which also contributed to specialty level impacts.

On a specialty-specific basis, CMS estimates that the combined impact of the proposed rule would have the greatest positive effect on payments to clinical social workers (+3 percent) and clinical psychologists (+2 percent); and the greatest negative effect on diagnostic testing facilities (-6 percent), allergy/immunology (-3 percent), cardiac surgery (-2 percent), cardiology (-2 percent), independent laboratory (-2 percent), oral/maxillofacial surgery (-2 percent), otolaryngology (-2 percent), pathology (-2 percent) and vascular surgery (-2 percent).

The proposed rule also establishes updates to the Quality Payment Program (QPP) for 2019, Year 3. The QPP is composed of 2 tracks: (1) The Merit-based Incentive Payment System (MIPS) and (2) Advanced Alternative Payment Models (APMs).

For the 2019 performance period (payment in 2021), CMS proposes to modify the definition of a MIPS eligible clinician to include the following eligible clinician types: physical therapist, occupational therapist, clinical social worker³, clinical psychologist⁴, and a group that includes such clinicians. CMS also proposes some modifications to three of the MIPS performance categories: Quality, Cost, and Improvement Activities. In addition to renaming the “Advancing Care Information” to “Promoting Interoperability” performance category, CMS proposes a new scoring methodology based on a combination of measures instead of the current base, performance and bonus score methodology. For the 2019 performance year final score, CMS proposes the following weights: 45 percent for quality, 15 percent for cost, 15 percent for improvement activities and 25 percent for promoting interoperability. CMS also proposes refinements to the methodology for determining the MIPS final score for the 2021 payment year.

With respect to APMs, CMS would maintain many of the policies it finalized for Advanced APM models and the requirements for MIPS eligible clinicians to be considered Qualifying APM Participants (QPs) or Partial QPs through their participation in Advanced APMS and Other Payer Advanced APMs. CMS proposes various changes and updates including extending the 8 percent revenue-based nominal amount standard for Advanced APMs through performance year

³ A clinical social worker as defined at section 1861 (hh)(1) of the Act.

⁴ A clinical psychologist as defined by section 1861(ii) of the Act.

2024 and increasing flexibility for the all-Payer Combination Option and Other Payer Advanced APMs for non-Medicare payers to participate in the QPP.

CMS estimates that approximately 43 percent of the nearly 1.5 million clinicians billing to Part B (650,165) will be assigned a MIPS score for 2021 payment because others will be ineligible for or excluded from MIPS. For 2021, CMS estimates that it will redistribute about \$372 million in payment adjustments on a budget neutral basis. Under the estimates, 96 percent of eligible clinicians will have a positive or neutral payment adjustment and 3.9 percent will have a negative payment adjustment. Approximately 160,000 to 215,000 clinicians will become QPS for the 2021 and an estimated \$600 to \$800 million in incentive payments are expected to be made.

The addenda to the proposed rule along with other supporting documents are only available through the Internet at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

II. Provisions of the Proposed Rule for PFS

A. Determinations of Practice Expense (PE) Relative Value Units (RVUs)

1. Practice Expense Methodology

CMS summarizes the history of the development of PE RVUs, the steps involved in calculating direct and indirect cost PE RVUs, and other related matters.

For 2019, CMS makes note of several issues in this section.

CMS has incorporated the available utilization data for two new specialties: hospitalists and advanced heart failure and transplant cardiology.⁵ CMS proposes to use proxy practice expense per hour (PE/HR) values for these new specialties by crosswalking the PE/HR from specialties that furnish similar services in the Medicare claims data. Hospitalists would use PE/HR data from emergency medicine, and advanced heart failure and transplant cardiology would use PE/HR data from cardiology. This relevant PE/HR data can be found in the 2019 PFS Proposed Rule PE/HR file published on CMS' website.⁶

CMS proposes to add 28 codes that it has identified as low volume services to the list of codes for which it assigns the expected specialty. CMS notes that for each of these codes, only the professional component is nationally priced, and that the global and technical components are priced by the Medicare Administrative Contractors (MACs). These new additions to the expected specialty list for low volume services can be found in Table 1 of the proposed rule (page 24 of the display copy), and the complete list of expected specialties (2,081 codes) can be found on CMS' website.⁷ CMS is following its approach finalized in 2018. Under this approach, CMS

⁵ These became recognized Medicare specialties in 2017.

⁶ See <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2019-PFS-NPRM-PEHR.zip>

⁷ See <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2019-PFS-NPRM-Specialty-Assignment.zip>

uses the most recent year of claims data to determine which codes are low-volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). Instead of assigning specialty mix based on the specialties reporting the services in the claims data, CMS assigns an expected specialty based on input from the RUC and other stakeholders. Services for which the specialty is automatically assigned based on previous policies (such as “always therapy” services) are unaffected by the list of expected specialty assignments. These service-level overrides also apply for both PE and MP calculations.

With respect to the formula for calculating equipment cost per minute, CMS notes that it currently uses an equipment utilization rate assumption of 50 percent for most equipment (90 percent for expensive diagnostic imaging equipment as required by statute). Stakeholders have suggested that particular equipment items are used less frequently than 50 percent of the time in the typical setting and that CMS should reduce this rate. As it has stated in the past, CMS continues to believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate. CMS welcomes submission of data that would justify an alternative equipment utilization rate. In addition, CMS also notes that it continues to investigate ways to determine equipment maintenance costs across the range of equipment items.

2. Changes to Direct PE Inputs for Specific Services

a. Standardization of Clinical Labor Tasks

CMS states that it continues to work on revisions to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the pre-service, service, and post-service periods for each code. CMS believes that by doing so, this will increase the transparency of the information used to set PE RVUs, facilitate the identification of exceptions to the usual values, provide greater consistency among codes that share the same clinical labor tasks, and improve relativity of values among codes. In addition, CMS notes the advantage that as medical practice and technologies change over time, changes in the standards could be updated at once for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In this rule, CMS proposes to maintain the 3 minutes of clinical labor time for the “prepare room, equipment and supplies” activity and remove the clinical labor time for the “confirm order, protocol exam” activity wherever it observes this pattern in the RUC- recommended direct PE inputs. For some codes, these activities have been split into two and CMS is combining them into one activity. CMS note that there would be no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being used in the calculation of PE RVUs.

CMS notes that beginning in 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. As it did for 2018, CMS continues to display two

versions of the Labor Task Detail public use file to facilitate rulemaking for 2019: one version with the old listing of clinical labor tasks, and one with the same tasks cross-walked to the new listing of clinical labor activity codes. These lists are available on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

b. Equipment Recommendations for Scope Systems

CMS states that during its routine reviews of direct PE input recommendations, it has regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. For example, some of the scopes include video systems bundled into the equipment item, while others include scope accessories as part of their price. To address this issue, CMS finalized in 2017 a structure that separates the scope and the associated video system as distinct equipment items for each code, and finalized a price of the endoscopy video system. These changes applied to reviewed codes for 2017 that made use of scopes, but CMS did not apply these policies to codes with inputs reviewed prior to 2017.

CMS states that it did not make further changes to existing scope equipment in 2017 in order to allow the RUC's PE Subcommittee the opportunity to provide feedback, but CMS believed there was miscommunication as the RUC's subcommittee believed no further action was required.

In 2018, CMS made additional proposals, to create a single scope equipment code for each of the five categories detailed in this proposed rule: (1) a rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. CMS stated its belief that the variation between these scopes was not significant enough to warrant maintaining these distinctions within a category, and that creating and pricing a single scope equipment code for each category would help provide additional clarity. After review of comments, CMS did not finalize its proposal and instead is continuing to seek detailed recommendations from expert stakeholders on an approach (as suggested by a commenter) that would create scope equipment codes on a per-specialty basis for six categories of scopes (including multi-channeled flexible video scopes).

For 2019, CMS proposes to delay proposals for any further changes to scope equipment until 2020, so that it can incorporate feedback from a RUC workgroup: the Scope Equipment Reorganization Workgroup. CMS, however, makes two proposals:

- Proposes to update the price of the scope video system (ES031) from its current price of \$33,391 to a price of \$36,306 to reflect the addition of the LED light and miscellaneous small equipment associated with the system.
- Proposes to update the name of the ES031 equipment item from “video system, endoscopy (processor, digital capture, monitor, printer, cart)” to “scope video system (monitor, processor, digital capture, cart, printer, LED light)”. CMS believes that this would clarify that the use of the ES031 scope video system is not limited to endoscopy procedures.

c. Balloon Sinus Surgery Kit (SA106) Comment Solicitation

Several stakeholders contacted CMS and advised that the price of the balloon sinus surgery kit (SA106) has decreased significantly since it was priced through rulemaking in 2011 (currently \$2,599.86). This kit is used in three CPT codes (31295, 31296, and 31297) related to sinus treatments. In addition, these commenters noted that the same catheter could be used to treat multiple sinuses rather than being a disposable onetime use supply. These commenters wanted CMS to examine this issue as marketing firms and sales representatives have been advertising these CPT codes as a way to generate additional profits (given that payments exceed typical resources needed).

In light of this information, CMS solicits comments on two aspects of the use of the balloon sinus surgery kit (SA106) supply: the supply quantity and the price. With respect to the supply quantity, CMS asks whether the 0.5 supply quantity of the balloon sinus surgery kit in CPT codes 31295-31297 would be typical for these procedures. CMS is concerned that even the 0.5 supply quantity may be overstating the resources typically needed to furnish each service. CMS also solicits comments on the pricing of the balloon sinus surgery kit or its individual components (Table 5 in the proposed rule lists the supply components that comprise the kit and the current prices for each).

c. Technical Corrections to Direct PE Input Database and Supporting Files

For 2019, CMS proposes to correct several clerical inconsistencies and make some technical corrections to the direct PE input database:

- The RUC alerted CMS that 165 CPT codes billed with an office E/M code have more minimum multi-specialty visit supply packs (SA048) than post-operative visits included in the code's global period. CMS proposes to align the number of minimum multi-specialty visit packs with the number of post-operative office visits included in these codes. CMS shows its proposed refinements for the 165 CPT codes in Table 6 of the proposed rule. For example, CPT code 27780 (treatment of fibula fracture) assumes 3.5 post-op office visits, but 4.5 visit supply packs. CMS proposes 3.5 visit supply packs for this code to align with the number of post-op office visits. CMS is not proposing any refinements for the three CPT codes being deleted or the 8 codes being reviewed by the RUC this year.
- CMS proposes to revise the direct PE inputs for CPT code 11311 (shave skin lesion 0.6-1.0 cm) to correct a data entry error. The direct inputs will be revised to reflect the values established through rulemaking in 2013.
- CMS notes in 2018 it assigned to many minutes of clinical labor time for the "Obtain vital signs" task to three therapy codes (CPT codes 97124, 97750, and 97755), as these codes are typically billed in multiple units and in conjunction with other therapy codes for the same patient on the same day. It wouldn't be typical for clinical staff to obtain vital signs each time these codes are reported. Thus, CMS proposes to refine the "Obtain vital signs" clinical labor task for these three codes back to their previous times of 1 minute for CPT codes 97124 and 97750 and to 3 minutes for CPT code 97755. CMS also proposes to refine the equipment

time for the table, mat, hi-lo, 6 x 8 platform (EF028) for CPT code 97124 to reflect the change in the clinical labor time.

- In response to a commenter, CMS proposes to add the endoscope disinfectant (ES005) to CPT code 52000, and to add 22 minutes of equipment time for that item to match the equipment time of the other non-scope items included in this code.

d. Updates to Prices for Existing Direct PE Inputs

For 2019, CMS proposes to update the prices of four supplies and one equipment item in response to public submission of invoices. These items include the kit, transurethral microwave thermotherapy (SA036); kit, transurethral needle ablation (SA037); stain, Wright's Pack (per slide), (SL140); neurobehavioral status forms, average (SK050); and Breast MRI computer aided detection and biopsy guidance software (EQ370). See Table 15 in the proposed rule for details on the updated prices, CPT codes affected, and number of services impacted.⁸

CMS notes that to be included a given year's proposed rule, it generally needs to receive invoices by February (February 10th deadline in 2019). CMS notes it will, of course, consider invoices submitted during the comment period following the publication of the proposed rule or during other times as part of its annual process.

For 2019, CMS also discussed two additional issues in this proposed rule in this section: market-based supply and equipment pricing update and breast biopsy software.

(1) Market-Based Supply and Equipment Pricing Update

CMS states that as part of its authority under section 1848(c)(2)(M) of the Act, as added by the PAMA, it initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing for 2019. CMS notes that these supply and equipment prices were last systematically developed in 2004-2005. StrategyGen has submitted a report with updated pricing recommendations for approximately 1,300 supplies and 750 equipment items currently used as direct PE inputs. CMS provided the list of supplies and equipment for the contractor to examine.

CMS discusses the approach StrategyGen took to obtain updated price data and the criteria it used to determine its recommended price for a given item. To obtain prices, for example, StrategyGen examined data sources of commercial prices (e.g. health system provider databases, Amazon Business, Cardinal Health), the General Services Administration (GSA) schedule, and a market research survey of vendors, among other sources. CMS notes that the preliminary data indicate that in the aggregate there were no statistically significant differences between the estimated commercial prices and the current CMS prices for both equipment and supplies. At the service level, however, CMS notes there may be large shifts in PE RVUs for individual codes that happened to contain supplies and/or equipment with major changes in pricing.

⁸ CMS incorrectly cites Table 16 in the proposed rule.

CMS proposes to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen. Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, CMS proposes to phase in its use of the new direct PE input pricing over a 4-year period. CMS notes that this approach is consistent with how it has previously incorporated significant new data into the calculation of PE RVUs, such as changing to the “bottom-up” PE methodology.

With respect to the phase-in, CMS proposes to implement this pricing transition such that one quarter of the difference between the current price and the fully phased in price is implemented for 2019, one third of the difference between the 2019 price and the final price is implemented for 2020, and one half of the difference between the 2020 price and the final price is implemented for 2021, with the new direct PE prices fully implemented for 2022. An example of the proposed transition from the current to the fully-implemented new pricing is provided in Table 7 in the proposed rule (reproduced below).

Current Price	\$100	
Final Price	\$200	
Year 1 (2019) Price	\$125	1/4 difference between \$100 and \$200
Year 2 (2020) Price	\$150	1/3 difference between \$125 and \$200
Year 3 (2021) Price	\$175	1/2 difference between \$150 and \$200
Final (2022) Price	\$200	

CMS highlights two instances where it proposes to fully implement those prices with no transition. This includes (1) new supply and equipment codes for which it establishes prices during the transition years (2019, 2020 and 2021) based on the public submission of invoices, and (2) existing supply and equipment codes, when it establishes prices based on invoices that are submitted as part of a revaluation or comprehensive review of a code or code family

CMS highlights two other instances where it proposes to phase-in any new or updated pricing over the remaining years of the proposed 4-year transition period. This includes (1) existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which its establishes prices based on invoices submitted by the public, and (2) any updated pricing on very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family.

The full report from the contractor, including the updated supply and equipment pricing as it is proposed to be implemented over the proposed 4-year transition period, and the public use file showing the updated pricing is available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2019-PFS-NPRM-Market-Based-Supply.zip>

CMS invites comments from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration. CMS states that it is particularly interested in comments regarding the supply and equipment pricing for

CPT codes 95165 and 95004 that are frequently used by the Allergy/Immunology specialty, as this specialty was disproportionately affected by the updated pricing.

CMS also seeks public comment regarding whether to update the clinical labor wages used in developing PE RVUs in future calendar years during the 4-year pricing transition for supplies and equipment, or whether it would be more appropriate to update the clinical labor wages at a later date following the conclusion of the transition for supplies and equipment.

(2) Breast Biopsy software (EQ370)

CMS received a request that it update the price for the Breast Biopsy software (EQ370) equipment, and that it be included in six CPT codes (19085, 19086, 19287, 19288, 77X51, and 77X52). This equipment item currently lacks a price in the direct PE database, and CMS decided when an invoice was first submitted (2014 PFS rule) that this item served clinical functions similar to other items already included in the Magnetic Resonance (MR) room equipment package (EL008) included in the same CPT codes under review. The stakeholder supplied an invoice with a purchase price of \$52,275 for the equipment.

After its review of the use of this software in these codes, CMS is not proposing to update the price or add the software to these procedures for the same reasons as cited previously. CMS plans to update the name of the EQ370 equipment item from “Breast Biopsy software” to the requested “Breast MRI computer aided detection and biopsy guidance software” to help better describe the equipment in question.

3. Adjustment to Allocation of Indirect PE for Some Office-Based Services

As background, CMS allocates indirect costs for each code on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. Indirect expenses include administrative labor, office expense, and all other expenses. For most services, the direct PE input costs are higher in the nonfacility setting than in the facility setting, and thus indirect PE RVUs allocated to these services are higher in the nonfacility setting than in the facility setting. In cases where direct PE inputs for a service are very low, however, the allocation of indirect PE RVUs is almost exclusively based on work RVUs, which results in a very small (or no) site of service differential between the total PE RVUs in the facility and nonfacility setting.

In 2018, CMS finalized a modification in the PE methodology for allocating indirect PE RVUs to better reflect the relative indirect PE resources involved in furnishing these services (mostly behavioral health services). CMS refers readers to the 2018 PFS final rule (FR 52999 through 53000) for a discussion of this revised methodology. CMS first began implementing this modification in 2018, the first year of a 4-year transition. For 2019, CMS proposes to continue with the second year of the transition of this adjustment to the standard process for allocating

indirect PE. There are 28 codes affected by this policy, and the list is available on CMS' website.⁹

B. Determination of Malpractice Relative Value Units (MP RVUs)

Section 1848(c) of the Act requires that each service paid under the PFS be comprised of three components: work, PE, and MP expense. By way of background, the resource-based formula to determine the MP for a given service is comprised of three major components: (1) specialty's risk factor, (2) specialty weight—or the mix of practitioners providing the service—compared to all other specialties, and (3) work value for the service. In 2015, CMS implemented the third comprehensive five-year review and update of MP RVUs, which updated each specialty's risk factor based upon updated insurance premium data. In 2016, CMS finalized a policy to conduct 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). CMS also finalized a policy to modify the specialty mix assignment methodology to use an average of the 3 most recent years instead of the most recent year of data.

In 2017, CMS finalized the eighth geographic practice cost indices (GPCI) update, which reflected updated MP premium data. With respect to updating specialty specific risk factors, CMS noted that the 2017 GPCI update reflects updated MP premium data, collected for the purpose of proposing updates to the MP GPCIs. CMS noted at the time that while it could have used the updated MP premium data to propose updates to the specialty risk factors, this would not be consistent with its current policy (updating as part of the 5-year review in 2020).

In 2018, CMS proposed to use the MP premium data (collected as part of the GPCI update) to update the specialty risk factors used in the calculation of MP RVUs prior to the next 5-year update (2020). After consideration of comments and differences it observed in raw rate filings and how those data were categorized to conform to the specialty risk factors, CMS did not finalize its proposal.

CMS is seeking additional comments regarding the next MP RVU update which must occur by 2020. Specifically, CMS seeks comment on how it might improve the way that specialties in the state-level raw rate filings data are crosswalked for categorization into CMS specialty codes which are used to develop the specialty-level risk factors and the MP RVUs.

C. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

CMS has generally used the term “Medicare telehealth services” to refer to the subset of services defined in section 1834(m) of the Act. Section 1834(m) of the Act defines Medicare telehealth services and specifies the payment amounts and circumstances under which Medicare makes

⁹ See <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2019-PFS-NPRM-Alt-Methodology-Indirect-PE.zip>

payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. CMS states that it has come to believe section 1834(m) of the Act does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology. Instead, CMS believes this section applies to a discrete set of physicians' services that ordinarily involve, and are defined, coded, and paid for as if they were furnished during an in-person encounter between a patient and a health care professional.

For CY 2019, CMS aims to increase access for Medicare beneficiaries to physicians' services that are routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology. CMS has several proposals for communication technology-based services, that it believes would not be subject to the limitations on Medicare telehealth services in section 1834(m) of the Act. These proposals are described below.

1. Brief Communication Technology-based Service, e.g., Virtual Check-in (HCPCS code GVCII)

CMS notes that historically, it has considered any routine non-face-to-face communication that takes place before or after an in-person visit to be bundled into the payment for the visit itself. CMS states that it recognizes that advances in communication technology have changed patients' and practitioners' expectations regarding the quantity and quality of information that can be conveyed via communication technology. CMS states that a broader range of services can be furnished by health care professionals via communication technology compared to 20 years ago.

CMS believes that among these services are the kinds of brief check-in services furnished using communication technology that are used to evaluate whether or not an office visit or other service is warranted. When these kinds of check-in services are furnished prior to an office visit, then CMS would currently consider them to be bundled into the payment for the resulting visit, such as through an evaluation and management (E/M) visit code. However, in cases where the check-in service does not lead to an office visit, then there is no office visit with which the check-in service can be bundled. CMS believes that check-in visits could be effective in mitigating the need for potentially unnecessary office visits, but there is little incentive for providers to provide these types of services given that they are not billable.

Therefore, CMS proposes to pay separately, beginning January 1, 2019, for a newly defined type of physicians' service furnished using communication technology. This service would be billable when a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication technology, to assess whether the patient's condition necessitates an office visit. **CMS is seeking comment on what types of communication technology are utilized by physicians or other qualified health care professionals in furnishing these services, including whether audio-only telephone interactions are sufficient compared to interactions that are enhanced with video or other kinds of data transmission.**

The proposed code would be described as GVCII (Brief communication technology based service, e.g. virtual check-in, by a physician or other qualified health care professional who can

report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion). CMS notes that that this service could be used as part of a treatment regimen for opioid use disorders and other substance use disorders. CMS makes the following specific proposals:

- CMS proposes that if the brief communication technology-based service originates from a related E/M service provided within the previous 7 days by the same physician or other qualified health care professional, this service would be considered bundled into that previous E/M service and would not be separately billable. This is consistent with code descriptor language for CPT code 99441 on which this service is partially modeled.
- CMS proposes in instances when the brief communication technology-based service leads to an E/M in-person service with the same physician or other qualified health care professional, this service would be considered bundled into the pre- or post- visit time of the associated E/M service, and therefore, would not be separately billable.
- CMS proposes pricing this distinct service at a rate lower than existing E/M in-person visits to reflect the low work time and intensity and to account for the resource costs and efficiencies associated with the use of communication technology.
- CMS proposes that this service can only be furnished for established patients because it believes that the practitioner needs to have an existing relationship with the patient, and therefore, basic knowledge of the patient's medical condition and needs, in order to perform this service
- CMS is not proposing to apply a frequency limit on the use of this code by the same practitioner with the same patient

CMS expects that these services would be initiated by the patient, especially since many beneficiaries would be financially liable for sharing in the cost of these services. Patients' consent to receiving these services would be necessary.

CMS seeks comments on a number of specific issues related to this brief communication technology-based service. This includes the following:

- Whether it should require, for example, verbal consent that would be noted in the medical record for each service.
- Whether it would be clinically appropriate to apply a frequency limitation on the use of this code by the same practitioner with the same patient, and on what would be a reasonable frequency limitation.
- Timeframes under which this service would be separately billable compared to when it would be bundled. CMS states that the general construct of bundling the services that lead directly to a billable visit is important, but it is concerned that establishing strict timeframes may create unintended consequences regarding scheduling of care.

- Whether it should consider broadening the window of time and/or circumstances in which this service should be bundled into the subsequent related visit.
- How clinicians could best document the medical necessity of this service, consistent with documentation requirements necessary to demonstrate the medical necessity of any service under the PFS.

As shown in Addendum B in the proposed rule, CMS proposes total nonfacility RVUs of 0.42 and facility RVUs of 0.37 for HCPCS code GVC11. This proposal would result in 2019 payments of \$15.13 and \$13.34, respectively. CMS estimates utilization for this service at 7.4 million (92 percent in nonfacility settings).

2. Remote Evaluation of Pre-Recorded Patient Information (HCPCS code GRAS1)

Stakeholders have requested that CMS make separate Medicare payment when a physician uses recorded video and/or images captured by a patient in order to evaluate a patient's condition. These services involve what is referred to under section 1834(m) of the Act as "store and forward" communication technology that provides for the "asynchronous transmission of health care information." Under section 1834(m) of the Act, payment for telehealth services furnished using such store-and forward technology is permitted only under Federal telemedicine demonstration programs conducted in Alaska or Hawaii, and these telehealth services remain subject to the other statutory restrictions governing Medicare telehealth services.

Effective January 1, 2019, CMS proposes to create specific coding that describes the remote professional evaluation of patient-transmitted information conducted via pre-recorded "store and forward" video or image technology. CMS states that because these services are not meant to substitute for an in-person service currently separately payable under the PFS, these services are distinct from the telehealth services described under section 1834(m) of the Act. These services are intended to determine whether or not an office visit or other service is warranted. CMS proposes that this service to be a stand-alone service that could be separately billed to the extent that there is no resulting E/M office visit and there is no related E/M office visit within the previous 7 days of the remote service being furnished.

The proposed code for this service would be described as GRAS1 (Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment). CMS notes that this service is distinct from the brief communication technology-based service described above in that this service involves the practitioner's evaluation of a patient-generated still or video image, and the subsequent communication of the resulting response to the patient, while the brief communication technology-based service describes a service that occurs in real time and does not involve the transmission of any recorded image.

CMS seeks comment as to whether these services should be limited to established patients; or whether there are certain cases, like dermatological or ophthalmological services, where it might be appropriate for a new patient to receive these services. For example, when a

patient seeks care for a specific skin condition from a dermatologist with whom she does not have a prior relationship, and part of the inquiry is an assessment of whether the patient needs an in-person visit, the patient could share, and the dermatologist could remotely evaluate, pre-recorded information.

As shown in Addendum B in the proposed rule, CMS proposes total nonfacility RVUs of 0.36 and facility RVUs of 0.28 for HCPCS code GRAS1. This proposal would result in 2019 payments of \$12.98 and \$10.09, respectively. CMS estimates utilization for this service at 5.7 million (about 92 percent in nonfacility settings).

3. Interprofessional Internet Consultation (CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99499).

As part of its standard rulemaking process, CMS received recommendations from the RUC over a period of 5 plus years to assist in establishing values for six CPT codes that relate to interprofessional telephone/Internet assessment and management service provided by a consultative physician:

- 99446 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5-10 minutes of medical consultative discussion and review),
- 99447 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11-20 minutes of medical consultative discussion and review),
- 99448 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21-30 minutes of medical consultative discussion and review),
99449 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review).
- 994X0 (Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes)
- 994X6 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time).

CMS is proposing separate payment for these services, discussed in section II.H.Valuation of Specific Codes. Currently, the resource costs associated with seeking or providing such a consultation are considered bundled, which provides an incentive for the specialist to schedule a separate visit for the patient when phone or internet-based interaction with the consulting practitioner would have sufficed.

Since these codes describe services that are furnished without the beneficiary being present, CMS proposes to require the treating practitioner to obtain verbal beneficiary consent in advance of these services, which would be documented by the treating practitioner in the medical record, similar to the conditions of payment associated with the care management services under the PFS. Obtaining advance consent includes ensuring that the patient is aware of any applicable cost sharing.

CMS has concerns about how these services can be distinguished from activities undertaken for the benefit of the practitioner, such as information shared as a professional courtesy or as continuing education. CMS highlights potential program integrity concerns around making separate payment for these interprofessional consultation services, and how to evaluate whether such interactions is reasonable and necessary.

CMS seeks comment on the overall proposal and highlights specific issues. CMS seeks comment on its assumption that these are separately identifiable services, and the extent to which they can be distinguished from similar services that are nonetheless primarily for the benefit of the practitioner. In addition, CMS seeks comment on how best to minimize potential program integrity issues, and are particularly interested in information on whether these types of services are paid separately by private payers and if so, what controls or limitations private payers have put in place to ensure these services are billed appropriately.

4. Medicare Telehealth Services under Section 1834(m) of the Act

In the 2003 PFS final rule (67 FR 79988), CMS established a process for adding or deleting services from the Medicare telehealth list. CMS assigns requests to two categories: Category 1 and Category 2. Category 1 services are similar to services that are currently on the telehealth list. Category 2 services are not similar to services on the telehealth list and CMS requires evidence demonstrating the service furnished by telehealth improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part. Requests to add services must be submitted and received no later than December 31 of each year to be considered for the next rulemaking cycle. Additional information for submitting a request is available at <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html>.

In response to requests received in 2017, CMS proposes to add two codes because it believes these services are sufficiently similar to services currently on the telehealth services list (this is known as qualifying on a category 1 basis):

- HCPCS codes G0513 and G0514: Prolonged preventive services that is beyond the typical service time of the primary procedure. HCPCS code G0513 is the first 30 minutes, and G0514 is each additional 30 minutes. These are reported in addition to the code for

the preventive service. CMS considers this service similar to office visits, and that all components of this service can be furnished via interactive telecommunications technology.

CMS is not proposing to add or modify the following services for the reasons noted:

- Chronic Care Remote Physiological Monitoring (CPT codes 990X0, 990X1, and 994X9).
 - CMS states that because these codes describe services that are inherently non face-to-face, it does not consider them Medicare telehealth services under section 1834(m) of the Act.
- Interprofessional Internet Consultation (CPT codes 994X0 and 994X6)
 - CMS believes these codes describe services that are inherently non face-to-face and CMS does not consider them as Medicare telehealth services. CMS notes, however, that it is proposing to adopt these codes (as described above) for payment under the PFS as these are distinct services furnished via communication technology.
- Initial Hospital Care Services (CPT codes 99221, 99222, and 99223)
 - CMS notes that it has previously considered requests to add these codes to the telehealth list. Based on the description of these services, CMS believes it is critical that the initial hospital visit by the admitting practitioner be conducted in person. Consistent with prior rulemaking, it does not believe these services should be added on a category 1 basis and that there is not sufficient evidence to add them on a category 2 basis.
- Subsequent Hospital Care Services (CPT codes 99231, 99232, and 99233).
 - These codes are currently on the list of Medicare telehealth services, but can only be billed via telehealth once every 3 days. CMS received a request to remove the frequency limitation. CMS continues to believe that the majority of these subsequent hospital care services should be in person to facilitate comprehensive, coordinated, and personal care. Thus, CMS is not proposing to remove the frequency limitation on these codes.
- Subsequent Nursing Facility Care Services (CPT codes 99307, 99308, 99309, and 99310).
 - These codes are currently on the list of Medicare telehealth services, but can only be billed via telehealth once every 30 days. A commenter requested that CMS remove the frequency limitation when these services are provided for psychiatric care. CMS states that it does not believe that it would be appropriate to remove the frequency limitation only for certain diagnoses. CMS also cites concerns regarding the potential acuity and complexity of SNF patients.

5. Expanding the Use of Telehealth under the Bipartisan Budget Act of 2018

a. Expanding Access to Home Dialysis Therapy under the Bipartisan Budget Act of 2018

Section 50302 of the BBA of 2018 expanded access to home dialysis therapy by providing telehealth options to individuals with end-stage renal disease receiving home dialysis.¹⁰

¹⁰ Requirements under Section 50302 of the BBA of 2018 amended sections 1881(b)(3) and 1834(m) of the Act

This allows an individual with end-stage renal disease receiving home dialysis to choose to receive certain monthly end-stage renal disease-related (ESRD-related) clinical assessments via telehealth on or after January 1, 2019. The statute requires that such an individual must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.

The statute also does not provide flexibility on the originating site or the location of an eligible Medicare beneficiary at the time the service furnished. Renal dialysis facility and the home of an individual were added as telehealth originating sites but only for the purposes of the monthly ESRD-related clinical assessments furnished through telehealth. Moreover, the statute provides that the geographic requirements for telehealth services (i.e., patient must be at an originating site in a non-MSA or rural area) do not apply to telehealth services furnished on or after January 1, 2019 for purposes of the monthly ESRD-related clinical assessments where the originating site is a hospital-based or critical access hospital-based renal dialysis center, a renal dialysis facility, or the home of an individual. As defined in statute, there is no originating site facility fee to be paid if the home of the individual is the originating site.

To conform its regulations with the statute, CMS makes several proposals related to telehealth requirements related to home dialysis therapy. CMS proposes to revise its regulation at §410.78(b)(3) to add a renal dialysis facility and the home of an individual as Medicare telehealth originating sites, but only for purposes of the home dialysis monthly ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act. CMS proposes to amend §414.65(b)(3) to reflect the requirement in section 1834(m)(2)(B)(ii) of the Act that there is no originating site facility fee paid a when the originating site for these services is the patient's home. Additionally, CMS proposes to add new §410.78(b)(4)(iv)(A), to reflect the provision in section 1834(m)(5) of the Act, added by section 50302 of the BBA of 2018, specifying that the geographic requirements described in section 1834(m)(4)(C)(i) of the Act do not apply with respect to telehealth services furnished on or after January 1, 2019, in originating sites that are hospital based or critical access hospital-based renal dialysis centers, renal dialysis facilities, or the patient's home, respectively under sections 1834(m)(4)(C)(ii)(VI), (IX) and (X) of the Act, for purposes of section 1881(b)(3)(B) of the Act.

b. Expanding the Use of Telehealth for Individuals with Stroke under the Bipartisan Budget Act of 2018

Section 50325 of the BBA of 2018 expanded the use of telehealth for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke (acute stroke telehealth services) for beneficiaries. Specifically, the statute removes the restrictions on the geographic locations and the types of originating sites where acute stroke telehealth services can be furnished. It specifies that acute stroke telehealth services can be furnished in any hospital, critical access hospital, mobile stroke units (as defined by the Secretary), or any other site determined appropriate by the Secretary, in addition to the current eligible telehealth originating sites. It also

limits payment of an originating site facility fee to acute stroke telehealth services furnished in sites that meet the usual telehealth restrictions (as defined under section 1834(m)(4)(C) of the Act).

To implement these requirements, CMS proposes to create a new modifier that would be used to identify acute stroke telehealth services. This modifier (appended to the HCPCS code) would be used by practitioner and, as appropriate, the originating site, would append this modifier when billing for an acute stroke telehealth service or an originating site facility fee, respectively. By billing with this modifier, practitioners would be indicating that the codes billed were used to furnish telehealth services for diagnosis, evaluation, or treatment of symptoms of an acute stroke. CMS notes its belief that the adoption of a service level modifier is the least administratively burdensome means of implementing this provision for practitioners, while also allowing CMS to easily track and analyze utilization of these services.

CMS also proposes to revise §410.78(b)(3) of its regulations to add mobile stroke unit as a permissible originating site for acute stroke telehealth services. CMS also proposes to define a mobile stroke unit as a mobile unit that furnishes services to diagnose, evaluate, and/or treat symptoms of an acute stroke. CMS notes that any additional sites would be adopted through future rulemaking and the originating site facility fee would not apply in instances where the originating site does not meet the originating site type and geographic requirements under section 1834(m)(4)(C) of the Act.

CMS also proposes to add §410.78 (b)(4)(iv)(B) to specify that the geographic requirements in section 1834(m)(4)(C) of the Act do not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

CMS seeks comment on other possible appropriate originating sites for telehealth services for acute stroke telehealth services. CMS also seeks comment on mobile stroke unit, as well as additional information on how these units are used in current medical practice.

6. Modifying §414.65 Regarding List of Telehealth Services

CMS proposes a technical revision to delete the description of individual services and exceptions for Medicare payment for telehealth services in §414.65, by amending §414.65(a) to note that Medicare payment for telehealth services is addressed in §410.78 and by deleting §414.65(a)(1).

7. Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders

CMS believes making separate payment for a bundled episode of care for management and counseling for substance use disorder (SUDs) could be effective in preventing the need for more acute services. CMS states that creating separate payment for a bundled episode of care for components of Medication Assisted Therapy (MAT) such as management and counseling treatment for SUDs, including opioid use disorder, treatment planning, and medication management or observing drug dosing for treatment of SUDs under the PFS could provide

opportunities to better leverage services furnished with communication technology while expanding access to treatment for SUDs. CMS cites several studies that support such an approach.¹¹

CMS seeks comment on whether such a bundled episode-based payment would be beneficial to improve access, quality and efficiency for SUD treatment. This includes the following issues:

- Developing coding and payment, assumptions about the typical number and duration of counseling sessions, which types of practitioners could furnish these services, and what components of MAT could be included in the bundled episode of care.
- How to define and value this bundle, what conditions of payment should be attached, and whether the concept of a global period might be applicable.
- Whether the counseling portion and other MAT components could also be provided by qualified practitioners “incident to” the services of the billing physician who would administer or prescribe any necessary medications and manage the overall care, as well as supervise any other counselors participating in the treatment.¹²

CMS also welcomes comments on potentially creating a bundled episode of care for management and counseling treatment for SUDs for future rulemaking consideration. Additionally, CMS invites comment and suggestions for regulatory and subregulatory changes to help prevent opioid use disorder and improve access to treatment under the Medicare program. This includes methods for identifying non-opioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these nonopioid alternatives including barriers related to payment or coverage.

D. Potentially Misvalued Services Under the Physician Fee Schedule

1. CY 2019 Identification and Review of Potentially Misvalued Services

a. Public Nominations

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) requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the RVUs for these services.

¹¹ See Van L. King, Robert K. Brooner, Jessica M. Peirce, Ken Kolodner, Michael S. Kidorf, “A randomized trial of Web based videoconferencing for substance abuse counseling,” *Journal of Substance Abuse Treatment*, Volume 46, Issue 1, 2014, Pages 36-42, <http://www.sciencedirect.com/science/article/pii/S0740547213001876>; and Pamela L. Owens, Ph.D., Marguerite L. Barrett, M.S., Audrey J. Weiss, Ph.D., Raynard E. Washington, Ph.D., and Richard Kronick, Ph.D. “Hospital Inpatient Utilization Related to Opioid Overuse Among Adults 1993-2012,” Statistical Brief #177. Healthcare Cost and Utilization Project (HCUP). July 2014. Agency for Healthcare Research

¹² CMS states that this approach is similar to similar to the structure of the Behavioral Health Integration codes which include services provided by other members of the care team under the direction of the billing practitioner on an “incident to” basis (81 FR 80231).

In the 2012 PFS final rule (76 FR 73058), CMS finalized a process for the public to nominate potentially misvalued codes. The public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10 of each year. CMS reviews the information and in the following year's PFS proposed rule, publishes a list of nominated codes and indicates whether it is proposing the code as a potentially misvalued code. CMS finalizes its list of potentially misvalued codes in the final rule.

CMS received one submission that nominated several high-volume codes for review under the potentially misvalued code initiative. In its submission, the commenter noted a systematic overvaluation of work RVUs citing GAO, MedPAC, and other sources. The requester requested that the codes listed in Table 8 (reproduced below) be prioritized for review,

CPT Code	Short Description
27130	Total hip arthroplasty
27447	Total knee arthroplasty
43239	Egd biopsy single/multiple
45385	Colonoscopy w/lesion removal
70450	CT head w/o contrast
93000	Electrocardiogram complete
93306	Tte w/doppler complete

Another commenter requested that CPT code 92992 (Revision of heart chamber) be reviewed in order to establish national RVU values for these services under the PFS (currently priced by the MACs).

b. Update on the Global Surgery Data Collection

CMS provides an update on its effort to collect data on how many postoperative visits are performed during the global period (within 10 or 90 days) for many surgeries. Section 523 of MACRA required CMS to use notice and comment rulemaking to implement a process to collect data on the number and level of postoperative visits and use these data to assess the accuracy of global surgical package valuation.¹³ In the CY 2017 PFS final rule, CMS adopted a policy to collect postoperative visit data.

This data collection effort began July 1, 2017 and was required for practitioners in groups with 10 or more in nine states (Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island). Practitioners were required to use the no-pay CPT code 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) to report postoperative visits.¹⁴

¹³MACRA added a new section 1848(c)(8) to the Act, which includes section 1848(c)(8)(B).

¹⁴The 293 procedures for which reporting is required are those 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. A list of the procedures for which reporting is required is updated annually to reflect any coding changes and is

CMS found that in these nine states over a 6-month period (July 1, 2017 through December 31, 2017), there were 990,581 postoperative visits reported using CPT code 99024. Only 45 percent of participating practitioners reported one or more visits using CPT code 99024 during this 6-month period¹⁵ The share of practitioners who reported any CPT 99024 claims varied widely by specialty. Most of the surgical specialties had high response rates (above 80 percent), including general surgery, orthopedic surgery, vascular surgery, colorectal surgery, hand surgery, and thoracic surgery. Primary care specialties had much lower response rates, including internal medicine (11%), family practice (18%), physician assistant (28%), and nurse practitioner (20%). Emergency medicine (one of the larger specialties reporting a global code), had a response rate of 4 percent.

CMS then examined by specialty what share of procedures had matched post-operative visits (reported with CPT code 99024). Among 10-day global procedures performed during this six-month period, only 4 percent overall had one or more matched visit reported with CPT code 99024. Table 11 in the proposed rule (extract of Table 11 reproduced below) shows that for many specialties less than 5 percent of the 10-day global procedures performed had a matched visit using CPT code 99024. General surgery had the highest share (17%) of those specialties performing more than 10,000 procedures during this period. Among all specialties, hand surgeons had the highest share of procedures with a matched post-operative visit of 44 percent.

Extract of Table 11: Share of Procedures with Matched Post-Operative Visits (those with > 10,000 10-day global procedures)			
Provider Specialty	Number of 10-day Global Procedures*	Number of 10-day Global Procedures with 1 or More Matched 99024 Claims**	Percentage of 10-day Global Procedures with 1 or More Matched 99024 Claims**
ALL	436,063	16,802	4%
Dermatology	205,594	6,920	3%
Physician Assistant	57,749	908	2%
Nurse Practitioner	31,937	509	2%
Family practice	16,770	629	4%
Ophthalmology	16,087	1,239	8%
Podiatry	12,639	547	4%
General surgery	12,113	2,095	17%
Diagnostic radiology	11,650	298	3%

*Limited to the 293 procedures where postoperative visit reporting is required and to those performed by practitioners who work in practices with 10 or more practitioners. Because matching may be unclear in these circumstances, multiple procedures performed on a single day and procedures with overlapping global periods were excluded.

**Matching was based on patient, service dates, and global period duration.

posted on the CMS web site at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/GlobalSurgery-Data-Collection-.html>.

¹⁵There were 32,573 practitioners who furnished at least one of the 293 procedures for which reporting is required.

Among 90-day global procedures, the percentage of practitioners reporting a post-operative visit with CPT code 99024 was much higher. During this six-month period (July 1, 2017 through December 1, 2017), 67 percent had one or more matched visits reported using CPT code 99024. Table 12 in the proposed rule (extract reproduced below) shows the variation in rates by specialty. For example, among 90-day global procedures performed by orthopedic surgery, 76 percent of these procedures performed had a matched visit using CPT code 99024.

Extract of Table 12: Share of Procedures with Matched Post-Operative Visits, for Procedure Codes with 90-Day Global Periods (those with > 10,000 90-day global procedures)			
Provider Specialty	Number of 90-day Global Procedures*	Number of 90-day Global Procedures with 1 or More Matched 99024 Claims**	Percentage of 90-day Global Procedures with 1 or More Matched 99024 Claims**
ALL	232,235	156,727	67%
Orthopedic surgery	71,991	54,876	76%
Ophthalmology	63,333	41,700	66%
General surgery	25,593	17,559	69%
Pathologic anatomy, clinical pathology	10,149	4,371	43%

*Limited to the 293 procedures where post-operative visit reporting is required and to those performed by practitioners who work in practices with 10 or more practitioners. Because matching may be unclear in these circumstances, multiple procedures performed on a single day and procedures with overlapping global periods were excluded.

**Matching was based on patient, service dates, and global period duration.

CMS recognized that a potential explanation for these findings could be that many practitioners are not consistently reporting postoperative visits using CPT code 99024. To examine this issue, CMS performed a subanalysis of “robust reporters;” these are practitioners who appear to be regularly reporting post-operative visits using CPT code 99024.¹⁶ CMS found that 87 percent of procedures with 90-day global periods had one or more associated post-operative visits. However, CMS found that only 16 percent of procedures with a 10-day global period had an associated postoperative visit reported using CPT code 99024. CMS concludes that these findings suggest that post-operative visits following procedures with 10-day global periods are not typically being furnished rather than not being reported.

CMS also provides an update on its effort to conduct a separate survey-based data collection that would augment its effort on collecting data on number of visits with the level of post-operative visits. This would include detailed information on the level of post-operative visits including the time, staff, and activities involved in furnishing post-operative visits and non-face-to-face services. CMS notes that RAND developed a survey and approach (as described in the 2017 PFS

¹⁶Robust reporters were defined as practitioners who (a) furnished 10 or more procedures with 90-day global periods where it is possible for CMS to match specific procedures to reported postoperative visits without ambiguity, and (b) reported a post-operative visit using CPT code 99024 for at least half of these 90-day global procedures.

final rule) that would have collected data on post-operative visits related to a full range of procedures with 10-day and 90-day global periods. RAND piloted this post-operative visit survey and had a very low response rate raising concerns that this approach would not provide useful or representative information. As a result, CMS has refocused its effort to collect information on post-operative visits and non-face-to-face services associated with a small number of high volume procedure codes. CMS stresses that it needs practitioner participation to get representative data and that future efforts may cover a broader range of services.

CMS seeks comments on its findings and how best to encourage practitioners to consistently report postoperative visits using CPT code 99024. This includes:

- Suggestions as to how to encourage reporting to ensure the validity of the data without imposing undue burden;
- Whether it needs to do more to make practitioners aware of their obligation and whether it should consider implementing an enforcement mechanism;
- Whether or not it might be reasonable to assume that many visits included in the valuation of 10-day global packages are not being furnished, or whether there are alternative explanations for what could be a significant level of underreporting of postoperative visits;
- Alternative explanations, such as whether it is likely that in many cases the practitioner reporting the procedure code is not performing the postoperative visit, or if the postoperative visit is being furnished by a different practitioner; and
- Whether it is possible that some or all of the postoperative visits are occurring after the global period ends and are, therefore, reported and paid separately.

CMS seeks comment on the best approach to 10-day global codes for which the preliminary data suggest that postoperative visits are rarely performed by the practitioner reporting the global code, and in particular, on whether it should consider changing the global period and reviewing the code valuation.

On a related issue, CMS also solicits comments on whether it should consider requiring use of the modifiers in cases where the surgeon does not expect to perform the postoperative visits, regardless of whether or not the transfer of care is formalized. Under current policy, in cases where practitioners agree on the transfer of care for the postoperative portion of the global period, the surgeon bills only for the surgical care using modifier 54 “for surgical care only” and the practitioner who furnishes the postoperative care bills using modifier 55 “postoperative management only.” The global surgery payment is then split between the two practitioners. However, practitioners are not required to report these modifiers unless there is a formal transfer of postoperative care.

E. Radiologist Assistants

CMS assigns a physician supervision level of general, direct or personal supervision for the technical component of all diagnostic tests.¹⁷ In response to the Request for Information on CMS Flexibilities and Efficiencies in the CY 2018 PFS proposed rule (82 FR 34172 through 34173), many commenters recommended revising the physician supervision requirement for diagnostic tests typically furnished by a radiologist assistant (RA) from personal to direct. In addition to increasing efficiency, stakeholders suggested that the current supervision requirements for certain diagnostic imaging services unduly restrict RAs from conducting tests consistent with their education and training and that they may do under current law in many states.

For diagnostic tests requiring personal supervision, CMS is proposing to only require direct supervision when permitted by state law and state scope of practice regulations and performed by:

- A registered radiologist assistant certified by the American Registry of Radiologic Technologists; and
- A radiology practitioner assistant certified by the Certification Board for Radiology Practitioner Assistants.

F. Payment Rates under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

CMS provides a detailed background on sections 1833(t)(1)(B)(v) and (t)(21) of the Act that preclude new office-campus provider-based departments (PBD) opened after November 2, 2015 (with certain exceptions) from being paid under the outpatient prospective payment system (OPPS). Effective January 1, 2017, these new off-campus departments are paid under a special physician fee schedule where payment is equal to 50 percent of the OPPS payment amount. Effective January 1, 2018, CMS changed the 50 percent adjustor to 40 percent. To identify services paid under this special physician fee schedule, new off-campus PBDs include the modifier “PN” on their claims. CMS adopted the same ancillary payment policies (packaging, multiple procedure payment reduction, C-APCs, etc.) for the special physician fee schedule that applies to new off-campus departments as apply under the OPPS.

As this provision was first implemented on January 1, 2017, the 2019 rate-setting cycle is the first one under which CMS will have claims data under the provision. CMS makes several technical adjustments to the prior analysis it used to develop the 50 and 40 percent adjustors. CMS describes the detailed analysis it used to determine whether it would change the current 40 percent adjustor. Using new data, CMS is proposing to leave the 40 percent adjustor unchanged. The proposed rule further indicates that it is maintaining the same policies as 2018 related to

¹⁷ “General supervision” means the procedure or service is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. “Direct supervision” means that the physician must be immediately available (although not in the room or within any physical boundary of the property) to furnish assistance and direction throughout the performance of the procedure. “Personal” supervision means a physician must be in attendance in the room during the performance of the procedure. (42 CFR §410.32(b)(3)).

supervision, beneficiary cost sharing, geographic payment adjustments and partial hospitalization services.

CMS indicates its belief that the payment policy under this provision should ultimately equalize payment rates between new off-campus PBDs and physician offices to the greatest extent possible, while allowing new off-campus PBDs to bill in a straight-forward way for services they furnish. CMS will continue monitoring claims for shifts in the mix of services furnished in new off campus PBDs that may affect payment relativity between the PFS and OPFS. The proposed rule further indicates that CMS intends to improve implementation of this provision through the development and refinement of a new set of payment rates under the PFS that reflect the relative resource costs of furnishing items and services in new off campus PBDs. **CMS is broadly interested in stakeholder feedback and recommendations for ways in which CMS can improve pricing and transparency with regard to the differences in the payment rates across sites of service.**

G. Valuation of Specific Codes

The proposed work RVUs, work time and other payment information for all the proposed payable codes in 2019 are available on the CMS website under downloads for the PFS proposed rule at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

The following tables in the proposed rule provide additional details:

- Table 13: Proposed 2019 Work RVUs for New, Revised, and Potentially Misvalued Codes;
- Table 14: Proposed 2019 Direct PE Information;
- Table 15: Proposed 2019 Existing Invoices; and
- Table 16: Proposed 2019 New Invoices

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

For the 2018 PFS, CMS generally proposed the RUC- recommended RVUs. In the 2018 PFS final rule, CMS clarified that it was not relinquishing its obligation to independently establish appropriate RVUs and discussed the many ways it makes an independent assessment of the RUC recommendations.

2. Methodology for Establishing Work RVUs

CMS reviews its methodology for proposing work RVUs, including potential information sources and specific approaches.¹⁸ CMS notes the importance of not only the RUC- recommended work and time values but also the accompanying rationales for setting those

¹⁸ Sources include the RUC (and RUC practitioner survey data), the HCPAC, other public commenters, medical literature, comparative databases, PFS code comparisons, Medicare claims data, and input from CMS and other federal government health care professionals. Approaches include RUC survey data, building block, key reference code crosswalks, magnitude estimation, incremental difference applications, and time ratio calculations.

values.¹⁹ CMS concerns about RUC rationales and their underlying practitioner survey data have increased in recent years, most often centering on the incorporation of service times and time changes into specific work RVU proposals.

CMS discusses the methodology it uses for adjusting work RVU and/or time, including the methodology used when it believes there is overlap between a service typically furnished on the same day as an E/M service. The work RVU for a service is the product of the time involved with furnishing the service multiplied by the work intensity. CMS notes that the pre-service and post-service time have a long-established intensity of work per unit time (IWPUT) of 0.0224; thus, 1 minute of pre-service or post-service time equates to 0.0224 of a work RVU. Using this information, when CMS is concerned about overlap between a service and an E/M service, it generally removes 2 minutes of pre-service time and 2 minutes of post-service time from the procedure which results in removing a work RVU of 0.09 (4minutes x 0.0224 IWPUT).

CMS welcomes comments from all interested parties about the proposed values.

3. Methodology for Direct PE Inputs to Develop PE RVUs

CMS reviews its methodology for proposing direct PE inputs, which include clinical labor, disposable medical supplies, and medical equipment. The RUC annually provides CMS with recommendations about PE inputs for new, revised, and potentially misvalued codes. CMS specifically evaluates the methodology, data, and decision-making rationales that accompany RUC recommendations, and it determines whether establishing facility or non-facility (or both) direct PE inputs are appropriate.

Table 14 details CMS' refinements of the RUC's direct PE recommendations at the code specific level. CMS notes that, on average, in any case where the impact on the direct cost for a particular refinement is \$0.30 or less, the refinement has no impact on the PE RVUs. CMS notes that nearly half of the refinements result in changes under the \$0.30 threshold and are unlikely to result in a change to the RVUs.

Common CMS refinements to RUC recommendations are related to or triggered by the following:

- Changes in work component times (e.g., intra-service time, postoperative visit levels);
- Changes in equipment time (e.g., pre-service clinical task is performed outside of highly technical equipment rooms and is excluded from equipment time);
- Clinical labor task times that are inconsistent with standard times in the CMS direct PE input database or overlap with associated E/M visit clinical labor time;
- Recommended items that are not direct PE inputs (e.g. items that are not clinical labor, disposable supplies or medical equipment or cannot be allocated to individual services or patients);
- New supply or equipment items (e.g., when invoices lack sufficient information)²⁰;

¹⁹ Time is parsed into pre-service, intra-service, and post-service components, summing to the total time for each service. To assist in the development of pre-service time recommendations, the RUC created standardized pre-service time packages. There are pre-service time packages for services typically furnished in the facility setting and pre-service packages for services typically furnished in the nonfacility setting.

- Clinical labor time in the facility minutes (i.e., facility payment is separate); and
- Application of the Multiple Procedure Payment Reduction (MPPR) and the OPPI Cap on imaging services.

CMS expects invoices received outside of the public comment period to be submitted by February 10th of the following year for consideration in future rulemaking (similar to the time for receiving RUC recommendations).

4. Proposed Valuation for Specific Codes

This section of the proposed rule discusses proposed RVUs for 72 code groups. Highlights of CMS' discussion are summarized below; the numbering is consistent with the preamble format. The reader is referred to the proposed rule for more specific details.

CMS seeks comments on the work values, direct PE inputs, or both, for all these code groups.

1. Fine Needle Aspiration Codes: CPT codes 10021, 10X12 - 10X19, 76492, 77002, and 77021

CMS discusses concerns that the recommended work pool for these codes is increasing by approximately 20 percent, while the recommended work time pool for these codes is only increasing by about 2 percent. CMS believes that in general, the recoding of a family of services should maintain the same total work pool, as the services are not changing, only the coding structure for reporting is changing.

2. Biopsy of Nail: CPT code 11755

This code was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000.

3. Skin Biopsy: CPT codes 11X02 - 11X07

This code was identified as potentially misvalued using a high expenditure services screen across specialties with Medicare allowed charges of \$10 million or more.

4. Injection Tendon Origin-Insertion: CPT code 20551

This code was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000.

5. Structural Allograft: CPT codes 209X3 – 209X5

These three new add-on codes describe allografts that were revised to more accurately describe the structural allograft procedures. These codes are all facility-only procedures with no recommended direct PE inputs.

²⁰ CMS may add an item to the direct PE input database as a zero price item to serve as a placeholder that is readily updated once accurate pricing information becomes available.

6. Knee Arthrography Injection: CPT code 27X69

CPT code 27370 (Injection of contrast for knee arthrography) repeatedly appeared on high volume screens. The RUC was concerned that the high volume growth was likely due to the code being incorrectly reported. The CPT Editorial Panel deleted CPT code 27370 and replaced it with a new code, 27X69, to report injection procedures for knee arthrography or enhanced CT/MRI knee arthrography.

7. Application of Long Arm Splint: CPT code 29105

8. Strapping of Lower Extremity: CPT codes 29540 and 29550

These codes were identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000.

9. Bronchoscopy: CPT codes 31623 and 31624

CPT code 31623 was identified on a high growth screen of services with total Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2009 through 2014. CPT code 31624 was included for review as part of the same family of codes.

10. Pulmonary Wireless Pressure Sensor Services: CPT codes 332X and 93XX1

The CPT Editorial Panel created a code to describe pulmonary wireless sensor implantation and another code for remote monitoring of patients with an implantable, wireless pulmonary artery pressure sensor monitor.

11. Cardiac Event Recorder Procedures: CPT codes 332X5 and 332X6

The CPT Editorial Panel created two new codes replacing cardiac event recorder codes to reflect new technology.

12. Aortoventriculoplastry with Pulmonary Autograft: CPT code 335X1

The CPT Editorial Panel created one new code to combine the efforts of aortic valve and root replacement with subvalvular left ventricular outflow tract enlargement to allow for an unobstructed left ventricular outflow tract.

13. Hemi-Aortic Arch Replacement: CPT code 33X01

The CPT Editorial Panel created one new add-on code to report hemi-aortic arch graft replacement.

14. Leadless Pacemaker Procedures: CPT codes 33X05 and 33X06

The CPT Editorial Panel replaced the five leadless pacemaker services Category III codes with the addition of two new CPT codes to report transcatheter leadless pacemaker procedures and revised five codes to include evaluation and interrogation services of leadless pacemaker systems.

15. PICC Line Procedures: CPT codes 36568, 36569, 36X72, 36X73, and 36584
CPT code 36569 was identified as potentially misvalued using a high expenditure services screen across specialties with Medicare allowed charges of \$10 million or more. As a result, the CPT Editorial Panel examined this family of codes.

This is another example where CMS is concerned that recoding of a family of services should not significantly increase the related RUC-recommended work pool. For these codes, the RUC-recommended work pool is increasing by approximately 68 percent for the PICC Line Procedures family as a whole, while the RUC-recommended work time pool for the same codes is only increasing by about 22 percent.

16. Biopsy or Excision of Inguinofemoral Node(s): CPT code 3853X
The CPT Editorial Panel created a new code to describe biopsy or excision of inguinofemoral node(s). This service was previously reported with unlisted codes.

17. Radioactive Tracer: CPT code 38792
This code was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for TUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes.

18. Percutaneous Change of G-Tube: CPT code 43760
This code was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000.

19. Gastrostomy Tube Replacement: CPT codes 43X63 and 43X64
The CPT Editorial Panel created two new codes that describe replacement of gastrostomy tube, with and without revision of gastrostomy tract, respectively.

20. Diagnostic Proctosigmoidoscopy- Rigid: CPT code 45300
This code was identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000.

21. Hemorrhoid Injection: CPT code 46500
This code was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes.

22. Removal of Intraoperative Catheter: CPT code 49422

This code was identified as a site of service anomaly because Medicare data from 2012-2014 indicated that it was performed less than 40 percent of the time in the inpatient setting, yet included inpatient hospital E/M services within the 10-day global period.

23. Dilation of Urinary Tract: CPT codes 50X39, 50X40, 52334, and 74485

These codes were identified as part of a family that had overlap with associated radiologic codes.

24. Transurethral Destruction of Prostate Tissue: CPT codes 53850, 53852, and 538X3

The CPT Editorial Panel created a new code to report transurethral destruction of prostate tissue by radiofrequency-generated water vapor thermotherapy. The family of codes was reviewed.

25. Vaginal Treatments: CPT codes 57150 and 57160

26. Biopsy of Uterus Lining: CPT codes 58100 and 58110

27. Injection Greater Occipital Nerve: CPT code 64405

28. Injection Digital Nerves: CPT code 64455

29. Removal of Foreign Body – Eye: CPT codes 65205 and 65210

30. Injection-Eye: CPT codes 67500, 67505, and 67515

These codes were identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000.

31. X-Ray Spine: CPT codes 72020, 72040, 72050, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120

CPT codes 72020 and 72072 were identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. The code family was expanded to include ten additional CPT codes. For these codes CMS proposes an alternative approach to the valuation of work RVUs. **CMS is also interested in data sources regarding the intraservice clinical labor times for services as they do not match the physician intraservice time.**

32. X-ray Sacrum: CPT codes 72200, 72202, and 72220

33. X-ray Elbow-Forearm: CPT codes 73030, 73080, and 73090

CPT code 72220 and CPT codes 73070 and 73090 were identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. The other codes were included for review as part of the same family of codes.

34. X-ray Heel: CPT code 73650

35. X-ray Toe: CPT code 73660

36. X-ray Esophagus: CPT codes 74210, 74220, and 74230

37. X-ray Urinary Tract: CPT code 74420

38. Fluoroscopy: CPT code 76000

These codes were identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually. For certain groups, additional codes were included for review as part of the same family of codes.

For the review of the X-ray Esophagus codes, CMS is not proposing to refine the quantity of the Polibar barium suspension; **CMS seeks additional comment about the typical use of the Polibar barium suspension in these procedures.**

39. Echo Exam of Eye Thickness: CPT code 76514

This code was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes.

40. Ultrasound Elastography: CPT codes 767X1 – 767X3

The CPT Editorial Panel created three new codes describing the use of ultrasound elastography to assess organ parenchyma and focal lesions. The most common use of this code set will be preparing patients with diseases of solid organs or lesions within solid organs.

41. Ultrasound Exam – Scrotum: CPT code 76870

These codes were identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually.

42. Contrast-Enhanced Ultrasound: CPT codes 76X0X and 76X1X

The CPR Editorial Panel created two new CPT codes describing the use of intravenous microbubble agents to evaluate suspicious lesions by ultrasound.

43. Magnetic Resonance Elastography: CPT code 76X01

The CPT Editorial Panel created a new stand-alone code describing the use of magnetic resonance elastography for the evaluation of organ parenchymal pathology. This code will most often be used to evaluate patients with diseases of solid organs (e.g., liver cirrhosis) within solid organs that manifest with increasing fibrosis or scarring.

44. Computed Tomography (CT) Scan for Needle Biopsy: CPT code 77012

These codes were identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually.

45. Dual-Energy X-Ray Absorptiometry: CPT code 77081

This code was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes.

46. Breast MRI with Computer-Aided Detection: CPT codes 77X49 – 77X52

CPT codes 77058 and 77059 were identified as potentially misvalued in 2016 using a high expenditure services screen across specialties with Medicare allowed charges of \$10 million or more. As a result, the CPT Editorial Panel examined this family of codes. When preparing to survey these codes, the specialties noted that the clinical indications had changed for these codes. Subsequently, the CPT Editorial Panel deleted the original codes and created four new CPT codes to report breast MRI with and without contrast (including computer-aided detection).

This code family included five new equipment items. CMS did not receive any invoices for these items and proposes to use crosswalks to similar equipment items as proxies for three of these items:

- CAD software (ED058) is crosswalked to flow cytometry analytics software (EQ380);
- Breast coli (EQ388) is crosswalked to breast biopsy device (coil) (EQ371); and
- CAD Workstation (CPU + Color Monitor) (ED056) is crosswalked to Professional PACS workstation (ED053),

CMS welcomes submission of invoices with pricing information for these three new equipment items to replace the use of proxies.

For the other two equipment items (CAD Server (ED057) and CAD-Software- Additional User License (ED059)), CMS does not propose prices because it believes these items would be included in the indirect PE methodology. CMS acknowledges that the use of software and other forms of digital tools is complex and believes these items are indirect costs, similar to office rent or administrative expenses. CMS believes that advances in technology have occurred but this does not change the statutory requirement to assign indirect PE on the basis of costs that must be individually allocable to a particular patient for a particular service.

47. Blood Smear Interpretation: CPT code 85060

48. Bone Marrow Interpretation: CPT code 85097

This code was identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually.

49. Fibrinolysins Screen: CPT code 85390

This code was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes.

50. Electroretinography: CPT codes 92X71, 92X73, and 03X0T

CPT code 92275 was identified as potentially misvalued using a high expenditure services screen across specialties with Medicare allowed charges of \$10 million or more. The specialty society noted that the code was being inappropriately used for a less intensive version of the test and that CPT changes were necessary to ensure appropriate utilization of the code. The CPT Editorial Panel deleted the code and created two new codes to describe electroretinography full field and multi focal. A category III code was retained for pattern electroretinography.

CMS notes that it typically assigns contractor pricing for Category III codes since they are temporary codes. When there is an unusually high volume of services performed under a Category III code, CMS has assigned an active status to the procedure and developed RVUs before a formal CPT code is created. The information provided by the RUC indicates that approximately 80 percent of the services currently reported using CPT code 92275 (estimated 100,000 services for 2019) will be reported under the new Category III code. Therefore, CMS proposes to assign an active status to Category III code 03X0T and crosswalks work RVU and

time values form CPT code 92250. **CMS welcomes comments about assigning pricing for this Category III code.**

51. Cardiac Output Measurement: CPT codes 93561 and 93652

These codes were identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. The specialty societies noted these codes are primarily performed in the pediatric population and the Medicare utilization is not over 1,000. The specialty societies and the RUC agreed that these services should be reviewed under the negative IWPUT screen.

52. Coronary Flow Reserve Measurement: CPT codes 93571 and 93572

CPT code 93571 was identified on a list of all services with a total Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2009 through 2014. CPT code 93572 was included in the review as part of the same family of CPT codes.

53. Peripheral Artery Disease (PAD) Rehabilitation: CPT code 93668

Before CMS issued a national coverage determination (NCD) for Medicare coverage of supervised exercise therapy for the treatment of PAD, this CPT code was assigned a noncovered status under the PFS. This code now has an active status. CMS used the most recent RUC-recommended work and direct PE inputs for this code and requested the RUC to review these values.

54. Home Sleep Apnea Testing: CPT codes 95800, 95801, and 95806

Because of rapid group in service, the CPT Editorial Panel flagged these codes and the RUC recommended that these services should be reviewed.

55. Neurostimulator Services: CPT codes 95970, 95X83 – 95X86

In 2013, CPT code 95971 was identified in the second iteration of the High Volume Growth screen. In 2014, the RUC recommended that CPT codes 95971, 95972 and 95974 be referred to the CPT Editorial Panel to address the time referenced in the CPT code descriptors for the entire family of codes. The CPT Editorial Panel revised and deleted codes and created four new codes. As part of this review, the CPT Editorial Panel differentiated between simple and complex programming: simple programming of a neurostimulator pulse generator/transmitter is the adjustment of one to three parameter(s) and complex programming is the adjustment of more than three parameters.

56. Psychological and Neuropsychological Testing: CPT codes 96105, 96110, 96116, 96125, 96127, and 963X0 – 96X12

These codes were identified as potentially misvalued using a high expenditure services screen across specialties with Medicare allowed charges of \$10 million or more. Because of changes in testing practices and technologic advances there was confusion about how to report these codes and the entire family of codes was referred for revision to the CPT Editorial Panel.

CMS discusses concerns a stakeholder representing the psychologist and neuropsychologist community raised about the significant reduction in payments for these services due to the

unbundling of the codes into codes for physician-administered tests and technician-administered tests. The stakeholder's analysis found that the RUC recommendations resulted in a reduction of total work RVUs even though the actual physician work had not changed. In order to maintain payment stability for these high-volume services, CMS proposes to implement work RVUs for this code family which would eliminate the approximately 2 percent reduction in work spending based on the RUC recommendations. CMS notes it has no evidence that the typical practice for these services has changed to merit a reduction in valuation of professional services. **CMS welcomes comments on its proposal to maintain the total work RVUs for this family of codes.**

57. Electrocorticography: CPT code 96X00

CPT code 95829 is used for the electrocorticogram performed at the time of surgery. A new code was needed to account for the non-face-to-face service for a review of a month's worth or more of stored data.

58. Chronic Care Remote Physiologic Monitoring: CPT codes 990X0, 990X1, and 994X9

In the 2018 PFS final rule, CMS indicated that there would be new coding describing remote monitoring from the CPT Editorial Panel and the RUC. For 2019, there are three new codes to describe remote physiologic monitoring and management.

59. Interprofessional Internet Consultant: CPT codes 994X6, 994X0, 99446 -99449
In 2017, the CPT Editorial Panel revised four codes and created two codes to describe interprofessional telephone/internet/electronic medical record consultation services. These CPT codes are currently assigned a procedure code status of B (bundled) and are not separately payable under Medicare. The CPT Editorial Panel revised these codes to include electronic health record consultations, and the RUC reaffirmed the work RVUs for these codes. With changes in medical practice and technology, CMS proposes to change the procedure status for CPT codes 99446 – 99449 from B (bundled) to A (active) and proposes the RUC work recommendations for these codes.

The CPT Editorial Panel also created two new codes for interprofessional internet consultation. CMS does not agree with the RUC work recommendations for this codes and proposes a work RVU of 0,50 for both CPT codes 994X0 and 994X6.

60. Chronic Care Management Services: CPT code 994X7

The CPT Editorial Panel created CPT code 994X7 to describe situations when the billing practitioner is doing the care coordination work that is attributed to clinical staff in CPT code 99490 (Chronic care management services).

61. Diabetes Management Training: HCPCS codes G0108 and G0109

62. External Counterpulsation: HCPCS code G0166

These codes were identified on a screen of CMS or Other source codes with Medicare utilization greater than 100,000 services annually.

63. Wound Closure by Adhesive: HCPCS code G0168

64. Removal of Impacted Cerumen: HCPCS code G0268

These codes were identified as potentially misvalued on a screen of 0-day global services reported with an E/M visit 50 percent of the time or more, on the same day of service by the same patient and the same practitioner, that have not been reviewed in the last 5 years with Medicare utilization greater than 20,000.

65. Structured Assessment, Brief Intervention, and Referral To Treatment for Substance Use Disorders: HCPCS codes G0396, G0397, and GSBR1

In the 2008 PFS final rule (72 FR 66371), CMS created two G-codes (G0396 and G0397) to allow for Medicare reporting and payment for alcohol and substance abuse assessment and intervention services that are not provided as screening services, but are performed in the context of the diagnosis or treatment of illness or injury. Medicare contractors were instructed to pay for these codes only when the services were considered reasonable and necessary.

CMS is concerned that the relatively low utilization of these services is due, in part, to the service-specific documentation requirements for these codes.²¹ CMS believes that removing the additional documentation requirements will ease the administrative burden. **CMS welcomes comments on its proposal to eliminate the service-specific documentation requirements for HCPCS codes G0397 and G0398.**

CMS also proposes to create a third HCPCS code GSBR1, with a lower time threshold in order to accurately account for the resource costs when practitioners furnish these services, but do not meet the requirements of the existing code. **CMS welcomes comments on this code descriptor (Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., AUDIT, DAST), and brief intervention, 5-14 minutes) and the proposed work RVU (0.33) for HCPCS code GSBR1.**

66. Prolonged Services: HCPCS code GPRO1

In response to stakeholders concerns that the time thresholds for CPT codes for prolonged service are too long and as part of CMS' proposal to implement a single PFS rate for E/M visits 2-5, CMS proposes HCPCS code GPRO1: Prolonged E/M 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; 30 minutes (List separately in addition to code for office or other outpatient E/M or psychotherapy service). This code could be billed with any level of E/M code. **CMS welcomes comment on the code descriptor and the proposed work RVU (1.17).**

67. Remote Pre-recorded Services: HCPCS code GRAS1

CMS proposes HCPCS code GRAS1: Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment. CMS proposes to value this service by a direct crosswalk to

²¹ The current requirements can be found at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/SBIRT_Factsheet_ICN904084.pdf.

CPT code 93793 (Anticoagulation management for patient taking warfarin). **CMS welcomes comments on the code descriptor and the proposed work RVU (0.18).**

68. Brief Communication Technology-based Service (e.g. Virtual Check-in): HCPCS code GVC11
CMS proposes HCPCS code GVC11: Brief communication technology based service, e.g. virtual check-in, by a physician or other qualified health care professional who may report E/M services provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion. CMS proposes to value this service based on CPT code 99411 (Telephone E/M services), which is currently not separately payable under the PFS. CMS proposes GVC11 because it believes another code is needed to encompass a broader array of communication modalities. **CMS welcomes comments on the code descriptor and the proposed work RVU (0.25). CMS is also interested in feedback from stakeholders, including the CPT Editorial Panel and the RUC, about whether separate coding and payment is needed to differentiate between communication modalities.**

69. Visit Complexity Inherent to Certain Specialist Visits: HCPCS code GCG0X
CMS proposes HCPCS code GCG0X: Visit complexity inherent to E/M associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care (Add-on code, list separately in addition to an E/M visit). CMS proposes crosswalking this code to 75 percent of the work RVU and time of CPT code 90785 (Interactive complexity), an add-on code that may be billed when a psychotherapy or psychiatric service requires more work due to the complexity of the patient. **CMS welcomes comments on the code descriptor and the proposed work RVU (0.25).**

70. Visit Complexity Inherent to Primary Care Services: HCPCS code GPC1X
CMS proposes HCPCS code GCG1X: Visit complexity inherent to E/M associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an E/M visit). **CMS welcomes comments on the code descriptor and the proposed work RVU (0.07).**

71. Podiatric E/M Services: HCPCS codes GPD0X and GPD1X
CMS proposes HCPCS code GPD0X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, new patient) and HCPCS code GPD1X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, established patient). CMS proposes a work RVU of 1.36 for GPD0X and a work RVU of 0.85 for GPD1X. **CMS welcomes comments on the code descriptor and the proposed work RVUs.**

72. Comment Solicitation on Superficial Radiation Treatment Planning and Management
CMS discusses the concerns that stakeholders have raised associated with the coding and reimbursement associated with superficial radiation treatment (SRT) delivery. In the 2018 PFS proposed rule, CMS proposed to make separate payments for the professional planning and

management associated with SRT using HCPCS code GRRR1. Many commenters did not support this proposal and were concerned it would represent a significant payment reduction. CMS did not finalize this proposal and solicited further comments about this issue.

CMS continues to believe that there are potential coding gaps for SRT-professional services. CMS acknowledges that deferring to the CPT process to address potential coding gaps is generally preferable and that its previous attempt at designing a coding solution did not gain stakeholder consensus.

For 2019, CMS is not proposing any coding or payment policies for SRT-related professional codes. **CMS seeks comments on the following related issues:**

- Creating multiple G-codes specific to services associated with SRT, including codes to separately report services including SRT planning, initial patient simulation visit, treatment device design and construction associated with SRT, SRT management, and medical physics consultation;
- Creating separate G codes to separate report services to mirror the coding of other types of radiation treatment delivery; and
- Creating separate codes for professional services associated with SRT in a coding structure parallel to radiation treatment delivery service such as HCPCS code G6003.

CMS is also interested in whether codes should be included in the 2019 PFS and whether these codes should be contractor priced for 2019. CMS notes this proposal would be an interim approach until the CPT Editorial Panel and the RUC could develop a coding solution that could be addressed in future rulemaking.

H. Evaluation & Management (E/M) Visits

1. Background

E/M Visits Coding Structure

CMS reviews the evaluation and management codes noting that they are comprised of three key components:

- History of Present Illness (History),
- Physical Examination (Exam) and
- Medical Decision Making (MDM).

E/M services account for a very high proportion of PFS allowed charges: 40 percent for all E/M services and 20 percent for office/outpatient E/M services only.

According to Medicare claims data, E/M visits are furnished by nearly all specialties but represent a greater share of total allowed services for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests. Generally, these practitioners include both primary care practitioners and specialists such as neurologists, endocrinologists and rheumatologists. Certain specialties, such as podiatry, tend to furnish lower level E/M visits more often than higher level E/M visits. Some specialties, such as dermatology and otolaryngology, tend to bill more E/M visits on the same day as minor procedures.

E/M Documentation Guidelines

There are five levels of E/M visit codes in the office or other outpatient setting. For coding and billing one of these five levels to Medicare, practitioners may use either the 1995 or 1997 E/M documentation guidelines. When counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter, the duration of the visit can be used to select the appropriate E/M visit level.

Stakeholders have long maintained that the E/M documentation guidelines are administratively burdensome and outdated with respect to the practice of medicine. Prior attempts to revise the E/M guidelines were unsuccessful due to lack of stakeholder consensus and differing perspectives on whether code revaluation would be necessary as a result of revising the guidelines.

CMS summarized public comments on potential changes to the E/M documentation guidelines in the CY 2018 PFS final rule (82 FR 53163 through 53166), held a listening session on March 18, 2018 and sought input in several listening sessions recently hosted by the Office of the National Coordinator for Health Information Technology in the course of implementing section 4001(a) of the 21st Century Cures Act; a provision that requires the Department of Health and Human Services to reduce regulatory or administrative burdens relating to use of EHRs. Based on stakeholder feedback, CMS concludes that the history and exam portions of the guidelines are most significantly outdated with respect to current clinical practice.

2. CY 2019 Proposed Policies

For CY 2019, CMS is proposing changes only to the office/outpatient visit codes (CPT codes 99201 through 99215), except as specified. CMS may address other E/M codes in future years. If CMS finalizes its proposal, it plans to make conforming changes to E/M program integrity and other sub-regulatory guidance over time.

Eliminating Extra Documentation Requirements for Home Visits

Medicare pays slightly more for home visits (CPT codes 99341-99350) than office/outpatient visits. The Medicare Claims Processing Manual (Pub. 100-04, Chapter 12, Section 30.6.14.1.B) requires documentation of the medical necessity of furnishing visits in the home rather than in the office. CMS is proposing to remove the requirement that the medical record must document the medical necessity of furnishing the visit in the home rather than in the office on the basis that it is an unnecessary requirement. The agency agrees with commenters that physicians are in the best position to determine where the patient should be seen.

Public Comment Solicitation on Eliminating Prohibition on Billing Same-Day Visits by Practitioners of the Same Group and Specialty

The Medicare Claims Processing Manual (Publication 100-04, Chapter 12, Section 30.6.7.B) prohibits Medicare from paying for two E/M office visits billed by a physician (or physician of the same specialty from the same group practice) for the same beneficiary on the same day

unless the physician documents that the visits were for unrelated problems that could not be provided during the same encounter. CMS is proposing to eliminate this policy to better recognize the changing practice of medicine and reduce administrative burden. The impact of this proposal on program expenditures and beneficiary cost sharing is unclear as these visits may already be occurring on two separate days instead of one. **CMS requests public comments on whether the policy should be retained but allow exceptions for specific clinical scenarios.**

Choice of Supporting Documentation

CMS is proposing to allow practitioners to use either: 1) 1995 or 1997 guidelines; 2) medical decision making (MDM); or 3) time as a basis to determine the appropriate level of E/M visit. If time is used to determine the appropriate level of E/M visit, CMS is proposing that it would not be limited to those visits where counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter (or, in the case of inpatient E/M services, the floor time). If finalized, CMS would monitor the results of this proposed policy for any program integrity issues, administrative burden or other issues.

CMS' proposal would allow different practitioners in different specialties to choose to document the factor(s) that matter most given the nature of their clinical practice. It would also reduce the impact Medicare may have on the standardized recording of history, exam and MDM data in medical records, since practitioners could choose to no longer document many aspects of an E/M visit that they currently document under the 1995 or 1997 guidelines for history, physical exam and MDM.

As described in further detail below, CMS is retaining the CPT E/M codes but is establishing a one payment rate for CPT codes 99202 through 99205 (new patient) and another payment rate for CPT codes 99212 through 99215 (established patient). For the purposes of PFS payment for an office/outpatient E/M visit, CMS is proposing that practitioners would only need to meet documentation requirements currently associated with a level 2 visit for history, exam and/or MDM (except when using time to document the service). Practitioners may continue to choose and report the level of E/M visit they believe to be appropriate under the CPT coding structure.

CMS is soliciting public comment on what total time should be for payment of the single, new rate for E/M visits levels 2 through 5 if time were to be used as a basis for payment.

One alternative is to apply the AMA's CPT codebook provision that, for timed services, a unit of time is attained when the mid-point is passed (at least 16 minutes for an established patient and at least 20 minutes for a new patient).²² Another alternative is to require documentation that the typical time for the CPT code selected is spent face-to-face with the patient (e.g. 10 minutes for 99212 and 25 minutes for 99214).²³ CMS asks commenters to take into consideration ways in which the time associated with, or required for, the billing of any add-on codes (especially the proposed prolonged E/M visit add-on code(s) would intersect with the time spent for the base E/M visit, when the practitioner is documenting the E/M visit using only time (see below for more detail about E/M visit add-on and prolonged services codes).

²² These times are based on ½ of a weighted average of the times provided by the Relative Value Update Committee to value these codes.

²³ These times are the typical times associated with doing the visit provided in CPT.

Removing Redundancy in E/M Visit Documentation

Under current policy, the billing practitioner does not have to repeat all of the documentation of Review of Systems “ROS” and/or a pertinent past, family, and/or social history “PFSH” obtained during an earlier encounter. ROS and PFSH are elements of the patient history. The billing practitioner only needs to describe any new ROS and/or PFSH information or note there has been no change in the information since the last visit. The ROS and/or PFSH may be recorded by ancillary staff or on a form completed by the patient. To document that the physician reviewed the information, there must be a notation supplementing or confirming the information recorded by others.

CMS is proposing to expand this policy to other components of the patient history. Practitioners would not need to re-record these elements (or parts thereof) if there is evidence that the practitioner reviewed and updated the previous information. **CMS solicits comments on whether analogous policies could be adopted for MDM and for new patients such as when prior data is available to the billing practitioner through an interoperable EHR.** In addition, CMS is proposing that for both new and established patients, practitioners would no longer be required to re-enter information in the medical record regarding the chief complaint and history of present illness that are already entered by ancillary staff or the beneficiary. The practitioner could simply indicate in the medical record that they reviewed and verified this information.

Podiatry Visits

CMS is proposing that, rather than reporting visits under the general E/M office/outpatient visit code set, podiatrists would instead report visits under new G-codes that more specifically identify and value their services. CMS is proposing to apply substantially the same documentation standards for these proposed new podiatry-specific codes as for other office/outpatient E/M visits and the same options for use of time to document the level of visit (more than ½ the time spent face-to-face with the patient or the typical times associated with the code).

Simplifying Payment Amounts

CMS is proposing to pay a single rate for the level 2 through 5 E/M visits. Eliminating the distinction in payment between visit levels 2 through 5 will provide immediate documentation burden relief and eliminate the need for auditing based on the level of visit billed. CMS is proposing to develop resource inputs for the proposed payment rates based on the current inputs for the individual E/M codes, generally weighted by the frequency at which they are currently billed, based on Medicare claims data from CY 2012 - CY 2017. CMS is proposing:

- CPT Codes 99202 – 99205:
 - Work RVU=1.90
 - Physician time= 37.79 minutes
 - Direct PE inputs = \$24.98

- CPT Codes 99212 – 99215:
 - Work RVU = 1.22
 - Physician time=31.31 minutes
 - Direct PE inputs=\$20.70

Tables 19 and 20 reflect the payment rates in dollars that would result from this approach using 2018 payment rates:

TABLE 19: Preliminary Comparison of Payment Rates for Office Visits New Patients

HCPCS	CY 2018 Non-facility Payment Rate	CY 2018 Non-facility Payment Rates under the Proposal
99201	\$45	\$44
99202	\$76	\$135
99203	\$110	
99204	\$167	
99205	\$211	

TABLE 20: Preliminary Comparison of Payment Rates for Office Visits Established Patients

HCPCS	CY 2018 Non-facility Payment Rate	CY 2018 Non-facility Payment Rates under the Proposal
99211	\$22	\$24
99212	\$45	\$93
99213	\$74	
99214	\$109	
99215	\$148	

Accounting for E/M Resource Overlap between Stand-Alone Visits and Global Periods

Standalone E/M visit codes included in a global period are not billable on the same day as a procedure code unless the billing professional specifically indicates that the visit is separately identifiable from the procedure and bills with modifier 25 appended to the claim. In this situation, the E/M code is paid at the full rate and not discounted. Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent service furnished to the same patient by the same physician on the same day, largely based on the presence of efficiencies in practice expense and pre- and post-surgical physician work. CMS is proposing to reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on the claim by an appended modifier -25. This policy is estimated to reduce expenditures under the PFS by approximately 6.7 million RVUs. To make this policy budget neutral, CMS is proposing to allocate the reduced RVUs toward the values of the add-on codes that reflect the additional resources associated with E/M visits for primary care and inherent visit complexity (see below for more details about new codes for these services).

HCPCS G-code Add-ons to Recognize Additional Relative Resources for Certain Kinds of Visits

CMS believes the proposed payment rates for E/M levels 2 through 5 new and established visit codes does not reflect additional resources inherent to primary care visits, as primary care visits are generally reported using level 4 E/M codes. Therefore, CMS proposes to create HCPCS

code GPC1X (Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an established patient evaluation and management visit)). This code may be billed as an add-on to E/M levels 2 through 5 to account for additional costs beyond the typical resources accounted for in the base code. HCPCS code GPC1X can be reported for an established patient and for face-to-face care management, counseling, or treatment of acute or chronic conditions not accounted for by other coding. CMS is proposing:

- HCPCS GPC1X
 - Work RVU=0.07,
 - Physician time = 1.75 minutes
 - PE RVU = 0.07
 - MP RVU = 0.01

The proposed rule indicates that the valuation accounts for the additional resource costs associated with furnishing primary care relative other E/M services and maintains work budget neutrality across the office/outpatient E/M code set. CMS says the proposed add-on G-code for primary care-focused E/M services would help to mitigate potential payment instability that could result from adoption of single payment rates that apply for E/M code levels 2 through 5. As this add-on G-code would account for the inherent resource costs associated with furnishing primary care E/M services, CMS anticipates that it would be billed with every primary care-focused E/M visit for an established patient.

While CMS expects that this code will mostly be utilized by primary care specialties (such as family practice or pediatrics), it may be billed by any physician performing these types of visits, regardless of Medicare enrollment specialty. **CMS is seeking comment on how best to identify whether or not a primary care visit was furnished, particularly in cases where a specialist is providing those services.** For especially complex patients, CMS also expects that this code may be billed alongside the proposed new code for prolonged E/M services described below.

CMS is also proposing HCPCS code GCG0X (Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit)). This code is being created to recognize the additional resource costs for specialty professionals for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches are generally reported using the level 4 and level 5 E/M visit codes rather than procedural coding. CMS is proposing:

- GCG0X
 - Work RVU=0.25
 - Physician time=8.25
 - PE RVU=0.07
 - MP=0.01

These values are based on 75 percent of the work and time of CPT code 90785 (Interactive complexity). Interactive complexity is an add-on code that may be billed when a psychotherapy or psychiatric service requires more resources due to the complexity of the patient. As CPT code 90875 is available to psychiatrists to describe work that might otherwise be reported with a level 4 or level 5 E/M visit, CMS further proposes that psychiatrists would not use either new add-on code for primary care E/M visit complexity or visit complexity for non-procedural specialties.

HCPCS G-code to Describe Podiatric E/M Visits

CMS is proposing to create two HCPCS G codes:

- GPD0X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, new patient); and
- GPD1X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, established patient).

Podiatric E/M services would be billed using these G-codes instead of the generic office/outpatient E/M visit codes (CPT codes 99201 through 99205 and 99211 through 99215). CMS proposes separate codes for podiatric medical visits because most podiatric visits are billed as level 2 or 3 E/M codes and it does not believe the new E/M coding structure is applicable to podiatry visits.

The coding structure and descriptors are based on CPT codes 92004 and 92012 for ophthalmology visits new and established patient respectively. The RVUs are based on the weighted average of podiatry utilization for level 2 and level 3 E/M codes. CMS proposes:

- GPD0X
 - Work RVU = 1.35
 - Physician time = 28.11 minutes
 - Direct PE inputs = \$22.53
- GPD1X
 - Work RVU = 0.85,
 - Physician Time = 21.60 minutes
 - Direct PE inputs = \$17.07

Proposed Adjustment to the PE/HR Calculation

Establishing a single PFS rate for new and established patient E/M levels 2 through 5 would have a large and unintended effect on many specialties due to the way that indirect PE is allocated based on the mixture of specialties that furnish a service. CMS does not believe it is in the public interest to allow the allocation of indirect PE to have such an outsized impact on the payment rates for this proposal. In the past, when utilization data are not available or do not accurately reflect the expected specialty mix of a new service, CMS has crosswalked the PE/HR value from another specialty (76 FR 73036) until utilization data is available to use in the practice expense methodology. CMS is proposing the same policy here—to create a crosswalk until utilization data is available to use in the practice expense methodology.

CMS proposes to create a single PE/HR value for E/M visits (including all of the proposed HCPCS G-codes discussed above) of approximately \$136, based on an average of the PE/HR across all specialties that bill these E/M codes, weighted by the volume of those specialties' allowed E/M services. CMS will consider revisiting the PE/HR after several years of claims data become available.

Proposed HCPCS G-Code for Prolonged Services

The current prolonged service codes are CPT 99354 for the first hour of prolonged E/M or psychotherapy and CPT 99355 for each additional ½ hour. In response to comments that the first hour threshold is difficult to meet, CMS proposes to create HCPCS code GPRO1 that may be billed when a prolonged E/M or psychotherapy services is 30 minutes beyond the usual service time. CMS proposes a work RVU of 1.17 which is ½ of the current prolonged service code.

Impacts

CMS qualifies that the impacts shown in Tables 21, 22 and 23 below are relatively imprecise compared to the specialty-level impacts displayed in the impact section of the final rule because they do not account for the full range of technical changes in the input data used in PFS rate-setting. Tables 21, 22, and 23 show the estimated change in expenditures for PFS services based on potential changes for E/M coding and payment isolated from other proposed changes. Additional data is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1693-P.html>

TABLE 21: Unadjusted Estimated Specialty Impacts of Proposed Single RVU Amounts for Office/Outpatient E/M 2 through 5 Levels

Specialty	Allowed Charges (in millions)	Estimated Potential Impact of Valuing Levels 2-5 Together, Without Additional Adjustments
PODIATRY	\$2,022	12%
DERMATOLOGY	\$3,525	7%
HAND SURGERY	\$202	6%
OTOLARNGOLOGY	\$1,220	5%
ORTHOPEDIC SURGERY	\$3,815	4%
ORAL/MAXILLOFACIAL SURGERY	\$57	4%
COLON AND RECTAL SURGERY	\$168	Less than 3% estimated increase in overall payment
OBSTETRICS/GYNECOLOGY	\$664	
OPTOMETRY	\$1,276	
PHYSICIAN ASSISTANT	\$2,253	
PLASTIC SURGERY	\$387	
ALLERGY/IMMUNOLOGY	\$240	Minimal change to overall payment
ANESTHESIOLOGY	\$1,995	

Specialty	Allowed Charges (in millions)	Estimated Potential Impact of Valuing Levels 2-5 Together, Without Additional Adjustments
AUDIOLOGIST	\$67	
CARDIAC SURGERY	\$313	
CHIROPRACTOR	\$789	
CRITICAL CARE	\$334	
EMERGENCY MEDICINE	\$3,196	
FAMILY PRACTICE	\$6,382	
GASTROENTEROLOGY	\$1,807	
GENERAL PRACTICE	\$461	
GENERAL SURGERY	\$2,182	
INFECTIOUS DISEASE	\$663	
INTERVENTIONAL PAIN MGMT	\$839	
INTERVENTIONAL RADIOLOGY	\$362	
MULTISPECIALTY CLINIC/OTHER PHYS	\$141	
NEUROSURGERY	\$812	
NUCLEAR MEDICINE	\$50	
NURSE PRACTITIONER	\$3,586	
OPHTHALMOLOGY	\$5,542	
OTHER	\$30	
PATHOLOGY	\$1,151	
PHYSICAL MEDICINE	\$1,120	
PSYCHIATRY	\$1,260	
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	\$1,776	
RADIOLOGY	\$4,898	
THORACIC SURGERY	\$360	
UROLOGY	\$1,772	
VASCULAR SURGERY	\$1,132	
CARDIOLOGY	\$6,723	
INTERNAL MEDICINE	\$11,173	
NEPHROLOGY	\$2,285	
PEDIATRICS	\$64	
PULMONARY DISEASE	\$1,767	
GERIATRICS	\$214	-4%
RHEUMATOLOGY	\$559	-7%
NEUROLOGY	\$1,565	-7%
HEMATOLOGY/ONCOLOGY	\$1,813	-7%

Less than 3% estimated decrease in overall payment

Specialty	Allowed Charges (in millions)	Estimated Potential Impact of Valuing Levels 2-5 Together, Without Additional Adjustments
ENDOCRINOLOGY	\$482	-10%
TOTAL	\$93,486	0%

Table 21 shows the estimated impact of establishing single payment rates for the new and established patient E/M code levels 2 through 5, without any of the additional coding or proposed payment adjustments. The proposal benefits specialties that tend to bill lower level E/M visits while those specialties that tend to bill more higher-level E/M visits would see the largest decreases in payment.

TABLE 22: Specialty Specific Impacts Including Payment Accuracy Adjustments

Specialty	Allowed Charges (in millions)	Estimated Potential Impact of Valuing Levels 2-5 Together, With Additional Adjustments
OBSTETRICS/GYNECOLOGY	\$664	4%
NURSE PRACTITIONER	\$3,586	3%
HAND SURGERY	\$202	Less than 3% estimated increase in overall payment
INTERVENTIONAL PAIN MGMT	\$839	
OPTOMETRY	\$1,276	
PHYSICIAN ASSISTANT	\$2,253	
PSYCHIATRY	\$1,260	
UROLOGY	\$1,772	
ANESTHESIOLOGY	\$1,995	
CARDIAC SURGERY	\$313	
CARDIOLOGY	\$6,723	
CHIROPRACTOR	\$789	
COLON AND RECTAL SURGERY	\$168	
CRITICAL CARE	\$334	
EMERGENCY MEDICINE	\$3,196	
ENDOCRINOLOGY	\$482	
FAMILY PRACTICE	\$6,382	
GASTROENTEROLOGY	\$1,807	
GENERAL PRACTICE	\$461	
GENERAL SURGERY	\$2,182	
GERIATRICS	\$214	
INFECTIOUS DISEASE	\$663	
INTERNAL MEDICINE	\$11,173	
INTERVENTIONAL RADIOLOGY	\$362	

Specialty	Allowed Charges (in millions)	Estimated Potential Impact of Valuing Levels 2-5 Together, With Additional Adjustments
MULTISPECIALTY CLINIC/OTHER PHYS	\$141	
NEPHROLOGY	\$2,285	
NEUROSURGERY	\$812	
NUCLEAR MEDICINE	\$50	
OPHTHALMOLOGY	\$5,542	
ORAL/MAXILLOFACIAL SURGERY	\$57	
ORTHOPEDIC SURGERY	\$3,815	
OTHER	\$30	
PATHOLOGY	\$1,151	
PEDIATRICS	\$64	
PHYSICAL MEDICINE	\$1,120	
PLASTIC SURGERY	\$387	
RADIOLOGY	\$4,898	
THORACIC SURGERY	\$360	
VASCULAR SURGERY	\$1,132	Less than 3% estimated decrease in overall payment
ALLERGY/IMMUNOLOGY	\$240	
AUDIOLOGIST	\$67	
HEMATOLOGY/ONCOLOGY	\$1,813	
NEUROLOGY	\$1,565	
OTOLARNGOLOGY	\$1,220	
PULMONARY DISEASE	\$1,767	
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	\$1,776	
RHEUMATOLOGY	\$559	-3%
DERMATOLOGY	\$3,525	-4%
PODIATRY	\$2,022	-4%
TOTAL	\$93,486	0%

Table 22 includes the impacts shown in Table 21 and the application of an MPPR to E/M visits when furnished by the same practitioner (or practitioner in the same practice) on the same-day as a global procedure code, the add-on G codes for primary care-focused services and inherent visit complexity, and the technical adjustments to the PE/HR value. It does not include any additional billing associated with the new prolonged services code. Table 22 assumes the G-code for visit complexity inherent to evaluation and management associated with primary medical care services will be billed with every office/outpatient visit furnished for specialties that practice primary care. It also assumes that endocrinologists, rheumatologists, hematology/oncologists, urologists, neurologists, obstetrics/gynecologists, allergy/immunologists, otolaryngologists and interventional pain specialists will bill the G-code for visit complexity inherent to evaluation and management with every office/outpatient E/M visit. The largest net reductions between Tables 21 and 22 are for those specialties that bill a large portion of E/M visits on the same day

as procedures. The largest net increases between Tables 21 and 22 are for those specialties that are assumed to bill the add-on codes for primary care and inherent visit complexity.

The following example shows how payment for a level 4 E/M visit would be affected by CMS' proposal in 2018 dollars:

	2018 Current Policy	2018 Proposed Policy	With E/M Primary Care Add-on	With E/M Inherent Visit Complexity Add-On
99214	\$109	\$93	\$98	\$105

Alternatives Considered

CMS considered establishing single payment rates for E/M visit levels 2 through 4 and retaining a distinct payment rate for E/M visit level 5. However, CMS rejected this idea as it would not allow for the same reduction in documentation burden and would require documentation requirements unique to the higher-level visits. Table 23 of the proposed rule shows the impact of a single payment rate for E/M visit levels 2 through 4 and retaining E/M visit level 5. The payment impacts are similar to Table 21.

TABLE 23: Unadjusted Estimated Specialty Impacts of Single PFS Rate for Office/Outpatient E/M Levels 2 through 4

Specialty	Allowed charges (millions)	Impact
Podiatry	\$2,022	10%
Dermatology	\$3,525	6%
Hand Surgery	\$202	5%
Oral/Maxillofacial Surgery	\$57	4%
Otolaryngology	\$1,220	4%
Cardiology	\$6,723	-3%
Hematology/Oncology	\$1,813	-3%
Neurology	\$1,565	-3%
Rheumatology	\$559	-6%
Endocrinology	\$482	-8%

Note: All other specialty level impacts were within +/- 3%.

The proposed rule indicates that CMS considered using voluntarily submitted patient relationship modifiers to adjust payment for E/M visits to the extent that these codes are indicative of differentiated resources provided in E/M visits. **CMS did not propose this alternative but requests comments about using these modifiers as an alternative to the new G codes it has proposed.**

Emergency Department and Other E/M Visit Settings

CMS is not making any changes at this time to the inpatient E/M codes due to concerns about the interaction with the hospital conditions of participation. Similarly, CMS is not making any changes to the E/M codes for emergency department visits because of a large variety of concerns (including medical-legal ones) raised in public comments in the 2018 PFS rule. CMS may

consider expanding efforts more broadly to additional sections of the E/M visit code set in future years.

Implementation Date

CMS is proposing to implement its new polices effective January 1, 2019 but notes that it considered a multi-year or delayed effective date for a variety of reasons explained in the rule. As the changes to the documentation requirements are optional, practitioners could choose to continue documenting visits using the current framework which may reduce the need for a delayed implementation. Nevertheless, practitioners who choose a new documentation framework may need time to deploy it. A delayed implementation date would also allow the AMA time to develop changes to the CPT coding definitions and guidance prior to implementation, such as changes to MDM or code definitions. It would also allow other payers time to react and potentially adjust their policies.

I. Teaching Physician Documentation Requirements for Evaluation and Management Services

1. Background

Medicare Part B makes payment under the PFS for teaching physician services when certain conditions are met, including that medical record documentation must reflect the teaching physician's participation in the review and direction of services performed by residents in teaching settings. Stakeholder feedback suggested that documentation requirements for E/M services furnished by teaching physicians are burdensome and duplicative of notations that may have previously been included in the medical records by residents or other members of the medical team.

2. Proposed Implementation

CMS is proposing to revise the regulations to require that the medical records must document that the teaching physician was present at the time the service was furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by a physician, resident, or nurse. Similarly, the extent of the teaching physician's participation in the review and direction of the services furnished to each beneficiary may be documented by a physician, a resident or a nurse and does not have to be documented by the teaching physician him or herself.

These changes do not apply to:

- §415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings),
- §415.176 (concerning renal dialysis services), and
- §415.184 (concerning psychiatric services).

J. Solicitation of Public Comments on the Low Expenditure Threshold Component of the Applicable Laboratory Definition under the Medicare Clinical Laboratory Fee Schedule (CLFS)

CMS appears to have included the same proposal in two different sections of the rule. The discussion of this section of the rule is included in III. A. below.

K. GPCI Comment Solicitation

CMS revises the GPICs every 3 years. The next GPCI update will be undertaken next year for the CY 2020 physician fee schedule. Commenters have raised concerns about the accuracy of the residential rent data source that CMS uses as a proxy for the physician office rent component of the practice expense GPCI. CMS will continue efforts to identify a nationally representative commercial rent data source. **In support of that effort, it requests comment on potential sources of commercial rent data for potential use in the next GPCI update for CY 2020.**

L. Therapy Services

1. Repeal of the Therapy Caps

From 1998 through 2017, therapy services were subject to annual per beneficiary cap on expenditures. There was one cap for physical therapy (PT) and speech language pathology (SLP) services and another cap for occupational therapy (OT) services. The caps were initially equal to \$1,500 per year. In subsequent years, the cap was increased by the Medicare Economic Index (MEI).

Section 50202 of the Bipartisan Budget Act of 2018 (BBA of 2018) repealed the caps effective January 1, 2018. However, the new law also requires that a modifier be included on the Medicare claim once the prior therapy cap amounts have been reached. For 2018, therapy providers are required to use the KX modifier when annual per beneficiary expenditures exceed \$2,010 for PT and SLP services combined, and \$2,010 for OT services. After the beneficiary's incurred expenditures for outpatient therapy services exceed these thresholds, claims for outpatient therapy services without the KX modifier are denied.

Along with the KX modifier thresholds, the law retains a medical review (MR) process. Under the prior process, all claims for therapy services above \$3,700 were subject to manual medical review. Under the revised process, the law establishes a targeted medical review process for therapy services above \$3,000. The \$3,000 threshold is retained until 2028 at which time it is indexed annually by the MEI. The MR threshold is \$3,000 for PT and SLP services and \$3,000 for OT services. The law retains the provider liability procedures which first became effective January 1, 2013, extending limitation of liability protections to beneficiaries who receive outpatient therapy services, when services are denied for certain reasons, including failure to include a necessary KX modifier.

2. Proposed Payment for Outpatient PT and OT Services Furnished by Therapy Assistants

BBA of 2018 established a provision that requires therapy services that are furnished in whole or in part by a therapy assistant to be paid at 85 percent of the PFS amount on or after January 1, 2022. The provision only applies to therapy services paid under the PFS (such as to therapists in private practice, outpatient hospitals, rehabilitation agencies, skilled nursing facilities, home health agencies and comprehensive outpatient rehabilitation facilities). The provision does not apply to critical access hospitals.

CMS does not believe SLPs use therapy assistants and is only proposing to require modifiers when services are furnished in whole or in part by a physical therapist assistant (PTA) or an occupational therapist assistant (OTA). Section 1834(v)(2)(B) of the Act requires that each bill submitted for an outpatient PT or OT service furnished in whole or in part by a therapy assistant on or after January 1, 2020, must include the established modifier even though the payment reduction will not apply until January 1, 2022.

CMS is proposing to define “therapy assistant” as an individual who meets the personnel qualifications set forth at §484.4 of the regulations for a PTA and OTA, respectively. It is also proposing that the two new therapy modifiers would be used to identify services furnished in whole or in part by a PTA or an OTA; and, that these new therapy modifiers would be used instead of the GP and GO modifiers that are currently used to report PT and OT services delivered under the respective plan of care.

Effective for dates of service on and after January 1, 2020, five therapy modifiers will be used to track outpatient therapy services instead of the current three. These five therapy modifiers include two new therapy modifiers to identify PT and OT services furnished by PTAs and OTAs, respectively, and three revised therapy modifiers – GP, GO and GN – that will be used when PT, OT, and SLP services, respectively, are fully furnished by therapists or when fully furnished by or incident to physicians and non-physician practitioners (NPPs include physician assistants, nurse practitioners and clinical nurse specialists). CMS proposal is as follows:

- New-PT Assistant services modifier (to be used instead of the GP modifier currently reported when a PTA furnishes services in whole or in part): Services furnished in whole or in part by a physical therapist assistant under an outpatient physical therapy plan of care;
- New-OT Assistant services modifier (to be used instead of the GO modifier currently reported when an OTA furnishes services in whole or in part): Services furnished in whole or in part by occupational therapy assistant under an outpatient occupational therapy plan of care;
- Revised GP Modifier-Services fully furnished by a physical therapist or by or incident to the services of another qualified clinician–physician or NPP–under an outpatient physical therapy plan of care;
- Revised GO Modifier-Services fully furnished by an occupational therapist or by or incident to the services of another qualified clinician–physician or NPP–under an outpatient occupational therapy plan of care; and
- Revised GN Modifier- Services fully furnished by a speech-language pathologist or by or

incident to the services of another qualified clinician—physician or NPP—under an outpatient speech-language pathology plan of care.

CMS anticipates allowing voluntary reporting of the new modifiers at some point during 2019, which it will announce to contractors and therapy providers through a Change Request, as part of the usual change management process.

PTAs and OTAs are not permitted by law to furnish therapy services “incident to” a physician or NPP service in an office setting. Therefore, the new PTA and OTA therapy modifiers cannot be used when the rendering practitioner is a physician or NPP.

The new therapy modifiers would be required to be used whenever a PTA or OTA furnishes all or part of any covered outpatient therapy service. CMS proposes to define “in part,” to mean any minute of the outpatient therapy service that is therapeutic in nature, and that is provided by the PTA or OTA when acting as an extension of the therapist. This definition would exclude non-therapeutic services such as scheduling the next appointment, greeting and gowning the patient, preparing or cleaning the room.

The rule reminds therapists and therapy providers that CMS does not allow PTAs and OTAs to wholly furnish PT and OT evaluations and re-evaluations but to the extent that they do furnish part of an evaluative service, the appropriate therapy modifier must be used and payment adjustment will apply. Even though it is not a billable service, CMS further reminds readers that the development of a therapy plan of care cannot be done by PTAs and OTAs and must be done by a physician, PT, OT, SLP or an NPP.

3. Proposed Functional Reporting Modifications

Since January 1, 2013, all providers of outpatient therapy services, including PT, OT, and SLP services, have been required to include functional status information on claims for therapy services. In response to the Request for Information (RFI) on CMS Flexibilities and Efficiencies that was issued in the CY 2018 PFS proposed rule (82 FR 34172 through 34173), CMS received comments requesting burden reduction related to the functional reporting requirements that were adopted to implement the requirements of section 3005(g) of the Middle Class Tax Relief and Jobs Creation Act (MCTRJCA) of 2012, effective January 1, 2013.

CMS goes through the history of functional reporting and its detailed requirements as well as the public comments that it has received requesting that the agency share the reporting results and suggesting changes to make it less burdensome. The majority of commenters urged CMS to substantially revise and repurpose functional reporting requirements for other programmatic purposes or to eliminate the functional reporting requirements altogether.

In response to these comments, CMS indicated that it has reviewed and analyzed the functional reporting data internally but did not find the results particularly useful in considering how to reform payment for therapy services as an alternative to the therapy caps. For this reason, CMS has not publicly shared functional reporting results. In the meantime, section 50202 of BBA of 2018 reformed therapy payment by eliminating the therapy caps. Because section 3005(g) of

MCTRJCA was not codified into the Act and did not specify how long functional reporting should last, CMS does not believe that functional reporting was intended to last indefinitely.

Given that functional reporting is overly complex and burdensome to report and that continuing to collect more years of these functional reporting data will not be helpful to inform future analyses, CMS is proposing to discontinue the functional reporting requirements for services furnished on or after January 1, 2019. Accordingly, with the conclusion of the functional reporting system for dates of service after December 31, 2018, CMS plans to eliminate the applicable regulations that require functional reporting as a condition of payment, make the relevant claims processing systems edits to no longer require functional reporting and delete the applicable non-payable HCPCS G-codes specifically developed to implement functional reporting.

M. Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-based Payments

Consistent with the statutory provisions in section 1847A of the Act, many Part B drug payments are based on the Average Sales Price (ASP) methodology and, by statute, include an add-on payment of 6 percent of the ASP amount. Some Part B drugs are based on wholesale acquisition cost (WAC) such as single-source drugs without ASP data. The add-on percentage for drug payments made under section 1847A of the Act is typically applied to the ASP; in certain situations, the same 6 percent add-on is also applied to the WAC for Part B drug payments. Payment for Part B drugs may be based on WAC and the 6 percent add-on payment in the following situations:

- For single source drugs, payment is made using the lesser of ASP or WAC (section 1847A(b)(4) of the Act) and a 6 percent add-on payment is required to be applied regardless of whether WAC or ASP is less (section 1847A(c)(4)).
- For drugs and biologicals where ASP price data is unavailable during the first quarter of sales, the Secretary may determine the payment amount for the drug or biological based on the WAC or payment methodologies in effect on November 1, 2003 (section 1847A(c)(4) of the Act). CMS notes this provision does not specify that an add-on percentage be applied if WAC based-payment is used, nor is an add-on percentage specified in the implementing regulations (§419.904(e)(4)).²⁴
- When Medicare Administrative Contractors (MACs) determine pricing for drugs that do not appear on the ASP pricing files and for new drugs.²⁵

CMS discusses the statutory differences in the incorporation of discounts in ASP and WAC. As defined in section 1847A(c)(3) of the Act, the ASP is net of many discounts such as volume discounts, prompt pay discounts, cash discounts, and rebates (other than rebates under the Medicaid drug rebate program). In contrast, as defined in section 1847A(c)(6)(B) of the Act, WAC is defined as the manufacturer's list price for the drug or biological to wholesalers or direct purchases in the US, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available as reported in wholesale price

²⁴ A discussion of the application of the add-on payment to WAC-based payments during a period where partial ASP data is available in the 2011 PFS final rule (75 FR 73465 through 73466).

²⁵ This is discussed in the Medicare Claims Processing Manual: Chapter17, Section 1.3.

guides or other publications of drug or biological pricing date. Because WAC-based pricing does not include discounts, it typically exceeds the ASP.

CMS and others, including MedPAC,²⁶ the Office of the Assistant Secretary for Planning and Evaluation (ASPE),²⁷ and the OIG,²⁸ have raised concerns about the use of a 6 percent add-on payment for both ASP and WAC, especially since this add-on payment for expensive drugs may create an incentive for the use of more expensive drugs. The June 2017 MedPAC Report to Congress included a recommendation to reduce WAC-based payment to WAC plus 3 percent.

CMS proposes that effective January 1, 2019, WAC based payments for Part B drugs made under section 1847A(c)(4) of the Act utilize a 3 percent add-on payment in place of the 6 percent add-on payment that is currently applied. CMS notes that a fixed percentage is consistent with other provisions of section 1847A of the Act which specify fixed add-on percentage of 6 percent (1847A(b)) or 3 percent (section 1847A(d)(3)(C)). This proposal is also consistent with recent MedPAC recommendations.

To conform the regulation text more closely to the statutory language at section 1847A(c)(4) of the Act, CMS proposes to strike the word “applicable” from §414.904(e)(4) to describe the payment methodologies in effect on November 1, 2003.

CMS acknowledges other approaches for modifying the add-on amount, such as a flat fee or percentages that vary with the cost of the drug. CMS thinks a fix percentage is administratively easier to implement and easier to understand. If this proposal were finalized, CMS would make the changes in the Claims Processing Manual to allow MACs to use an add-on percentage of up to 3 percent for WAC-based new drugs. CMS notes that when a new drug becomes available, MACs have longstanding authority to make payment determinations when a payment limit is not included in the national Part B drug pricing files.

CMS notes this proposal does not include WAC-based payments for single source drugs under section 1847A(b) of the Act; this provision of the statute specifies that the payment is 106 percent of the lesser of ASP or WAC. In addition, this proposed policy would not alter the OPSS payment limit (95 percent of the published Average Wholesale Price (AWP)).

CMS believes this proposal will improve Medicare payment rates by better aligning payment rates with drug acquisition costs. The proposal will decrease beneficiary cost sharing; a 3 percentage point reduction in the total payment allowance will reduce a patient’s 20 percent Part B copayment.

²⁶ The MedPAC June 2017 Report to Congress is available at http://www.medpac.gov/docs/default-source/reports/june17_reporttocongress_sec.pdf.

²⁷ The ASPE March 8, 2016 Issue Briefing is available at <https://aspe.hhs.gov/pdf-report/medicare-part-b-drugs-pricing-and-incentives>.

²⁸ The OIG report is available at <https://oig.hhs.gov/oei/reports/oei-12-13-00040.asp>.

III. Other Provisions of the Proposed Rule

A. Clinical Laboratory Fee Schedule

1. Background

Under a provision of law implemented January 1, 2018, CMS set clinical laboratory fee schedule (CLFS) rates based on the weighted median of private payer rates reported by “applicable laboratories.” CMS collects data from applicable laboratories every three years. Applicable laboratories will next report private payer rates from January 1, 2020 through March 31, 2020 for services furnished between January 1, 2019 to June 30, 2019.

An applicable laboratory is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA)) that bills Medicare Part B under its own National Provider Identifier (NPI) and receives more than 50 percent of its Medicare revenues during the 6-month data collection period from physician fee schedule and CLFS services. Using authority provided in the statute, CMS exempts clinical laboratories receiving less than \$12,500 in Medicare revenues for CLFS services during the 6-month data collection period from having to report private payer rates.

2. Recent Stakeholder Feedback and Proposed Change to “Applicable Laboratory”

Stakeholders have expressed concerns that 2018 CLFS payments rates are based on reporting from a relatively small number of laboratories and does not reflect payment rates for most hospital-based laboratories. Other stakeholders were concerned that the low expenditure threshold excluded most physician office laboratories and many small independent laboratories from reporting.

CMS responds that it is important to achieve a balance between collecting sufficient data to reflect the private market rate while minimizing the reporting burden for entities. In response to stakeholder feedback and in the interest of facilitating this goal, CMS is proposing to remove payments from Medicare Advantage (MA) plans from the denominator of the fraction that is used to determine whether a laboratory received more than 50 percent of its revenues from physician fee schedule and CLFS services. CMS believes that excluding MA plan revenues from total Medicare revenues will result in more laboratories of all types meeting the majority of Medicare revenues threshold and reporting private payer rates.

The proposed rule stresses that its proposed policy of considering MA plan revenues as “private payor” payments would only be applicable for this provision and will have no bearing on how CMS considers MA plan payments in other contexts. CMS has taken this position because section 1834A(a)(8)(B) defines a “Medicare Advantage plan under Part C” as a type of private payor for reporting of private payor rates. CMS believes it is more logical to consider MA plan payments as non-Medicare both for determining applicable laboratory status and for reporting private payor rates.

3. Solicitation of Public Comments on Other Approaches to Defining Applicable Laboratory

CMS is continuing to consider additional refinements to its policies that could lead to including even more applicable information for the next data reporting period. To that end, CMS is considering alternative approaches suggested by stakeholders for defining an “applicable laboratory” even though some of these suggestions were previously considered and rejected in prior rulemaking.

Using Form CMS-1450 bill type 14x to determine majority of Medicare revenues and low expenditure thresholds

Some commenters have suggested using bill type 14x in determining whether a laboratory is an applicable laboratory or exempt from reporting under the low expenditures threshold. Under this suggested approach, a laboratory could determine whether it meets the majority of Medicare revenues threshold and low expenditure threshold using only the revenues from services reported on the 14x bill type, which is used only by hospital outreach laboratories. Among other concerns, CMS believes this approach would be inconsistent with the statute. By virtue of the majority of Medicare revenues threshold, the statute defines applicable laboratory in such a way that not all laboratories qualify as applicable laboratories. However, if CMS were to use the 14x bill type to define an applicable laboratory, all hospital outreach laboratories that use the 14x bill type would meet the majority of Medicare revenues threshold and none of them would be excluded.

Using CLIA Certificate to Define Applicable Laboratories

CMS addressed this suggestion in prior rulemaking (80 FR 59392 and 81 FR 41045). Under this approach, the majority of Medicare revenues threshold and low expenditure threshold would be determined at the CLIA certificate level instead of the NPI level. Among other reasons that CMS previously rejected this suggestion is that the CLIA certificate is not associated with Medicare billing. Unlike the NPI, the CLIA certificate cannot be used to identify revenues for specific services. Nevertheless, CMS is again soliciting comments on using CLIA certificate as the mechanism to identify whether a laboratory receives the majority of its revenues from physician fee schedule or clinical diagnostic laboratory services.

4. Solicitation of Public Comments on the Low Expenditure Threshold in the Definition of Applicable Laboratory

Using authority provided in the statute, CMS exempts clinical laboratories receiving less than \$12,500 in Medicare revenues for CLFS services during the 6-month data collection period from reporting private payer rates. The \$12,500 low expenditure threshold is intended to balance between collecting sufficient data to calculate a weighted median that reflects the private market rate for a laboratory test and minimizing the reporting burden for laboratories that receive a relatively small amount of revenues under the CLFS. CMS estimated that it was able to exclude 95 percent of physician office laboratories from reporting and 55 percent of independent

laboratories but retain reporting for 92 percent and 99 percent of CLFS spending in physician office laboratories and independent laboratories respectively.

In response to concerns from stakeholders that the low expenditure threshold is resulting in incomplete data, and therefore, inaccurate CLFS pricing, **CMS is requesting public comment on whether it should reduce the low expenditure threshold to \$6,250.** However, CMS also indicates that physician offices are generally not prepared to report private payer data and doing so would be a significant administrative burden on physician's offices that would have minimal overall impact on payment rates. Nevertheless, CMS is providing the opportunity for public comment in the event some physician office laboratories and small independent laboratories want to report applicable information, despite the administrative burden. **CMS is also soliciting public comments on increasing the low expenditure threshold from \$12,500 to \$18,750 so that fewer laboratories would have to report private payer rates.**

B. Proposed Changes to the Regulations Associated with the Ambulance Fee Schedule

Ground Ambulance Services in Urban and Rural Areas

Medicare pays for ambulance services under a fee schedule. Since July 1, 2008, Congress has temporarily enacted provisions of the Act that increase payment for ground ambulance services as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts were increased by 3 percent each year from July 1, 2008 through December 31, 2017.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts were increased by 2 percent each year from July 1, 2008 through December 31, 2017

These provisions were most recently extended by the Bipartisan Budget Act of 2018 (BBA) through December 31, 2022. CMS is proposing to revise its regulations to conform to this statutory requirement.

Ground Ambulance Services in Super Rural Areas

Using authority provided by the statute, CMS increased payments rates by 22.6 percent for ambulance transports originating in “super rural” areas (areas comprising the lowest 25th percentile of all rural populations arrayed by population density.) Known as the “super rural” bonus, this additional payment has expired and been extended several times. Congress has extended the “super rural” bonus most recently in the BBA 2018 through December 31, 2022. CMS is proposing to revise its regulations to conform to the statutory provision.

Ground Ambulance Transports for ESRD Patients

The law requires Medicare to apply a 10 percent reduction for non-emergency basic life support services involving transport of an individual with end-stage renal disease for renal

dialysis services. BBA 2018 increases the reduction from 10 percent to 23 percent effective for ambulance services furnished on or after October 1, 2018. CMS is conforming its regulation to the statutory provision.

C. Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

The payment rates for RHCs and FQHCs are designed to reflect the cost of all the services and supplies that are furnished to a patient in a single day. The rates are not adjusted for the complexity of the health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care.

1. Payment for Care Management Services

As discussed in section II.H. Valuation of Specific Codes in the proposed rule and this summary, CMS proposes for 2019 a new CPT code 994X7, which would correspond to 30 minutes or more of CCM furnished by a physician or other qualified health care professional and is similar to CPT codes 99490 and 99487. For RHCs and FQHCs, CMS proposes to add CPT code 994X7 as a general care management service and to include it in the calculation of HCPCS code G0511. CMS proposes that starting on January 1, 2019, RHCs and FQHCs would be paid for G0511 based on the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 994X7.

CMS proposes to revise §405.2464 to reflect the current payment methodology that was finalized in the 2018 PFS and incorporate the addition of new CPT codes to HCPCS G0511.

2. Communication Technology-Based Services and Remote Evaluation

As discussed in more detail in section II.D. Modernizing Medicare Physician Payment by Recognizing Communication Technology in the proposed rule and this summary, CMS proposes for 2019 separate payment for certain communication technology-based services. This includes separate payment for what CMS refers to as "Brief Communication Technology-based Service" for a "virtual check-in" and for remote evaluation of recorded video and/or images. CMS states that it recognizes that it may be beneficial to both the patient and the RHC or FQHC to utilization communications-based technology to determine the best available course of action for a health issue. This could, for example, prevent unnecessary visits, which may be particularly beneficial to those beneficiaries who live in rural areas where transportation is limited and distances to these clinics are far.

For RHCs and FQHCs, CMS proposes payment for communication technology-based services or remote evaluation services when at least 5 minutes of communications-based technology or remote evaluation services are furnished by an RHC or FQHC practitioner to a patient that has been seen in the RHC or FQHC within the previous year. These services may only be billed when the medical discussion or remote evaluation is for a condition not related to an RHC or FQHC service provided within the previous 7 days, and does not lead to an RHC or FQHC service within the next 24 hours or at the soonest available appointment, since in those situations the services are already paid as part of the RHC or FQHC per-visit payment.

CMS proposes to create a new Virtual Communications G code for use by RHCs and FQHCs only, with a payment rate set at the average of the PFS national non-facility payment rates for HCPCS code GVC11 for communication technology-based services, and HCPCS code GRAS1 for remote evaluation services. RHCs and FQHCs would be able to bill the Virtual Communications G-code either alone or with other payable services. CMS will update this code annually based on the PFS amounts.

CMS also proposes to waive the RHC and FQHC face-to-face requirements when these services are furnished to an RHC or FQHC patient. Coinsurance would be applied to FQHC claims, and coinsurance and deductibles would apply to RHC claims for these services.

CMS also considered adding communication technology-based and remote evaluation services as an RHC or FQHC standalone service (lesser of total charges or the PPS rate), but believes they do not meet the requirement of billable visits for these settings and this approach would be inconsistent with its goal of obtaining efficiencies. In addition, CMS also considered allowing RHCs and FQHCs to bill HCPCS codes GVC11 or GRAS1 separately on an RHC or FQHC claim. CMS rejected this option because it believes that a combined G code is less burdensome.

CMS invites comments on its proposal and is particularly interested in comments regarding the appropriateness of payment for communication technology-based and remote evaluation services in the absence of an RHC or FQHC visit, the burden associated with documentation for billing these codes (RHC or FQHC practitioner’s time, medical records, etc.), and any potential impact on the per diem nature of RHC and FQHC billing and payment structure as a result of payment for these services. CMS also seeks public comment on whether it would be clinically appropriate to apply a frequency limitation on the use of the new Virtual Communications G code by the same RHC or FQHC with the same patient, and on what would be a reasonable frequency limitation.

D. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

1. Background

Section 218(b) of the PAMA amended Title XVIII of the Act to add section 1834(q) directing CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. AUC are a set of individual criteria that present information in a manner that links a specific clinical condition or presentation, one or more services, and an assessment of the appropriateness of the service(s). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual context. AUC must be integrated into the clinical workflow.

There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date: (1) establishment of AUC by November 15, 2015 (section 1834(q)(2)); (2) mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3)); (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4)); and (4) annual identification of

outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5)). CMS notes it did not identify mechanisms for consultation by April 1, 2016 and will not have specified or published the list of qualified clinical decision support mechanisms (CDSMs) by January 1, 2017; therefore, ordering professionals were not required to consult CDSMs and furnishing professionals were not able to report information on the consultation by January 1, 2017.

In the 2016 PFS final rule, CMS primarily addressed the first major component under section 1834(q)(2) – the process for establishment of AUC, along with relevant aspects of the definitions under section 1834(q)(1). CMS finalized that an “applicable imaging service” must be an advanced imaging service as defined in section 1834(e)(1)(B) of the Act, which defines “advanced diagnostic imaging services” to include diagnostic magnetic resonance imaging, computed tomography, nuclear medicine (including positron emission tomography), and other diagnostic imaging services CMS may specify in consultation with physician specialty organizations and other stakeholders. However, the definition excludes x-ray, ultrasound and fluoroscopy services.

CMS defined the term provider-led entities (PLE) to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the National Comprehensive Cancer Network. Qualified PLEs may also collaborate with third parties. In June 2016, CMS identified 11 qualified PLEs.²⁹

In the 2017 PFS final rule, CMS primarily addressed the second major component of the AUC program - the identification of qualified CDSMs that could be used by ordering professionals for consultation with applicable AUC under section 1834(q)(3) of the Act. CMS defined CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient’s specific condition. In June 2017, CMS identified 6 qualified CDSMs and 9 CDSMs with preliminary qualifications.³⁰

In the 2018 PFS final rule, CMS addressed the third major component of the AUC program under section 1834(q)(4) of the Act, Consultation with Applicable Appropriate Use Criteria. CMS established a January 1, 2020 effective date for the ACU consultation and reporting requirements. A voluntary period was also established during which ordering professionals can begin reporting limited information on Medicare claims from July 2018 through December 2019. On January 1, 2020, CMS will begin an educational and operations testing period during which claims will continue to be paid whether or not they correctly include AUC consultation information. CMS also established the information furnishing professionals must report on Medicare claims for advanced diagnostic imaging services. Proposed clarifying revisions are discussed below.

²⁹ The list of qualified PLEs can be accessed at <https://www.cms.gov/Medicare/Quality-Initiative-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html>.

³⁰ The list of qualified CDSMs can be accessed at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html>.

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 significant hardship. In the 2017 PFS final rule, CMS specified the circumstances under which AUC consultation and reporting requirements are not applicable. Proposed changes to the significant hardship exceptions are discussed below.

The fourth major component of the AUC program is in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. This section facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. In the 2017 PFS final rule, CMS finalized the first list of priority clinical areas³¹ which may serve as part of the basis for identifying outlier ordering professionals. CMS notes that because it established a start date of January 1, 2020 for AUC consultation and reporting requirements, it will not have identified any outlier ordering professionals by that date.

2. Proposals for Implementation

CMS proposes to amend §414.94, “Appropriate Use Criteria for Certain Imaging Services” to reflect the following proposals. CMS will continue to post information about the AUC program on the CMS website at www.cms.gov/Medicare/Quality-Initiative-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html.

a. Expanding Applicable Settings

Section 1834(q)(1)(D) of the Act specifies that AUC consultation and reporting requirements apply only in an applicable setting which means a physician’s office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary. CMS proposes to revise the definition of an applicable setting to add an independent diagnostic testing facility (IDTF). CMS believes the addition of IDTFs to the definition of applicable setting will ensure that the AUC program is in place across outpatient settings in which outpatient diagnostic imaging services are furnished.

CMS invites comments on this proposal and on the possible inclusion of any other applicable setting. CMS notes that the application of the AUC program is not only limited to applicable settings, but also to services for which payment is made under applicable payment systems (the PFS, the OPFS, and the ASC payment system).

³¹ The first list of priority clinical areas includes coronary artery disease (suspected or diagnosed, suspected pulmonary embolism, headache (traumatic and non-traumatic), hip pain, low back pain, shoulder pain (includes suspected rotator cuff injury), cancer of the lung (primary or metastatic, suspected or diagnosed), and cervical or neck pain.

b. Consultations by Ordering Professionals

Section 1834(q)(1)(E) of the Act defines the term “ordering professional” as a physician (defined in section 1861(r)) or a practitioner (defined in section 1842(b)(18)(C)) who orders an applicable imaging service. The AUC consultation requirement applies to these ordering professionals.

In response to the 2018 PFS proposed rule, CMS received several comments requesting clarification about who is required to perform the AUC consultation. Some commenters recommended that CMS strictly interpret the statutory language and only allow the ordering clinician to perform the AUC consultation and others recommended that CMS allow others to perform the AUC consultation on behalf of the clinician.

CMS proposes that the AUC consultation through a qualified CDSM may be performed by clinical staff working under the direction of the ordering professional, subject to applicable State licensure and scope of practice law, when the consultation is not performed personally by the ordering professional whose NPI will be listed on the order for an advanced imaging service. CMS proposes the consultation may be performed by auxiliary personnel incident to the ordering physician’s or non-physician practitioner’s professional service. CMS notes that the ordering professional is ultimately responsible for the AUC consultation. It is the ordering professional (identified as the furnishing professional on the claim) that could be identified as an outlier professional and become subject to prior authorization based on his or her ordering pattern.

c. Reporting AUC Consultation Information

Section 1834(q)(4)(B) of the Act requires that payment for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system may only be made if the claim for the service includes certain information about the AUC consultation. In the 2018 PFS final rule, CMS specified only that “furnishing professionals” must report AUC consultation information. Many stakeholders interpreted this to mean that AUC consultation information would be required only on practitioner claims.

To better reflect the statutory language, CMS proposes to revise its regulations (§414.94(k)) to clarify that AUC consultation information must be reported on all claims paid under applicable payment systems without exclusion. CMS believes that the claims furnished from both furnishing professionals and facilities must include AUC consultation information: the practitioner’s claim for the professional component and the provider’s or supplier’s claim for the facility portion or TC of the imaging service.

d. Claims-based Reporting

In the 2018 PFS proposed rule, CMS proposed to establish a series of G-codes and HCPCS modifiers to capture AUC consultation information on Medicare claims. As discussed in the 2018 PFS final rule, CMS received numerous public comments objecting to this proposal. Many commenters suggested using a unique consultation identifier (UCI) instead of using combinations of G-codes and modifiers. CMS did not finalize a proposal and planned to conduct

stakeholder outreach during 2018 to develop a standard taxonomy for an identifier and explore options of where to place an identifier on claims.

CMS discusses the various suggestions stakeholders have made for a taxonomy that could be used to develop a UCI to report the required information. CMS notes that the majority of UCI suggestions would not allow CMS to attribute the CDSM used or the AUC adherence status (adherent or not adherent, or not applicable) to a specific imaging service. CMS concludes it is not feasible to create a uniform UCI taxonomy, determine a location of the UCI on the claims forms, obtain the support and permission by national bodies to use claim fields for this purpose, and solve the underlying UCI limitations. CMS states that existing coding structures (such as G-codes and modifiers) would allow CMS to establish reporting requirements prior to January 1, 2020.

CMS proposes to use established coding methods, to include G-codes and modifiers, to report the required AUC information on Medicare claims. It will consider future opportunities to use a UCI. **CMS welcomes comments on this proposal, including additional feedback about UCI options.**

e. Significant Hardship 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. In the 2017 PFS final rule, CMS aligned the significant hardship exception with the Medicare EHR Incentive Program exception. In the 2018 PFS proposed rule, with the payment adjustments under the Medicare EHR Incentive Program sunseting, CMS proposed to align the significant hardship exception with the significant hardship exception for MIPS. In response to comments, CMS did not finalize this proposal.

CMS proposes criteria specific to the AUC program for the significant hardship exception that are independent of other programs. The proposed criteria for an AUC consultation significant hardship exception include:

- Insufficient internet access – specific to the location where an advanced diagnostic imaging service is ordered by the ordering professional;
- EHR or CDSM vendor issues – including situations where ordering professionals experience temporary technical problems, installations or upgrades that temporarily impede access to the CDSM, vendors cease operations, or CMS de-qualifies a CDSM; or
- Extreme and uncontrollable circumstances – including disasters, natural or man-made, that have a significant negative impact on healthcare operations, area infrastructure or communication systems.

CMS expects EHR or CDSM vendor issues to be irregular and unusual. Based on 2016 data from the Medicare EHR Incentive Program and the 2019 payment year MIPS eligibility and special status file, CMS estimates that approximately 6,699 eligible clinicians could request an exception due to extreme and uncontrollable circumstances or as a result of decertification of an EHR; this represents less than 1 percent of available ordering professionals.

CMS also proposes that ordering professionals would self-attest if they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order. The attestation must be supported with documentation of significant hardship. Ordering professionals attesting to a significant hardship would communicate that information, along with the AUC consultation information, to the furnishing professional with the order. This information would be reflected on the furnishing professional's and furnishing facility's claim by appending a HCPCS modifier. Claims for advanced diagnostic imaging services that include a significant hardship exception modifier would not be required to include AUC information.

CMS invites comments on this proposal including any additional circumstances that would cause the act of consulting AUC to be particularly difficult and for which it may be appropriate for an ordering professional to be granted a significant hardship exception under the AUC program. CMS notes that circumstances that are not specific to AUC consultation, such as the ordering professional having a limited number of Medicare patients, would not impede clinicians from consulting AUC through a CDSM as required by this program.

f. Identification of Outliers

CMS invites public comment on a possible methodology, including data elements and thresholds, that CMS should consider when identifying outliers. CMS expects to address outlier identification and prior authorization in 2022 or 2023 PFS rulemaking cycle.

3. Information Collection Requirements Regarding AUC Criteria

For the estimates related to ordering professionals, CMS uses “family and general practitioners.” General practitioners are the largest group of practitioners who order applicable imaging services and would be required to consult AUCs. Based on the proposal to modify the AUC consultation requirement to allow auxiliary personnel, working under the direction of the ordering professional, to interact with the CDSM, CMS also used the “registered nurse” occupation to calculate revised cost estimates.

To derive the burden associated with the January 1, 2020 implementation, CMS estimates it would take 2 minutes (0.033 hr.) at \$70.72/hour for auxiliary personnel (a registered nurse) to consult with a qualified CDSM. Based on market research and claims data, CMS anticipates 43,181,818 AUC consultations. CMS estimates that 90-percent of the AUC consultations could be performed by auxiliary personnel, with the remaining 10 percent performed by ordering professionals. In aggregate, CMS estimates an annual burden of 1,282,500 hours at a cost of approximately \$90,698,400 or \$2.33 per consultation.

E. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

1. Background

Under the Medicaid Promoting Interoperability Program, Medicaid EPs and eligible hospitals can receive incentive payments for the adoption, implementation, upgrade, and meaningful use of Certified Electronic Health Record Technology (CEHRT). To demonstrate meaningful use of electronic health records technology (EHR), the EHR user is required to report clinical quality measures selected by CMS or a state and submit them in the form and manner specified by CMS or the state. In selecting electronic clinical quality measures (eCQMs) for EPs to report, Section 1848(o)(2)(B)(iii) of the SSA requires the Secretary to avoid redundant or duplicative reporting.

For 2017, Medicaid EPs were required to report on any six eCQMs relevant to the EPs scope of practice. CMS expressed, in the FY 2018 Hospital Inpatient Prospective Payment System final rule establishing that requirement, that it was their intention to align the eCQM requirements with those for Medicare quality improvement programs to the extent practical.³²

2. eCQM Reporting Requirements for EPs under the Medicaid Promoting Interoperability Program for 2019

CMS proposes to align the eCQMs for Medicaid EPs for 2019 with those available for MIPS eligible clinicians for the CY 2019 performance period by making the list of quality measures for Medicaid EPs the same as the list proposed for MIPS.

CMS states that aligning the eCQMs for the two programs would reduce burden for Medicaid EPs who are also participating in MIPS and would encourage more EP participation in Medicaid. CMS expects the change to require only minor adjustments to state systems.

CMS proposes that the Medicaid EPs would report on any six eCQMs that are relevant to the EPs scope of practice. CMS points out that this practice improved flexibility for the 2017 reporting as finalized in the FY 2018 Hospital Inpatient Prospective Payment System final rule and would be aligned with the MIPS data submission requirement. At least one of those measures would need to be an outcome measure (or if an applicable outcome measure is not available or relevant, one other high priority measure).

Comments are requested on how high priority measures should be identified for Medicaid EPs. CMS proposes to use all three of the following methods to identify high priority measures, but invites comments on whether all three, a subset, or only one of those approaches should be used:

³² Final Rule: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices” (82 FR 37990, 38487).

- Use the high priority measures identified for eligible clinicians under the MIPS program (incorporating proposed changes to MIPS measures described below in section III.H. in this summary);
- Include as high priority measures those available eCQMs in previous year’s “Core Sets” that are also on the MIPS list of eCQMs. CMS is required to develop and annually update two sets of quality measures that states may voluntarily report. The measures specifically focus on populations served by the Medicaid and CHIP programs. These “core sets” are comprised of quality measures for children (the Child Core Set) and for adults (Adult Core Set). CMS notes that because the child and adult Core Sets are released at the beginning of each year, it would not be possible to update the list of high-priority eCQMs with those added to the current year’s Core Sets. This approach would result in the following measures identified as high priority:
 - CMS2, “Preventive Care and Screening: Screening for Depression and Follow-Up Plan”
 - CMS4, “Initiation and Engagement of Alcohol and Other Drug Dependence Treatment”
 - CMS122, “Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%)”
 - CMS125, “Breast Cancer Screening”
 - CMS128, “Anti-depressant Medication Management”
 - CMS136, “Follow-Up Care for Children Prescribed ADHD Medication (ADD)”
 - CMS153, “Chlamydia Screening for Women”
 - CMS155, “Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents”
 - CMS165, “Controlling High Blood Pressure”
- Give each state the flexibility to identify which of the available eCQMs selected by CMS are high priority measures for EPs in that state, with review and approval from CMS, through their State Medicaid HIT Plans (SMHP); this is similar to the flexibility granted states to modify the definition of Meaningful Use at §495.332(f).

CMS proposes that the reporting period for EPs in the Medicaid Promoting Interoperability Program would be for a full CY in 2019 for EPs who demonstrated meaningful use in a prior year. This period also aligns with the MIPS performance period.

CMS requests comments for years beyond 2019 as to whether it should include all e-specified measures from the Core Sets as additional options for Medicaid EPs.

CMS states that including the Core Sets as eCQM reporting options for Medicaid EPs would increase EP utilization of these measures and provide states with better data to report. At this time, the only measure within the Core Sets that would not be available as an option for Medicaid EPs in 2019 (because it is not on the MIPS eCQM list) would be NQF-1360, “Audiological Diagnosis No Later Than 3 Months of Age.”

3. Proposed Revisions to the EHR Reporting Period and eCQM Reporting Period in 2021 for EPs Participating in the Medicaid Promoting Interoperability Program

Consistent with statute, CMS established in prior rules that no Medicaid EP can receive an incentive payment after December 31, 2021. To ensure that deadline is met, CMS proposes to amend §495.4 to establish an EHR reporting period and an eCQM reporting period of any continuous 90-day period within CY 2021 provided that the end date is before October 31, 2021. States would be allowed under the proposal, however, to establish an alternative earlier end date for those periods within CY 2021 for any continuous 90-day period within CY 2021. Such an alternate date may not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting in that state.

CMS notes that a similar timing issue would arise with respect to hospitals eligible to receive Medicaid Promoting Interoperability Program payments in 2021, but it doesn't expect that there will be any hospitals eligible for those payments in 2020 or 2021. It doesn't propose any changes with respect to hospital timelines, but if it becomes necessary, CMS would address this in a future proposed rule specifically related to hospital payment.

4. Proposed Revisions to Stage 3 Meaningful Use Measures for Medicaid EPs.

CMS proposes changes to the following measures:

- Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging) of Meaningful Use Stage 3 EP Objective 6 (Coordination of care through patient engagement). CMS proposes to amend the threshold for the two measures of Objective 6 (Coordination of Care through Patient Engagement). Instead of phasing up from 5% over time, the threshold for the two measures would remain at 5% for 2019 and subsequent years. CMS notes that it has received feedback that the two measures present the largest barriers to demonstrating meaningful use especially in rural areas and safety net clinics. Because Medicaid patients have low rates of internet access, internet literacy and health literacy, this functionality is not highly used by this patient population.
- Objective 8 (Public health and clinical data registry reporting), Measure 2 (Syndromic surveillance reporting measure). CMS proposes to amend the syndromic surveillance reporting measure (§495.24(d)(8)(i)(B)(2)). It would eliminate language restricting the use of syndromic surveillance reporting for meaningful use only to EPs practicing in an urgent care setting. The proposed measure would allow for any EP as defined by the state or local public health agency to submit such data.

F. Medicare Shared Savings Program (MSSP)

CMS reviews the regulatory history of the MSSP program and notes that it has historically used the annual CY PFS rules to address quality reporting for the program. CMS states that the MSSP program is intended to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare FFS beneficiaries and to reduce the rate of Medicare spending growth by forming or participating in ACOs.

CMS proposes changes for the 2019 performance year and subsequent years to quality performance measures in two areas: Patient Experience of Care Survey measures and CMS Web Interface and Claims-Based measures.

Changes to CAHPS Measure Set

CMS reviews the background describing the use of the CAHPS survey for quality measures under MSSP. For performance year 2018, 31 quality measures are used to determine ACO quality performance. They are submitted through the CMS Web Interface and collected via a patient experience of care survey referred to as the Consumer Assessment of Healthcare Provider and Systems (CAHPS) for ACOs Survey. That survey is based on the Clinician and Group CAHPS (CG-CAHPS) survey which is maintained by the Agency for Healthcare Research and Quality.

CMS proposes several changes to the quality measure set used to assess quality performance of ACOs under the Shared Savings Program and indicates that the changes would enhance patient and caregiver experience and would better align with MIPS.

CMS proposes to begin scoring 2 summary survey measures (SSMs) that are already collected but are currently used only for information purposes:

- ACO-45, CAHPS: Courteous and Helpful Office Staff, and
- ACO-46: CAHPS: Care Coordination.

The measures would be scored and included in the ACO quality determination starting in 2019. Consistent with existing rules regarding scoring of new quality measures, CMS proposes that the additional SSMs would be pay-for-reporting for all ACOs for 2 years (PY 2019 and 2020). The measures would then phase into pay-for-performance for ACOs in their first agreement period in the program according to the schedule in Table 25 (page 485 of the public display version of the proposed rule) beginning in performance year 2021. Both of these SSMs are currently designated by AHRQ as CG-CAHPS core measures. For performance year 2016, the mean performance rates across all ACOs for these two measures were 87.18 for Care Coordination and 92.12 for Courteous and Helpful Office Staff.

CMS seeks comment on potentially converting the Health and Functional Status SSM (ACO-7) to pay for performance in the future. CMS has not to date converted it from pay for reporting because of concerns that the scores may reflect the underlying health of beneficiaries of ACO providers rather than the quality of care provided by the ACO. Other possible enhancements that CMS may consider would be to allow for measuring changes that occurred while beneficiaries were receiving care from ACO providers/suppliers. CMS seeks stakeholder feedback on this approach or other recommendations regarding the potential inclusion of a functional status measure in the assessment of ACO quality performance in the future.

Changes to Web Interface and Claims-based Quality Measure Sets

CMS restates its objective to streamline measurements of quality and to reduce regulatory burden. It reviews its Meaningful Measures initiative.³³ Under that initiative, CMS committed to

³³ See CMS Press Release, CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LANSummit, October 30, 2017, available at

assessing only those core issues most vital to providing high-quality care and improving patient outcomes, with the aim of focusing on outcome-based measures, reducing unnecessary burden on providers, and putting patients first. CMS notes that in doing so, it considers the reporting requirements for other initiatives including the MIPS and Million Hearts Initiative.

In this proposed rule, CMS proposes to reduce the total number of measures in the MSSP quality measure set. By eliminating the measures, CMS states that it would not only reduce the burden of ACOs, but it would better enable them to focus on patient care and their removal would align with proposed changes to the CMS Web Interface measures reported under MIPS (discussed below in section III.H.). CMS proposes to retire the following claims-based quality measures which it states have a high degree of redundancy and overlap with other measures that remain in the measure set:

- ACO-35-Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM)
- ACO-36-All-Cause Unplanned Admissions for Patients with Diabetes
- ACO-37-All-Cause Unplanned Admission for Patients with Heart Failure

CMS also proposes removing:

- ACO-44-Use of Imaging Studies for Low Back Pain because its denominator (beneficiaries ages 18 – 50) is often too small to make the measure meaningful. Further, its removal would align with its removal from MIPS.

Because those measures are claims-based and do not impose any reporting burden on ACOs, CMS would continue to provide information to ACOs on their performance so that plans could use them in their quality improvement activities. This information would be provided through a new quarterly claims-based quality outcome report that ACOs will begin receiving in 2018.

CMS seeks comment on the possibility of adding the Skilled Nursing Facility Quality Reporting Program (SNFQRP) measure “Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facilities” to the MSSP quality measure set in future rulemaking. This measure differs from ACO-35 (proposed to be eliminated) because the SNFQRP measure looks only at unplanned, potentially preventable readmissions for Medicare FFS beneficiaries within 30 days of discharge to a lower level of care from a SNF, while ACO-35 assesses readmissions from a SNF, regardless of cause, that occur within 30 days following discharge from a hospital. As a result, the SNFQRP measure would have less overlap with ACO 8 (Risk-Standardized All Cause Readmission measure) than does ACO-35 (SNFRM).

CMS notes that elsewhere in the proposed rule, it has proposed changes to QPP Web Interface measures. If they are finalized, ACOs would no longer be responsible for reporting the following measures for the Shared Savings Program beginning with performance year 2019:

- ACO-12 (NQF #0097) Medication Reconciliation Post-Discharge
- ACO-13 (NQF #0101) Falls: Screening for Future Fall Risk
- ACO-15 (NQF #0043) Pneumonia Vaccination Status for Older Adults

- ACO-16 (NQF #0421) Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up
- ACO-41 (NQF #0055) Diabetes: Eye Exam
- ACO-30 (NQF #0068) Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic

Finally, CMS proposes to add ACO-47 (NQF #0101) Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. ACOs would begin reporting the measure starting in PY 2019.

Table 25, reproduced at the end of this section, shows the entire proposed quality measure set for the Shared Savings Program for PYs beginning with 2019.

Table 26, reproduced below, provides a summary of the number of measures by domain and the total domain weights that would be used for scoring purposes under the Shared Savings Program quality performance standards for performance year 2019 and subsequent performance years.

Table 26: Number of Measures and Total Points for Each Domain within the Shared Savings Program Quality Performance Standard, Starting with Performance Year 2019

Domain	Number of Individual Measures	Total Measures for Scoring Purposes	Total Possible Points	Domain Weight
Patient/Caregiver Experience	10	10 individual survey module measures	20	25%
Care Coordination/ Patient Safety	5	5 measures, including double-weighted EHR measure	12	25%
Preventive Health	6	6 measures	12	25%
At-Risk Population	3	3 individual measures	6	25%
Total in all Domains	24	24	50	100%

Table 25: Proposed Measure Set for Use in Establishing the Shared Savings Program Quality Performance Standard, Starting with Performance Year 2019

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 N/A	Survey	R	P	P
	ACO – 2	CAHPS: How Well Your Providers Communicate		NQF N/A AHRQ	Survey	R	P	P
	ACO – 3	CAHPS: Patients' Rating of Provider		NQF N/A 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 AHRQ	Survey	R	P	P

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
	ACO – 6	CAHPS: Shared Decision Making		NQF #N/A AHRQ	Survey	R	P	P
	ACO – 7	CAHPS: Health Status/Functional Status		NQF #N/A AHRQ	Survey	R	R	R
	ACO-34	CAHPS: Stewardship of Patient Resources		NQF #N/A AHRQ	Survey	R	P	P
	ACO-45	CAHPS: Courteous and Helpful Office Staff	X ¹	NQF #N/A AHRQ	Survey	R	R	P
	ACO-46	CAHPS: Care Coordination	XError! Bookmark not defined.	NQF #N/A AHRQ	Survey	R	R	P
Care Coordination/Patient Safety	ACO - 8	Risk-Standardized, All Condition Readmission		Adapted NQF #1789 CMS	Claims	R	R	P
	ACO-38	Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions		NQF#2888 CMS	Claims	R	R	P
	ACO-43	Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment) ²		AHRQ	Claims	R	P	P
	ACO-47	Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls		NQF #0101 NCQA	CMS Web Interface	R	R	P
	ACO-11	Use of certified EHR technology		NQF #N/A CMS	Quality Payment Program Advancing Care Information	R	P	P
AIM: Better Health for Populations								
Preventive Health	ACO-14	Preventive Care and Screening: Influenza Immunization		NQF #0041 AMA-PCPI	CMS Web Interface	R	P	P
	ACO-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 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
Clinical Care for At Risk Population - Depression	ACO-40	Depression Remission at Twelve Months		NQF #0710 MNCM	CMS Web Interface	R	R	R

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 - Diabetes	ACO-27	Diabetes Hemoglobin A1c (HbA1c) Poor Control (>9%)		NQF #0059 NCQA	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Hypertension	ACO-28	Hypertension: Controlling High Blood Pressure		NQF #0018 NCQA	CMS Web Interface	R	P	P

¹ Measures that are currently collected as part of the administration of the CAHPS for ACO survey, but will be considered new measures for purposes of the pay for performance phase-in.

² The language in parentheses has been added for clarity and no changes have been made to the measure

G. Physician Self-Referral Law

Section 50404 of the Bipartisan Budget Act of 2018 (BBA18) codified in statute certain regulatory clarifications CMS made concerning rules under the Prohibition on Physician Self-Referral law (Stark law) for certain writing and signature requirements for compensation arrangements as well as holdover arrangements.

Specifically, the law clarifies the following for writing and signature requirements:

- Parties to a compensation arrangement that is required to be in writing may satisfy the writing requirement through a collection of documents (including contemporaneous documents that evidence the course of conduct between the parties) and through such other means as the Secretary may determine.
- Parties to a compensation arrangement that is required to be signed and in writing may satisfy the signature requirement by obtaining the requisite signatures as late as 90 consecutive calendar days after the date the compensation arrangement became noncompliant as long as the compensation arrangement otherwise complies with all of the criteria of the applicable exception.

CMS states that it proposes to revise its regulations (i) to address any actual or perceived differences between the statutory and regulatory language; (ii) to codify its policy on satisfying the writing requirement in many Stark law exceptions; and (iii) to apply the BBA18 policies to exceptions to compensation arrangements that CMS has created through its authority under the law.

Writing Requirement. CMS proposes to add to its regulations (in new §411.354(e)) a special rule for Stark law compensation arrangements that specifies the writing requirement may be satisfied by a collection of documents, including contemporaneous documents, evidencing the course of conduct between the parties. CMS notes that this special rule codifies its policy as previously set forth in the 2016 PFS final rule.

Signature Requirements. CMS notes that the BBA18 provision for certain arrangements involving temporary noncompliance with signature requirements differs from current CMS

policy in that the requirement under BBA18 (i) is not limited to specific exceptions and (ii) entities are not limited to using this rule once every 3 years for the same referring physician. Thus CMS proposes to amend its regulation at §411.353(g) to apply the signature requirements broadly under the Stark law regulations; to remove references to occurrence of referrals or payment of compensation during the 90-day period when the signature requirement is not met; and to delete the limitation on use of the rule once every 3 years with respect to the same physician. Alternatively, CMS may simply codify the statutory language. **CMS seeks comment from stakeholders on the best approach.**

The effective date of BBA18 section 50404 is February 9, 2018, and CMS notes with respect to the statutory clarification for arrangements involving temporary noncompliance with signature requirements under section 1877(h)(1)(E) that, beginning February 9, 2018, parties who satisfy the statutory requirements under that section may use them, including those who would otherwise have been barred from using the special rule under §411.353(g)(1) because of the 3-year limitation under §411.353(g)(2).

Holdover Arrangements

As noted above, section 50404 of BBA18 also codified requirements relating to lease and personal service holdover arrangements. The law clarified the following:

- Payments made by a lessee to a lessor under a holdover lease arrangement of office space or equipment shall not be considered a compensation arrangement where (i) the holdover lease arrangement immediately follows a lease of at least one year in length that met existing requirements under section 1877(e)(1)(A) or (B) of the Act, (ii) the holdover lease arrangement is under the same terms and conditions as the immediately preceding arrangement; and (iii) the holdover arrangement continues to meet requirements under such section 1877(e)(1)(A) or (B).
- Remuneration from an entity under a holdover personal service arrangement shall not be considered a compensation arrangement where (i) the holdover personal service arrangement immediately follows a personal service arrangement for a term of at least one year in length that met existing requirements under section 1877(e)(1)(A) of the Act, (ii) the holdover personal service arrangement is under the same terms and conditions as the immediately preceding arrangement; and (iii) the holdover arrangement continues to meet requirements under such section 1877(e)(1)(A).

CMS believes that these BBA18 provisions effectively mirror the existing regulatory clarifications; thus, the agency does not propose to make changes to the regulations.

H. 2019 Updates to the Quality Payment Program (QPP)

1. Introduction

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) ended the Sustainable Growth Rate (SGR) formula for updates to the PFS and established the QPP. The QPP has two participation options: The Merit-based Incentive Payment System (MIPS) and the Advanced Alternative Payment Models (APMs).

For 2019, the third year of the QPP, CMS states how its proposals address stakeholder input (including MedPAC) and are designed to reduce clinician burden, revise the MIPS Promoting Interoperability (formerly known as Advancing Care Information) performance category, and continue to support small and rural practices. CMS believes the Meaningful Measures Initiative will produce quality measures that are more focused on meaningful outcomes.³⁴ For the 2019 MIPS performance period, CMS proposes adding 10 new MIPS quality measures, including 4 patient reported outcome (PRO) measures, and removes 34 quality measures.

Payment Adjustments

For the 2019 MIPS performance period, CMS estimates that approximately 650,000 clinicians will be MIPS eligible clinicians. CMS bases the estimate on historical 2016 PQRS and Medicare and Medicaid EHR Incentive Program data; CMS states it is unable to analyze data from the 2017 performance period for this proposed rule.³⁵ For the 2021 MIPS payment year, including the statutory requirement for budget neutrality, CMS estimates that payment adjustments will be equally distributed between negative payment adjustments at \$372 million and positive payment adjustments at \$372 million. Positive payment adjustment will also include an additional \$500 million for exceptional performance to MIPS eligible clinicians who have a final score that meets or exceeds the proposed additional performance threshold of 80 points.

CMS also estimates that between 160,000 and 215,000 clinicians will be Qualifying APM Participants (QP) and the total lump sum APM incentive payment for QPs will be approximately \$600-800 million for the 2021 MIPS payment year. A QP is an eligible clinician that is exempt from the MIPS reporting requirements and payment adjustment, and qualifies for a lump sum incentive payment based on 5 percent of their aggregate payment amounts for covered professional services for the prior year.

CMS anticipates it will update these estimates with the data from the first year of the MIPS performance period in the 2019 QPP final rule.

³⁴ Meaningful Measures web page: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo?MMF/General-info-Sub.Page.html>

³⁵ For more information see a CMS blog at: <https://blog.cms.gov/2018/05/31/quality-payment-program-exceeds-year-1-participation-goal/>.

2. Program Details

a. Definition of a MIPS Eligible Clinician

Section 1848(q)(1)(C)(i) of the Act, as added by section 101(c)(1) of MACRA, outlines the general definition of a MIPS eligible clinician for the first and second years of the MIPS program and allows the Secretary flexibility to specify additional clinician types as MIPS eligible clinicians in the third and subsequent years. Such clinicians may include physical therapists, occupational therapists, or qualified speech language pathologists; qualified audiologists (section 1861(II)(3)(B) of the Act); certified nurse-midwives (section 1861(gg)(2) of the Act); clinical social workers (1861(hh)(1) of the Act); clinical psychologists (section 1861(ii) of the Act); and registered dietitians or nutrition professionals.

In the 2017 QPP final rule, CMS finalized the following:

- To define a MIPS eligible clinician as a physician (as defined in section 1861(r)³⁶ of the Act), a physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS) (as such terms are defined in section 1861(aa)(5) of the Act), a certified registered nurse anesthetist (CRNA) (as defined in section 1861(bb)(2) of the Act), and a group that includes such clinicians.
- To exclude Qualifying APM Participants (QPs), Partial Qualifying APM participants (Partial QPs) who choose not to report data under MIPS, low-volume threshold eligible clinicians, and new Medicare-enrolled eligible clinicians (as defined at §414.1305) from the definition of a MIPS eligible clinician per the statutory exclusions.

To assess whether additional eligible clinicians could successfully participate in MIPS, CMS evaluated whether there would be sufficient measures and activities applicable for each additional eligible clinician type. CMS' determination was based on quality and improvement activities because it is proposing to automatically assign a zero percent weighting for the Promoting Interoperability performance category for new types of eligible clinicians (discussed in section H.3.h.(4)) and the cost performance category is currently only applicable to a subset of eligible clinicians.

CMS found that all the additional eligible types would have sufficient improvement activities. For the quality measures, if CMS finalizes its proposal to remove specific quality measures (discussed in section H.3.h.(2)), CMS thinks qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutritional professionals would have less than 6 MIPS quality measures available to them. Without sufficient quality measures, CMS would not propose to include these clinicians in the MIPS eligible clinician definition. CMS notes that it did find QCDR measures for the 2018 performance period that are either high priority and/or outcome measures but that would require these clinicians to utilize a QCDR.

Non-physician associations recommended CMS consider “ramp-up” policies for clinicians joining MIPS after the first year. In response, CMS notes that the MIPS program is still ramping

³⁶ Physicians are defined in section 1861(r) of the Act to include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors.

up and will continue to have a gradual and incremental transition until the sixth year of the QPP. Additional eligible clinicians joining with the 2019 performance year will have 4 years in the program before ramping up is complete.

Beginning with the 2021 MIPS payment year, CMS proposes to amend §414.1305 to modify the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to include the following additional clinician types:

- Physical therapist,
- Occupational therapist,
- Clinical social worker (section 1861(hh)(1) of the Act),
- Clinical psychologist (as defined by section 1861(ii) of the Act, and
- A group that includes such clinicians.

Alternatively, if the quality measures proposed for removal are not finalized, CMS proposes to include additional eligible clinician types (specifically, qualified speech-language pathologist, qualified audiologist, certified nurse-midwives, and registered dietitians or nutritional professionals), provided each applicable eligible clinician type would have at least 6 MIPS quality measures. CMS requests comments on these proposals.

b. MIPS Determination Period

CMS discusses the various MIPS determination periods used to identify certain MIPS eligible clinicians for consideration of certain specific policies. The low-volume threshold, non-patient facing, small practice, hospital-based and ASC-based determinations have different determination processes. CMS acknowledges this causes additional complexity and confusion and proposes to consolidate several of the policies into a single MIPS determination period.

Beginning with the 2021 MIPS payment year for purposes of the low-volume threshold and to identify MIPS eligible clinicians as non-patient facing, a small practice, hospital-based, and ASC-based as applicable, CMS proposes the MIPS determination period would be a 24-month assessment period including a two-segment analysis of claims consisting of:

- (1) An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period; and
- (2) A second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance and ending on September 30 of the calendar year in which the applicable period occurs.

The first segment would include a 30-day claims run out. The second segment would not include a claims run out; if technically feasible, it would include quarterly snapshots for informational use. CMS believes the quarterly snapshots would be helpful for new TIN/NPIs and TINs created between the first segment and the second segment to allow them to see their preliminary status sooner than just before the submission period.

CMS proposes that the determination based on the initial segment period would continue to be used as the determination for the applicable MIPS payment year regardless of the determination based on the second segment. For example, for the 2021 MIPS payment year, the first segment would be October 1, 2017 through September 30, 2018 and the second segment would be

October 1, 2018 through September 30, 2019. If a clinician met the low-volume threshold criteria in the first segment but not the second segment, the clinician would still be considered to have met the low-volume threshold criteria. CMS notes it believes that some eligible clinicians whose TIN or TIN/NPIs are identified as eligible during the first segment but do not exist in the second segment because they are no longer utilizing the same TIN or TIN/NPI combination. In this example, CMS states that this clinician would not be eligible to participate in MIPS based on either segment of the determination period because the TIN that was assess for the first segment of the determination no longer exists. However, if a TIN or TIN/NPI did not exist in the first segment but does exist in the second segment, these eligible clinicians could be eligible for MIPS.

CMS is not proposing to include the facility-based or virtual group eligibility determination periods or the rural and HPSA determinations in the proposed MIPS determination period. CMS believes each of these determinations require a different process or timeline.

CMS notes that during the final 3 months of the calendar year in which the performance period occurs, it does not believe it would be feasible for many MIPS eligible clinicians who join an existing practice (existing TIN) or join a newly formed practice (new TIN) to participate in MIPS as individuals. For these MIPS eligible clinicians, as discussed in greater detail below (section H.3.i.), CMS proposes to assign a weight of 0% to each of the four performance categories and a final score equal to the performance threshold.

CMS requests comments on these proposals, including comments on the possibility of incorporating other determination periods into this proposed definition.

c. Low-Volume Threshold

Section 1848(q)(1)(C)(iv) of the Act, as amended by section 51003(a)(1)(A)(ii) of the BBA of 2018, provides that for performance periods beginning on or after January 1, 2018, the Secretary can define the low-volume threshold exclusion based on one or more of the following criteria for MIPS eligible clinicians for a particular performance period:

- (1) The minimum number of Part B-enrolled individuals who are furnished covered professional services (as defined in section 1848(k)(3)(A) of the Act by the MIPS eligible clinician;
- (2) The minimum number of covered professional services furnished to Part B-enrolled individuals by the MIPS eligible clinician; and
- (3) The minimum amount of allowed charges for covered professional services billed by the MIPS eligible clinician.

As enacted in 2015, MIPS payments apply to payments for Medicare Part B “items and services” furnished on or after January 1, 2019. Effective for MIPS performance periods beginning on or after January 1, 2018, MIPS payments apply to “covered professional services” as that term was applied under the Physician Quality Reporting System (PQRS).³⁷

³⁷ The elimination of the term “items” from MIPS payment calculations allows the Secretary to implement this provision by eliminating Part B drugs from these calculations since Part B drugs were not included as covered professional services under PQRS.

Eligible clinicians who do not exceed the low-volume threshold for the performance are excluded from MIPS (§414.1310(b)(1)(iii)). For the 2018 MIPS performance year and future years, CMS defined an individual MIPS eligible clinicians or groups who do not exceed the low-volume threshold as an individual MIPS eligible clinician or group who, during the performance period, has Medicare billing charges less than or equal to \$90,000 or provides care for 200 or fewer Part B-enrolled Medicare beneficiaries.

Proposed Amendments to Comply with the BBA of 2018

For the 2018 MIPS performance year, CMS proposes to define the low-volume threshold as:

- The minimum number (200 patients) of Part B-enrolled individuals who are furnished covered professional services by the eligible clinician or group during the low-volume threshold determination period or
- The minimum amount (\$90,000) of allowed charges for covered professional services to Part B-enrolled individuals by the eligible clinicians or group during the low-volume threshold determination period.

CMS requests comments on this proposal.

MIPS Program Details

CMS requests comments on its proposal to modify the following:

- §414.1310 (Applicability) to specify in paragraph (a) Program Implementation, that except as specified in paragraph (b), MIPS applies to payment for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019.
- §414.1310(b)(1)(ii) to specify that for a year, a MIPS eligible clinician does not include an eligible clinician that is a Partial Qualifying APM Participant (as defined in §414.1305) and does not elect to report on applicable measures and activities under MIPS.
- §414.1310(d) to specify that, in no case will a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) apply to payments for covered professional services furnished during a year by eligible clinicians (including those described in paragraphs (b) and (c) of this section) who are not MIPS eligible clinicians, including those who voluntarily report on applicable measures and activities under MIPS.

Proposed Addition of Low-Volume Threshold Criterion Based on Number of Covered Professional Services

For the 2019 MIPS performance year and future years, CMS proposes that eligible clinicians or groups who meet at least one of the following three criteria during the MIPS determination period would not exceed the low-volume threshold:

- (1) Those who have allowed charges for covered professional services \leq to \$90,000;
- (2) Those who provide covered professional services to \leq 200 Part B-enrolled individuals; or
- (3) Those who provide \leq 200 or fewer covered professional services to Part B- enrolled individuals.

CMS discusses the reasons it is proposing to set the threshold at \leq 200 covered professional services. It believes this threshold allows it to ensure that a significant number of eligible clinicians have the ability to opt-in if they wish to participate in MIPS (discussed in the

following section). CMS estimates that no additional clinicians would be excluded if it adds the third criterion because a clinician that cares for at least 200 beneficiaries would have at least 100 or 200 services. However, CMS estimates 42,025 clinicians would opt-in with the low-volume threshold at 200 services, as compared to 19,621 clinicians if it did not add the third criterion. With the third criterion at 100 services, CMS estimates 50,260 clinicians would opt-in.

Low-Volume Threshold Opt-in

In the 2018 QPP final rule, CMS proposed the option to opt-in to MIPS participation if clinicians might otherwise be excluded under the low-volume threshold. Although commenters supported this proposal, CMS did not finalize the proposal because of operational concerns.

After consideration of operational issues, CMS proposes an approach it believes can be implemented with the least clinician burden. Beginning with the 2019 MIPS performance year, CMS proposes that if an eligible clinician or group meets or exceeds one or two, but not all of the proposed low-volume threshold determinations, then these eligible individuals or groups may choose to opt-in to MIPS.

CMS proposes that this policy would not apply to individual eligible clinicians and groups who exceed all of the low-volume threshold criteria, who unless otherwise excluded, are required to participate in MIPS. In addition, this policy would not apply to individual eligible clinicians and groups who do not exceed any of the low-volume threshold criteria; these individuals would be excluded from MIPS participation without the ability to opt-in to MIPS.

CMS proposes that applicable eligible clinicians and groups would be required to make a definitive choice to opt-in by making an election via the QPP by logging into their account and selecting either the option to opt-in (and receive a MIPS adjustment) or remain excluded from MIPS and voluntarily report (no MIPS adjustment). If the decision was not to participate, then no action would be required. The decision to opt-in to MIPS would be irrevocable and could not be changed for the applicable performance period. CMS has designed a website to illustrate the three different approaches to MIPS participation: voluntary reporting, opt-in reporting, and required participation (additional information is available at <https://qpp.cms.gov>).

The low-volume threshold opt-in option would also apply to virtual groups. CMS proposes that a virtual group election would constitute a low-volume threshold opt-in for any prospective member of the virtual group (solo practitioner or group) that exceeds at least one, but not all, of the low-volume threshold criteria. Solo practitioners and groups opting-in to participate in MIPS as part of a virtual group would not need to independently make a separate election to opt-in because being identified as a TIN in a submitted virtual group election signifies an election to participate in MIPS as part of a virtual group. CMS encourages virtual groups that may only consist of sole practitioners and groups that exceed at least one of the low-volume threshold elements to form a virtual group that would include a sufficient number of TINs to ensure the group is able to meet program requirements such as case minimum criteria.

CMS also proposes that APM Entities in MIPS APMS, which meet one or two, but not all of the low-volume threshold elements would be required to make a definitive choice at the APM Entity level to participate in MIPS. The APM entities would make an election to opt-in via a similar

process that individual eligible clinicians and groups will use to make an election to opt-in. CMS notes that APM Entities in MIPS APMs that do not decide to opt-in to MIPS cannot voluntarily report. CMS also proposes for applicable eligible clinicians participating in a MIPS APM, whose APM does not decide to opt-in to MIPS, the eligible clinician is still excluded from MIPS even though the eligible clinician is part of a TIN or virtual group. Because the low-volume threshold determinations are currently conducted at the APM Entity level for all applicable eligible clinicians in MIPS APMS, CMS believes the low-volume threshold opt-in option should similarly be determined at the APM Entity level and not at the individual eligible clinician, TIN or virtual group level.

CMS requests comments on these proposals.

Part B Services Subject to MIPS Payment Adjustment

CMS proposes to amend §414.1405(e) to modify the application of both the MIPS adjustment factor and, if applicable, the additional MIPS adjustment factor. Beginning with the 2019 MIPS payment year, the MIPS adjustment factors will apply to Part B payments for covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by MIPS eligible clinicians during the year. CMS notes that it will make this change with the first MIPS payment year and that adjustment factors will not apply to Part B drugs and other items furnished by a MIPS eligible clinician, but will apply to covered professional services furnished by a MIPS eligible clinician (discussed below in section H.3.j.)

d. Partial QPs Elections within Virtual Groups

In the 2018 QPP final rule, CMS clarified that an eligible clinician participating in both a virtual group and an Advanced APM who has achieved Partial QP status would be excluded from the MIPS payment adjustment unless the eligible clinician elects to report under MIPS (82 FR 53615). CMS acknowledges it incorrectly stated that affirmatively agreeing to participate in MIPS as part of a virtual group would constitute an explicit election to report under MIPS for all Partial QPs. CMS notes that an election made prior to the start of an applicable period to participate in MIPS as part of a virtual group is separate from an election made during the performance period as a result of an individual eligible clinician or APM Entity achieving Part QP status during the applicable performance period.

CMS restates that affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period does not constitute an explicit election to report under MIPS. CMS proposes that beginning with the 2019 MIPS performance year, when an eligible clinician is determined to be a Partial QP for a year at the eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. This proposed policy eliminates the scenario in which affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period would constitute an explicit election to report under MIPS for eligible clinicians who are determined to be Partial QPs and make no explicit election to either report to MIPS or be excluded from MIPS.

e. Group Reporting

As discussed in the 2018 QPP final rule, stakeholders continue to request a group option that would allow a portion of a group to report as a separate subgroup on measures and activities that are more applicable to the subgroup and be assessed and scored based on the subgroup performance. CMS solicited comments on ways to define a subgroup.

Because of operational challenges with implementing a subgroup option, CMS is not proposing any changes but is considering the use of a sub-group identifier in the QPP program Year 4 through future rulemaking. CMS is concerned that providing a subgroup option may provide potential gaming opportunities by creating subgroups comprised of only the high performing clinicians in the group.

CMS specifically requests comments on the following:

- (1) Whether and how a sub-group should be treated as a separate group from the primary group: for example, if there is one sub-group within a group, how would it assess eligibility, performance, scoring, and application of the MIPS payment adjustment at the subgroup level;
- (2) Whether all of the sub-group's MIPS performance data should be aggregated with that of the primary group or treated as a distinct entity for determining the subgroup's final score, MIPS payment adjustments, and public reporting, and eligibility be determined at the whole group level;
- (3) Possible low burden solutions for identification of subgroups: for example, whether it show require registration similar to the CMS Web Interface or to the mechanism proposed to the low-volume opt-in; and
- (4) Potential issues or solutions needed for sub-groups utilizing submission mechanisms, measures, or activities, such as APM participation, that are different than the primary group.

f. Virtual Groups

In the 2018 QPP final rule, CMS finalized that an official designated virtual group representative must submit an election on behalf of the virtual group by December 31 of the calendar year prior to the start of the applicable performance period. CMS finalized that the election for the 2018 and 2019 performance periods would occur via e-mail to the QPP Program Service Center at MIPS_VirtualGroups@cms.hhs.gov.

For the 2018 and 2019 performance periods, CMS defined the “virtual group eligibility determination period” as an analysis of claims data during an assessment period of up to 5 months that would begin on July 1 and end as late as November 30 of the calendar year prior to the applicable period and includes a 30-day claims run out.

Beginning with the 2020 MIPS performance year and future years, CMS proposes the following policy modifications:

- The virtual group eligibility determination period would align with the first segment of the MIPS determination period, which includes an analysis of claims during the 12-

month assessment period (fiscal year) that would begin on October 1 of the calendar year 2 years prior to the applicable period and end on September 30 of the calendar year preceding the applicable performance period and include a 30-day claims run out. As part of the virtual group eligibility determination period, TINs would be able to inquire about their TIN size prior to making an election during a 5-month timeframe, which would begin on August 1 and end on December 31 of a calendar year prior to the applicable performance period. CMS notes the proposed modification would provide real-time information regarding TIN size for informational purposes.

- MIPS eligible clinicians would be able to contact their designated technical assistance (TA) representative or beginning with the 2020 MIPS performance year, the QPP Service Center to inquire about their TIN size. This information would be for informational purposes in order to assist MIPS eligible clinicians in determining whether or not to participate in a virtual group.
- A virtual group representative would make an election on behalf of a virtual group by registering to participate in MIPS as a virtual group in a form and manner specified by CMS. CMS anticipate that a virtual group representative would make the election via a web-based system developed by CMS.

CMS requests comments on these proposals.

g. MIPS Performance Period

For purposes of the 2020 MIPS performance year and future years, CMS makes the following proposals:

- The performance period for the quality and cost performance categories would be the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year.
- The performance period for the improvement activities performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.
- The performance period for the Promoting Interoperability performance calendar would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

CMS requests comments on these proposals.

h. MIPS Performance Category Measures and Activities

(1) Performance Category Measures and Reporting

(a) Collection Types, Submission Types, and Submitter Types

CMS notes that the way it has described data submission by MIPS eligible clinicians, groups and third party intermediaries does not precisely reflect the experience users have when submitting data. It has used the term “submission mechanisms” to refer not only to the mechanism by which data is submitted but also to certain types of measures and activities on which data are submitted, and to entities submitting the data.

To ensure clarity, CMS proposes to define the following terms:

- **Collection type** as a set of quality measures with comparable specifications and data completeness criteria including as applicable: electronic clinical quality measures (eCQMs); MIPS clinical quality measures (CQMs); Qualified Clinical Data Registry (QCDR) measures; Medicare Part B claims measures; CMS Web Interface measures; the CAHPS for MIPS survey measures; and administrative claims measures. The term MIPS CQMs would replace what was formerly referred to as registry measures.
- **Submitter type** as the MIPS eligible clinician, group, or third party intermediary acting on behalf of a MIPS eligible clinician or group, as applicable, that submits data on measures and activities under MIPS.
- **Submission type** as the mechanism by which the submitter type submits data to CMS, including, as applicable: direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web Interface. There is no submission type for cost data because the data is only submitted for payment purposes.

CMS solicits additional feedback and alternative suggestions on terminology that appropriately reflects the concepts described in the proposed definitions.

Tables 29 and 30 (reproduced below) summarize the CMS proposals for data submission for MIPS eligible clinicians reporting as individuals and as groups.

Performance Category/Submission Combinations Accepted	Submission Type	Submitter Type	Collection Type
Quality	Direct Log in and upload Medicare Part B claims (small practices) ¹	Individual or Third Party Intermediary ² Individual	eCQMs MIPS CQMs QCDR measures Medicare Part B claims measures (small practices)
Cost	No data submission required ²	Individual	-
Promoting Interoperability	Direct Log in and upload Log in and attest	Individual or Third Party Intermediary	-
Improvement Activities	Direct Log in and upload Log in and attest	Individual or Third Party Intermediary	-

¹Third part intermediary does not apply to Medicare Part B claims submission type
²Requires no separate data submission to CMS: measures are calculated based on data available from MIPS eligible clinicians’ billings on Medicare claims. NOTE: As used in this proposed rule, the term “Medicare Part B claims” differs from “administrative claims” in that “Medicare Part B claims” require MIPS eligible clinicians to append certain billing codes to denominator-eligible claims to indicate the required quality action or exclusion occurred.

Performance Category/Submission Combinations Accepted	Submission Type	Submitter Type	Collection Type
Quality	Direct Log in and upload CMS Web Interface (groups of 25 or more eligible clinicians) Medicare Part B claims (small practices) ¹	Group or Third Party Intermediary	eCQMs MIPS CQMs QCDR measures CMS Web Interface measures Medicare Part B claims measures (small practices) CMS approved survey vendor measures Administrative claims measures
Cost	No data submission required ^{1,2}	Group	-
Promoting Interoperability	Direct Log in and upload Log in and attest	Group or Third Party Intermediary	-
Improvement Activities	Direct Log in and upload Log in and attest	Group or Third Party Intermediary	-
¹ Third part intermediary does not apply to Medicare Part B claims submission type ² Requires no separate data submission to CMS: measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare claims. NOTE: As used in this proposed rule, the term "Medicare Part B claims" differs from "administrative claims" in that "Medicare Part B claims" require MIPS eligible clinicians to append certain billing codes to denominator-eligible claims to indicate the required quality action or exclusion occurred.			

Medicare Part B Claims. CMS discusses its desire to move away from claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out. CMS realizes that eliminating claims reporting may limit successful participation by small practices and believes that Medicare Part B claims measures should be available to small practices, regardless of whether they are reporting as individual MIPS eligible clinicians or as a group. Beginning with the 2019 MIPS performance year, CMS proposes to make the Medicare Part B claims collection type available only to MIPS eligible clinicians in small practices.

CMS Web Interface. CMS previously finalized that groups (consisting of 25 or more eligible clinicians) may submit their MIPS data using the CMS Web Interface for the quality, improvement activities and promoting interoperability performance categories. For the 2019 performance year, CMS proposes that the CMS Web Interface submission type would no longer be available for groups to submit data for the improvement activities and promoting interoperability performance categories. CMS recognizes the benefit of having data submitted by a third party intermediary and proposes to allow third party intermediaries to submit data using the CMS Web Interface on behalf of groups. **CMS seeks comment on expanding the CMS Web Interface submission type to groups consisting of 15 or more eligible clinicians to inform future rulemaking.**

Administrative Claims Data. CMS calculates performance using administrative claims data for the cost performance category and for certain quality measures used to assess performance in the quality performance category. CMS finalized that for Medicare Part B claims, data must be submitted on claims with dates of services during the performance period and must be processed no later than 60 days following the close of the performance period. CMS neglected to codify this requirement and proposes to amend §414.1325(a)(2)(i) to reflect this policy.

b. Submission Deadlines

As discussed in the previous section, the terms submission mechanism does not align with the existing process of data submission to the QPP. CMS proposes to revise regulatory text language (§414.1325(e)) to outline data submission deadlines for all submission types for individual and eligible clinicians and groups for all performance categories. CMS also proposes to revise §414.1325(e)(1) to allow flexibility for CMS to alter submission deadlines for the direct, login and upload, the CMS Web Interface, and login and attest submission types. This would allow CMS to extend the submission period when the March 31st deadline falls on a weekend or holiday to the next business day. CMS notes this would also allow extension of the submission period due to unforeseen technical issues.

(2) Quality Performance Category

(a) Background

Assessing Performance on the Quality Performance Category. CMS proposes to amend §414.1330(a) to account for facility-based measurements and the APM scoring standard. CMS proposes to specify, for a MIPS payment year, it uses the following quality measures, as applicable, to assess performance in the quality performance category: measures included in the MIPS final list of quality measures established by CMS through rulemaking; QCDR measures approved by CMS (§414.1440); facility-based measures (as described under §414.1380); and MIPS APM measures (as described at §414.1370).

Contribution to Final Score. Section 1848(q)(5)(E)(i)(I) of the Act, as amended by section 5003(a)(1)(C)(i) of the BBA of 2018, provides that 30 percent of the final score shall be based on performance with respect to the quality performance category, but for each of the first through fifth years for which MIPS applies to payments, the quality performance category percentage shall be increased so that the total percentage points of the increase equals the total number of percentage points by which the cost performance category percentage is less than 30 percent for the respective year. For the 2021 payment year, CMS proposes to weight the cost performance category at 15 percent. Thus, for the 2021 payment year, CMS proposes to weight the quality performance category at 45 percent of a MIPS eligible clinician's final score.

Quality Data Submission Criteria.

Submission Criteria for Groups Reporting Quality Measures, Excluding CMS Web Interface Measures and the CAHPS for MIPS Survey Measure. MIPS eligible clinicians and groups must submit data on at least six measures, including at least one outcome measure. If an applicable outcome measure is not available, one other high priority measure must be submitted. When fewer than six measures apply, MIPS eligible clinician or groups report on each measure that is applicable.

Beginning with the 2019 MIPS performance year, CMS proposes that MIPS eligible clinicians and groups that report on a specialty or subspecialty measure set, must submit data on at least six measures within that set, provided the set contains at least six measures. If the set contains fewer than six measures or if fewer than six measured apply, then eligible clinicians and groups report on each measure that is applicable.

Submission Criteria for Group Reporting CMS Web Interface Measures. CMS seeks comment on expanding the CMS Web Interface option to groups with 16 or more eligible clinicians. Preliminary analysis, however, indicates that expanding this option will likely result in many of these new groups not being able to fully satisfy measure case minimums on multiple measures. CMS notes it could require smaller groups, with 16-24 eligible clinicians, to report only on a subset of the CMS Web Interface measures, such as the preventive care measures. **CMS requests feedback on this possibility as well as other factors it should consider.**

The CMS Web Interface measures for MIPS are applicable to ACO quality reporting under the Shared Savings Program. For the 2019 MIPS performance year, CMS proposes to remove 6 measures from the CMS Web Interface in MIPS³⁸. If this were finalized, groups reporting CMS Web Interface measures would not be responsible for reporting these removed measures.

The CMS Web Interface has a two-step attribution process that associates beneficiaries with TINs during the period in which performance is assessed. The CAHPS for MIPS survey utilizes the same two-step attribution process. CMS clarifies that for the CMS Web Interface and the CAHPS for MIPS survey, attribution would be conducted at the TIN level.

Submission Criteria for Groups Electing to Report CAHPS for MIPS Survey. Beginning with the 2019 MIPS performance year, CMS proposes to clarify that for the CAHPS for MIPS survey, for the 12-month performance period, a group that wants to voluntarily elect to participate in the CAHPS for MIPS survey measure must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measure data to CMS.

Summary of Data Submission Criteria. CMS is not proposing any changes to the quality data submission criteria for the 2019 MIPS performance year. As previously discussed, CMS proposes changes to existing and additional submission related terminology. Tables 31 and 32, reproduced below, summarize the data completeness requirements and submission criteria by collection type for individual clinicians and groups.

³⁸ The measures are listed in the Measures Appendix, Table 6: Measures with substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years,

Collection Type	Performance Period	Data Completeness
Medicare Part B claims measures	Jan 1- Dec 31 (or 90 days for selected measures)	60 percent of individual MIPS eligible clinician's or group's (beginning with the 22121 MIPS payment year) Medicare Part B patients for the performance period
Administrative claims measures	Jan 1- Dec 31	100 percent of individual MIPS eligible clinician's Medicare Part B patients for the performance period
QCDR measures, MIPS CQMs, and eCQMs	Jan 1- Dec 31 (or 90 days for selected measures)	60 percent of individual MIPS eligible clinician's or group's patients across all payers for the performance period.
CMS Web Interface measures	Jan 1- Dec 31	Sampling requirements for the group's Medicare Part B patients: populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries
CAHPS for MIPS survey	Jan 1- Dec 31	Sampling requirement for the group's Medicare Part B patients

Clinician Type	Submission Criteria	Measure Collection Types (or Measure Sets) Available
Individual Clinicians	Report at least 6 measures including one outcome measure or if an outcome measure is not available report another high priority measures. If less than 6 measures apply then report on each measure that is applicable. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	Individual MIPS eligible clinicians select their measures from the following collection types: Medicare Part B claims measures (individuals in small practice only), MIPS CQMs, QCDR measures, eCQMs, or reports on one of the specialty measure sets if applicable.
Groups (non-CMS Web Interface)	Report at least 6 measures including one outcome measure or if an outcome measure is not available report another high priority measures. If less than 6 measures apply then report on each measure that is applicable. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	Groups select their measures from the following collection types: Medicare Part B claims measures (individuals in small practice only), MIPS CQMs, QCDR measures, eCQMs, or the CAHPS for MIPS survey – or reports on one of the specialty measure sets if applicable. Groups of 16 or more clinicians who meet the case minimum of 200 will also be automatically scored on the administrative claims based all-cause hospital readmission measure.

Table 32: Summary of Quality Data Submission Criteria for MIPS Payment Year 2021 for Individual Clinicians and Groups		
Clinician Type	Submission Criteria	Measure Collection Types (or Measure Sets) Available
Groups (CMS Web Interface for group of at least 25 clinicians)	Report on all measures included in the CMS Web Interface collection type and optionally the CAHPS for MIPS survey. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	Groups report on all measures included in the CMS Web Interface collection type and optionally the CAHPS for MIPS survey. Groups of 16 or more clinicians who meet the case minimum of 200 will also be automatically scored on the administrative claims based all-cause hospital readmission measure.

Application of Facility-Based Measures. Section 1848(q)(2)(C)(ii) of the Act allows the Secretary to use measures used for payment systems other than for physicians, such as inpatient hospitals, for purposes of the quality and cost performance categories. Except for services furnished by emergency physicians, radiologists, and anesthesiologists, the Secretary may not use measures used for hospital outpatient departments.

(b) Selection of MIPS Quality Measures for Individual MIPS Eligible Clinicians and Groups Under the Annual List of Quarterly Measures Available for MIPS Assessment
CMS discusses the Meaningful Measures Initiative designed to identify the highest priority areas for quality measurement and quality improvement.³⁹ Through subregulatory guidance, CMS will categorize quality measures by the 19 Meaningful Measure areas.

Beginning with the 2019 performance period, CMS proposes to amend the definition of a high priority measure to include quality measures that relate to opioids. CMS proposes to define a high priority measure to mean an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures would include intermediate-outcome and patient reported outcome (PRO) measures. **CMS requests comments on this proposal including suggestions on what aspects of opioids should be measured.** For example, should CMS focus solely on opioid overuse?

Previously finalized MIPS quality measures can be found in the 2017 and 2018 QPP final rules. Appendix 1 in the proposed rule includes the following detailed tables

- Table Group A: New Quality Measures Proposed for Inclusion in MIPS for the 2021 Payment Year and Future Years
- Table Group B: Proposed New and Modified MIPS Specialty Measure Sets for the 2021 Payment Year and Future Years
- Table C: Quality Measures Proposed for Removal in the 2021 Payment Year and Future Year
- Table D: Measures with Substantive Changes Proposed for 2021 Payment Year and Future Years

³⁹ A link to the Meaningful Measures will page will be provided at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>.

For eCQMs, CMS encourages MIPS eligible clinicians to work with their EHR vendors to ensure they have the most recent version of the eCQM. CMS will not accept an older version of an eCQM as a submission for the quality performance category or the end-to-end electronic reporting bonus. The annual updates to the eCQM specifications are available on the electronic quality improvement (eCQI) Resource Center at <https://ecqi.healthit.gov>.

CMS notes there are a limited number of CMS Web Interface measures. **CMS seeks comments about expanding the core set of measures available to include other specialty specific measures (such as surgery).**

Topped Out Measures. In the 2018 QPP final rule, CMS finalized a 4-year timeline to identify topped out measures, after which it may propose to remove the measure through future rulemaking. In the 4th year, if finalized through rulemaking, the measure would be removed. The 2018 MIPS Quality Benchmarks' file on the QPP resource library lists which measures are topped out for 2018 and would be subject to the cap if they are also topped out in the 2019 MIPS Quality Benchmarks' file which will be released in late 2018.⁴⁰

CMS proposes that once a measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), CMS may propose the measure for removal in the next rulemaking cycle, regardless of the measure's status in the measure lifecycle. CMS is concerned that topped out non-high priority process measures require data collection burden without added value. CMS would consider retaining the measure if there are compelling reasons why it should not be removed (for example, if the removal would impact the number of measures available to a specialist type of addressed an area of importance to the Agency).

For QCDR measures, CMS proposes excluding QCDR measures from the topped out timeline. CMS states that when a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period.

Removal of Quality Measures. CMS discusses its concerns about the large number of process measures in the quality measure set. In the 2018 quality measure set, 102 of the 275 quality measures are process measures that CMS does not consider high priority. Because removing all non-high priority process measures would impact approximately 94 percent of the specialty measure sets, CMS believes it should incrementally remove these measures through notice and comment rulemaking.

Beginning with the 2019 performance period, CMS proposes to implement an approach to remove process measures where prior to removal, considerations will be given to, but is not limited to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.

⁴⁰ The MIPS Quality Benchmarks' files are located at <https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html>.

- Whether the measure addresses a priority area highlighted in the Measure Development Plan.⁴¹
- Whether the measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure’s performance data.
- Whether the measure is designated as high priority or not.
- Whether the measure has reached a topped out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made.

A list of the 34 quality measures proposed for removal is included at the end of this section. Additional information about these measures is provided in Appendix 1, Table C.

Categorizing Measures by Value. CMS acknowledges that all measures do not provide equal value or information and wants to ensure that the collection and submission of data is valuable to clinicians and worth the burden and cost of collecting.

CMS seeks comment on implementing a system where measures are classified at a particular value (gold, silver, or bronze) and points are awarded based on the value of a measure. For example, higher value measures that are considered “gold”, could include outcome measures, composite measures, or measures that address agency priorities. The CAHPS for MIPS survey may also be considered a high measure. Second tier or “silver” measures could be process measures that are directly related to outcomes and have a good gap in performance. Lower value measures or “bronze” measures could be standard of care process measures or topped out measure. (The discussion on the assignment of value and scoring based on measured value is below in section H.3.i).

Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years*			
NQF #	Quality #	Collection Type	Measure Title
0086	012	Medicare Part B Claims eCQM MIPS CQMs	Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation
0088	018	eCQM	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy
0134	043	MIPS CQMs	Coronary Artery Bypass Graft (CABG): Use of Mammery artery in Patients with Isolated CABG Surgery
N/A	048	Medicare Part B Claims	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women 65 Years and Older
0391	099	Medicare Part B Claims MIPS CQMs	Breast Cancer Resection Pathology Reporting: pT Category and pN Category with Histologic Grade
0392	100	Medicare Part B Claims MIPS CQMs	Colorectal Cancer Resection Pathology: pT Category and pN Category with Histologic Grade
N/A	122	MIPS CQMs	Adult Kidney Disease: Blood Pressure Management
0566	140	Medicare Part B Claims	Age-Related Macular Degeneration (AMD) Counseling on

⁴¹ Available at <https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.html>.

Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years*			
NQF #	Quality #	Collection Type	Measure Title
		MIPS CQMs	Antioxidant Supplement
0101	154	Medicare Part B Claims MIPS CQMs	Falls: Risk Assessment
0101	155	Medicare Part B Claims MIPS CQMs	Falls: Plan of Care
0382	156	Medicare Part B Claims MIPS CQMs	Oncology: Radiation Dose Limits to Normal Tissue
0056	163	eCQM	Comprehensive Diabetes Care: Foot Exam
0659	185	Medicare Part B Claims MIPS CQMs	Colonoscopy Interval for Patients with a History of Adenomatous Polyps
0068	204	Medicare Part B Claims eCQM CMS Web Interface MIPS CQMs	Ischemic Vascular Disease: Use or Aspirin or another Antiplatelet
0562	224	MIPS CQMs	Melanoma: Overutilization of Imaging Studies in Melanoma
1855	251	Medicare Part B Claims MIPS CQMs	Quantitative Immunohistochemical Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients
1519	257	MIPS CQMs	Statin Therapy at Discharge after Lower Extremity Bypass
N/A	263	MIPS CQMs	Preoperative Diagnosis of Breast Cancer
N/A	276	MIPS CQMs	Sleep Apnea: Assessment of Sleep Symptoms
N/A	278	MIPS CQMs	Sleep Apnea: Positive Airway Pressure Therapy Prescribed
0100	318	eCQM CMS Web Interface	Falls: Screening for Future Fall Risk
N/A	327	MIPS CQMs	Pediatric Kidney Disease: Adequacy of Volume Management
N/A	334	MIPS CQMs	Adult Sinusitis: More than One CT Scan Within 90 Days for Chronic Sinusitis (Overuse)
N/A	359	MIPS CQMs	Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for CT Imaging
N/A	363	MIPS CQMs	Optimizing Patient Exposure to Ionizing Radiation: Search for Prior CT Studies
N/A	367	eCQM	Bipolar Disorder and Major Depression: Appraisal for Alcohol or Chemical Substance Use
N/A	369	eCQM	Pregnant Women that had HBsA Testing
N/A	373	eCQM	Hypertension: Improvement in Blood Pressure
N/A	375	eCQM	Functional Status Assessment for Total Knee Replacement
N/A	386	MIPS CQMs	Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences
N/A	423	Medicare Part B Claims MIPS CQMs	Perioperative Anti-Platelet Therapy for Patients Undergoing Carotid Endarterectomy
N/A	426	MIPS CQMs	Post-Anesthetic Transfer of Care: Procedure Room to a Post Anesthesia Care Unit
N/A	427	MIPS CQMs	Post-Anesthetic Transfer of Care: Checklist or Protocol for Direct Transfer of Care from Procedure Room to a Intensive Care Unit
N/A	447	MIPS CQMs	Chlamydia Screening and Follow-up

* Information obtained from Appendix, Table C

(3) Cost Performance Category

(a) Weighting in the Final Score.

As previously discussed, the BBA of 2018 provided flexibility in the weighting of the cost performance category in the final score. Instead of requiring this category to have a weight of 30% in Year 3 of the program (performance period 2019) the weight is required to be not less than 10% and not more than 30% for the third, fourth and fifth years of the QPP.

For the 2021 MIPS payment year, CMS proposes the cost performance category would make up to 15% of a MIPS eligible clinician's final score.

CMS proposes to only modestly increase the weight of the cost performance category because it recognizes that cost measures are still relatively early in development and clinicians are not familiar with the measures. CMS considered maintaining the weight of the cost performance category at 10% for the 2021 MIPS payment year. CMS anticipates that it would increase the weight of the cost performance category by 5 percentage points each year until it reaches the required 30% weight for the 2024 MIPS payment year. **CMS invites comment on whether it should consider an alternative weight for the 2021 MIPS payment year and its approach for increasing the weight in subsequent years.**

(b) Cost Criteria

In the 2018 QPP final rule, CMS established two cost measures: the total per capita cost measure and the Medicare spending per beneficiary (MSPB) measure. CMS expects to evaluate cost measures according to the measure revaluation and maintenance process outlined in the “Blueprint for the CMS Measures Management System”.⁴² To the extent that updates would constitute a substantive change, CMS would ensure the changes are proposed through rulemaking. It will also comprehensively reevaluate measures every 3 years to ensure they meet measure priorities. CMS will continue to update measure specifications to accommodate changes in coding, risk adjustment and other factors and expects to continue to seek stakeholder input.

The BBA of 2018 requires the Secretary to post on the CMS website information on cost measures in use under MIPS, cost measures under development and the time frame for such development, potential future cost measures topic, a description of stakeholder engagement, and the percent of expenditures under Medicare Part A and Part B that are covered by cost measures. This information is to be posted no later than December 31 of each year beginning with 2018.

Episode-Based Measures Proposed for the 2019 and Future Performance Periods. CMS notes that episode-based measures are different from the total per capita cost measure and the MSPB measure because episode-based measure specifications only include items and services that are related to the episode of care for a clinical condition or procedure, as opposed to including all services that are provided to a patient over a given timeframe. For the 2019 MIPS performance period, CMS proposes 8 episode-based measures (see Table 33, reproduced below).

⁴² The “Blueprint for the CMS Management System” is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-130.pdf>.

CMS developed episode-based measures to represent the cost to Medicare for the items and services furnished to a patient during an episode of care (“episode”). CMS defines cost based on the allowed amounts on Medicare claims, which include Medicare payments, beneficiary deductible and coinsurance amounts. Episode-based measures are calculated using Medicare Part A and B fee-for-service claims data and are based on episode groups.

An episode group represents a clinically cohesive set of medical services rendered to treat a given medical condition; aggregates all items and services provided for a defined patient cohort to assess the total cost of care; and are defined around treatment for a condition (acute or chronic) or performance of a procedure. Items and services in the episode group could be treatment services, diagnostic services and ancillary items and services directly related to treatment. Items and services could be used after the initial treatment period that may be furnished to patients as follow-up care or to treat complications resulting from the treatment. Items and services will be included if they are the trigger event for the episode or if a service assignment rule identifies them as a clinically related item or service during the episode. The detailed specifications for these measures can be reviewed at <https://qpp.cms.gov>.

An episode is a specific instance of an episode group for a specific patient and clinician. For example, a clinician might be attributed 20 episodes (instances of the episode group) from the episode group for heart failure.

Episode costs are payment standardized and risk adjusted. Payment standardization adjusts the allowed amounts to facilitate cost comparison and limit observed differences in costs that may result from health care delivery choices. CMS removed any Medicare payment differences due to adjustments for geographic differences in wage levels or policy-driven payments adjustments such as those for teaching hospitals. Risk adjustment accounts for patient characteristics that can influence spending and are outside of a clinician’s control.

CMS discusses the processes used for the development of episode measures including stakeholder feedback. Stakeholders could review draft measure specifications for each of the 8 new episode-based measures. The episode-based measures were considered by the NQF-convened Measure Applications Partnership (MAP) and were all conditionally supported by the MAP, with the recommendation of obtaining NQF endorsement. CMS intends to submit these measures to NQF for endorsement in the future. Table 33, reproduced below, are the 8 episode-based measures proposed for the 2019 MIPS performance period and future performance periods.

Measure Topic	Measure Type
Elective Outpatient Percutaneous Coronary Intervention (PCI)	Procedural
Knee Arthroplasty	Procedural
Revascularization for Lower Extremity Chronic Critical Limb Ischemia	Procedural
Routine Cataract Removal with Intraocular Lens (IOL) Implantation	Procedural
Screening/Surveillance Colonoscopy	Procedural
Intracranial Hemorrhage or Cerebral Infarction	Acute inpatient medical condition
Simple Pneumonia with Hospitalization	Acute inpatient medical condition
ST-Elevation Myocardial Infarction (STEMI) with PCI	Acute inpatient medical condition

Reliability. CMS examined the reliability of the proposed 8 episode-based measures at various case minimums and found that all these measures meet the reliability threshold of 0.4 for the majority of clinicians and groups at a case minimum of 10 episodes for procedural measures and 20 episodes for acute inpatient medical condition episodes. Table 34 (reproduced below) represents the percentage of TINs and TIN/NPIs with 0.4 or higher reliability as well as the mean reliability for the subset of TINs and TIN/NPIs who meet the proposed case minimums.

Measure Name	Percentage TINs with 0.4 or higher reliability	Mean Reliability for TINs	Percentage TINs with 0.4 or higher reliability	Mean Reliability for TIN/NPIs
Elective Outpatient PCI	100.0%	0.73	84.1%	0.53
Knee Arthroplasty	100.0%	0.87	100.0%	0.81
Revascularization for Lower Extremity Chronic Critical Limb Ischemia	100.0%	0.74	100.0%	0.64
Routine Cataract Removal with IOL Implantation	100.0%	0.95	100.0%	0.94
Screening/Surveillance Colonoscopy	100.0%	0.96	100.0%	0.93
Intracranial Hemorrhage or Cerebral Infarction	100.0%	0.70	74.9%	0.48
Simple Pneumonia with Hospitalization	100.0%	0.64	31.8%	0.40
STEMI with PCI	100.0%	0.59	100.0%	0.59

Based on this analysis, CMS proposes a case minimum of 10 episodes for the procedural episode-based measures and 20 episodes for the acute inpatient medical condition episode-based measures. CMS believes that calculating episode-based measures with these case minimums would accurately and reliably measure the performance of a large number of clinicians.

CMS acknowledges that the percentage of TIN/NPIs with 0.4 or greater reliability for the Simple Pneumonia with Hospitalization measure, meets the reliability threshold based but is lower than all the other proposed measures. CMS considered an alternative case minimum of 30 for this measure and found that although the mean reliability would increase, the number of TINs and TIN/NPIs that would meet this case minimum would decrease. **CMS invites comment on this alternative case minimum for this episode.**

CMS will continue a case minimum of 35 for the MSPB measure and 20 for the total per capita cost measure.

CMS is concerned that some clinicians and smaller groups may never see enough patients in a single year to meet the case minimum for a specific episode-based measure. **CMS seeks comment on whether it should consider expanding the performance period for the cost measures from a single year to 2 or more years.** CMS notes, that expanding the performance period would increase the time between the measurement of the performance and the application of the MIPS payment adjustment.

Attribution Rules for the Proposed Episode-Based Measures. CMS proposes the attribution methodology would be the same for all of the measures within each type of episode groups – acute inpatient medical condition episodes groups and episode-based measures.

Beginning in the 2019 performance period, for acute inpatient medical condition episode groups, CMS proposes:

- To attribute episodes to each MIPS eligible clinician who bills inpatient E&M claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E&M claim lines in that hospitalization. A trigger inpatient hospitalization is a hospitalization with a particular MS-DRG identifying the episode group.
- The measure score for an individual clinician (TIN/NPI) is based on all of the episodes attributed to the individual. The measure score for a group (TIN) is based on all the episodes attributed to a TIN/NPI in the given TIN. If a single episode is attributed to multiple TIN/NPIs in a single TIN, the episode is only counted once in the TIN's measure score.

CMS believes that establishing a 30 percent threshold for the TIN would ensure that the clinician group is collectively measured across all of its clinicians who are likely responsible for the oversight of care for the patient during the trigger hospitalization. CMS provides an example of the proposed attribution rules where 3 MIPS eligible clinicians are part of the same TIN.

CMS notes this proposed attribution approach differs from the approach previously established for acute inpatient medical condition episode groups. Stakeholders were concerned the prior approach did not capture patients' episodes when a group collaborates to manage a patient but no individual clinician exceeds the 30 percent threshold. CMS believes the proposed approach emphasizes team-based care.

Beginning in the 2019 MIPS performance period, for procedural episode groups, CMS proposes:

- To attribute episodes to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.
- The measure score for an individual clinician (TIN/NPI) is based on all the episodes attributed to the individual. The measure score for a group (TIN) is based on all the episodes attributed to a TIN/NPI in the given TIN. If a single episode is attributed to multiple TIN/NPIs in a single TIN, the episode is only counted once in the TIN's measure score.

(4) Improvement Activities Performance Category

(a) Weighting in the Final Score

In the 2017 QPP final rule, CMS finalized that the improvement activities performance category would account for 15 percent of the final score. CMS defined an improvement activity as an activity that relevant MIPS eligible clinicians, organizations, and other relevant stakeholders identify as improving clinical practice or care and that the Secretary determines, when effectively executed, are likely to result in improved outcomes.

Appendix 2 to the proposed rule includes the following detailed tables:

- Table A: Proposed New Improvement Activities for the MIPS 2019 Performance Period and Future Years
- Table B: Proposed Changes to Previously Adopted Improvement Activities for the MIPS 2019 Performance Period and Future Years

CMS is proposing 6 new improvement activities; modifying 5 existing activities; and removing 1 existing activity.

(b) Submission Criteria

CMS finalized that for MIPS Year 2 and future years, MIPS eligible clinicians or groups must submit data on improvement activities in one of the following manners: qualified registries; EHR submission mechanisms; QCDR; CMS Web Interface; or attestation. For activities that are performed for at least a continuous 90-days during a performance period, MIPS eligible clinicians must submit a yes response for activities within the improvement activities inventory. When an individual MIPS eligible clinicians or group is using a health IT vendor, QCDR, or qualified registry for data submission, eligible clinicians or group must certify all improvement were performed and the health IT vendor, QCDR, or qualified registry would submit on their behalf.

As previously discussed, CMS proposes to update the terminology for the data submission process. CMS proposes to revise §414.1360(a)(1) to state that data would be submitted “via direct, login and upload, and login and attest” instead of “via qualified registries; EHR submission mechanisms; QCDR; CMS Web Interface; or “attestation”. CMS also proposes to specify, submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.

(c) Subcategories

In the 2017 QPP final rule, CMS finalized at §414.1365 that the improvement activities performance category includes specific subcategories. CMS is not proposing any changes to the subcategories. It is proposing to move delete §414.1365 and move the same improvement activities subcategories to §414.1355(c).

(d) Improvement Activities Inventory

Annual Call for Activities. In the 2018 QPP final rule, CMS formalized the Annual Call for Activities process for Year 3 and future years and added additional criteria for submitting nominations for improvement activities. Applicants would need to indicate that one or more of the 11 criteria were applicable to the improvement activity.

For the 2019 performance period and future years, CMS proposes to adopt an additional criterion entitled “Include a public health emergency as determined by the Secretary” to the criteria for nominating new improvement activities.

Under the promoting interoperability performance category, CMS is proposing a scoring that moves away from the base, performance, and bonus score established (discussed below in section H.3.h.(5)). This proposal would remove the availability of a bonus score for attesting to completing one or more specified improvement activities using CEHRT beginning with the 2019

performance period. If this policy is finalized, then CMS proposes to remove the criterion for selecting improvement activities entitled “Activities that may be considered for an advancing care information bonus”.

CMS’ proposed list of criteria for nominating new improvement activities for the 2019 performance period and future years would be:

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved health outcomes;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Alignment with patient-centered medical homes;
- Focus on meaningful action from the person and family’s point of view;
- Support the patient’s family or personal caregiver;
- Representative of activities that multiple MIPS eligible clinicians or groups could perform (for example, primary care and specialty care);
- Feasible to implement, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes;
- Include a public health emergency as determined by the Secretary; or
- CMS is able to validate the activity.

CMS clarifies that these criteria are but one factor in determining which improvement activities it proposes. CMS notes it also takes into account other factors, such as whether the nominated activity uses publically available products or techniques, or whether the activity duplicates any current activity.

Weighting of Improvement Activities. CMS summarizes past considerations used to previously assign weights to improvement activities. CMS believes that an activity that requires significant investment of time and resources should be high-weighted. For example, the CAHPS for MIPS survey is high-weighted because it requires a significant investment of time and resources. In contrast, CMS believes medium-weighted improvement activities are simpler to complete and require less time and resources. CMS considers the Cost Display for Laboratory and Radiologic Orders activity as medium-weighted because the information required to be used is readily available at no cost. CMS clarifies that an improvement activity is by default medium-weight unless it meets the considerations for high-weighting.

CMS intends to more thoroughly revisit the weighting policies in next year’s rulemaking and invites public comment on the following:

- The need for additional transparency and guidance on the weighting of improvement activities.
- Applying high-weighting for any improvement activity employing CEHRT.

Timeframe for the Annual Call for Activities. CMS discusses how the current timeline does not provide sufficient time for processing and reviewing all the improvement activities nominations.

Beginning with the 2019 performance period and future years, CMS proposes:

- To change the performance year for which the nominations of prospective new and modified improvement activities would apply, such that activities nominated in a particular year will be vetted and considered for next year's rulemaking cycle for possible implementation in a future year. For example, an improvement activity nominated during the 2020 Annual Call would be vetted, and if accepted by CMS, would be proposed during the 2021 rulemaking cycle for possible implementation in 2022.
- To change the submission timeframe for the Call for Activities from February 1st through March 1st to February 1st through June 30th.

(e) CMS Study on Factors Associated with Reporting Quality Measures

In the 2017 QPP final rule, CMS created the Study on Improvement Activities and Measurement. This study of practice improvement and measurement is designed to examine clinical quality workflows and data capture using a simpler approach to quality measures. Participants receive a full credit (40 points) for the improvement activities performance category. In the 2018 QPP final rule this study evolved into the "CMS Study on Burdens Associated with Reporting Quality Measures".

CMS is not proposing any changes to the study purpose, aim, eligibility or credit. For the 2019 performance period and future years, CMS proposes changes to the: (1) title of the study; (2) sample size to allow enough statistical power for rigorous analysis within some categories; (3) focus group and survey requirements; and (4) measure requirements.

Title. CMS proposes to change the title to "CMS Study on Factors Associated with Reporting Quality Measures". CMS believes this new title more accurately reflect the study's intent and purpose.

Sample Size. CMS proposes to increase the sample size from a minimum of 102 to a minimum of 200 MIPS eligible clinicians. CMS believes this will enable it to more rigorously analyze the statistical difference between the burden and factors associated with individuals and groups of varying sizes.

Focus Group. Study participants are required to attend monthly focus groups to share lessons learned in submitting quality data along with providing survey feedback to monitor effectiveness. With the proposal to increase the sample size of the study to a minimum of 200 MIPS eligible clinicians, CMS believes only a subset of clinicians need to participate in focus groups. CMS proposes to make the focus group participation a requirement only for a selected subset of study participants, using purposive sampling and random sampling methods.

Measure Requirements. CMS proposes to continue the previously required minimum number of measures: participants must submit data and workflows for a minimum of three MIPS quality measures for which they have baseline data. For the 2019 performance period, CMS proposes that at least one of the three measures must be a high priority measure.

(5) Promoting Interoperability (PI) (previously known as the Advancing Care Information Performance Category)

CMS proposes several scoring and measurement policies that increase the focus of this performance category on interoperability and improving patient access to health information. To better reflect this focus, CMS renamed the advancing care information performance category to the Promoting Interoperability (PI) performance category.

(a) Certification Requirements Beginning in 2019

For the 2017 and 2018 performance periods, MIPS eligible clinicians could use EHR technology certified to either the 2014 or 2015 Edition certification criteria, or a combination of the two Editions, to meet the objectives and measures specified for the PI performance category. Beginning with the 2019 performance period, MIPS eligible clinicians must use EHR technology certified to the 2015 Edition certification criteria as specified in §414.1305.

CMS states that the 2014 Edition certification criteria are out of date and impose limits on interoperability and the access, exchange, and use of health information. Moving from certifying to the 2014 Edition to the 2015 Edition also eliminates the inconsistencies that are inherent with maintenance of two separate certification programs. CMS discusses the benefits from moving to the 2015 Edition, which include monetary savings and reduced burden to clinicians and health IT developers. In addition, the Application Programming Interface (API) functionality in the 2015 Edition supports health care providers and patient electronic access to health information.

Using Medicare and Medicaid EHR Incentive Programs attestation data, ONC tracks the number of MIPS eligible clinicians with 2015 Edition CEHRT. At the beginning of the first quarter of 2018, ONC confirmed that at least 66 percent of MIPS eligible clinicians have 2015 Edition CEHRT. Based on this data, CMS believes the transition from the 2014 Edition to the 2015 Edition is on schedule for the 2019 performance period.

(b) Proposed Scoring Methodology Beginning with the MIPS Performance Period in 2019

For the 2017 and 2018 MIPS performance period, CMS finalized that the score would be comprised of a score for participation and reporting, referred to as the “base score”, a score for performance at varying levels above the base score requirements, referred to as the “performance score”, and potential bonus points for reporting on certain measures and activities. Based on concerns expressed by stakeholders, CMS proposes a new scoring methodology based on performance on individual measures. The goal of this new scoring methodology is to provide increased flexibility to clinicians and enable them to focus more on patient care and health data exchange through interoperability. CMS notes this proposed methodology will also align the requirements of the PI performance category with the requirements of the PI program for eligible hospitals and CAHs.

Tables 36 and 37, reproduced below, summarize CMS’ proposal for the scoring methodology for the MIPS performance period in 2019 (table 36) and 2020 (table 37).

Objectives	Measures	Maximum Points
e- Prescribing	e-Prescribing	10 points
	<i>Bonus:</i> Query of Prescription Drug Monitoring Program (PDMP)	5 points bonus
	<i>Bonus:</i> Verify Opioid Treatment Agreement	5 points bonus
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Choose two of the following: <ul style="list-style-type: none"> • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting 	10 points

Objectives	Measures	Maximum Points
e- Prescribing	e-Prescribing	5 points
	Query of Prescription Drug Monitoring Program (PDMP)	5 points
	Verify Opioid Treatment Agreement	5 points
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	35 points
Public Health and Clinical Data Exchange	Choose two of the following: <ul style="list-style-type: none"> • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting 	10 points

The new scoring methodology would have four objectives: e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. CMS states it is promoting these objectives to promote specific HHS priorities and satisfy the requirements of section 1848(o)(2) of the Act. MIPS eligible clinicians would be required to report certain measures from each objective, with performance-based scoring at the individual measure-level. Each measure would be scored based on the performance for that measure, which is based on the submission of a numerator and denominator, except for the measures associated with the Public Health and Clinical Data Exchange objective, which requires “yes or no” submissions.

The score for each individual measure would be added together to calculate the PI performance score of up to 100 possible points for each MIPS eligible clinician. In general, the PI performance category score makes up 25 percent of the MIPS final score. If an eligible clinician

fails to report on a required measure or claim an exclusion for a required measure, if applicable, the clinician would receive a total score of zero for the PI performance category.

CMS considered an alternative approach: scoring would occur at the objective level, instead of the individual measure level, and MIPS eligible clinicians would be required to report on only one measure from each objective to earn a score for that objective. Under this methodology, the total PI performance category score would be based on only four measures instead of six measures. Each objective would be weighted similar to the proposed methodology and bonus points would be awarded for reporting any additional measures beyond the required four. **CMS seeks public comment on this alternative approach and whether additional flexibilities should be considered as well as additional scoring approaches or methodologies that should be considered. CMS also seeks comment on whether the measures are weighted appropriately or whether a different weighting distribution, such as equal distribution across all measures would be better suited to the proposed scoring methodology.**

The e-Prescribing objective would contain three objectives. In addition to the existing e-Prescribing measure, CMS proposes to add two new measures: Query of the Prescription Drug Monitoring Program (PDPM) and Verify Opioid Treatment Agreement. CMS proposes different weights for each objective to reflect their potential availability and applicability to clinicians. CMS believes the e-Prescribing measure would be applicable to most clinicians and this measure would be required and weighted at 10 points. For the 2019 performance period, MIPS eligible clinicians that meet the criteria and claim the exclusion for the e-Prescribing measure, the 10 points for the measure would be redistributed equally between the two measures under the Health Information Exchange objective. **CMS seeks public comment on whether this distribution is appropriate or whether the points should be distributed differently.**

For the 2019 performance period, CMS proposes that the Query of PDMP and Verify Opioid Treatment Agreement measures would be optional. CMS is concerned these measures may not be available to all MIPS eligible clinicians because they have not been fully developed by health IT vendors or not fully implemented in time for data capture and reporting. Beginning with the 2020 performance period, CMS proposes to reweight the e-Prescribing measure from 10 to 5 points and reweight the Provide Patients Electronic Access to Their Health Information measure from 40 to 35 points.

For the 2020 performance period, CMS is proposing to require the Query of PDMP and Verify Opioid Treatment Agreement measures but is also proposing an exclusion for any eligible clinician unable to report the measures because of varying State requirements, which do not allow e-prescribing of controlled substances. CMS proposes that the 5 points assigned to the measure would be redistributed to the e-Prescribing measure. CMS also proposes that if a MIPS eligible clinician qualifies for the e-Prescribing exclusion and is excluded from reporting all three of the measures, the 15 points for the objective would be redistributed evenly among the two measures associated with the Health Information Exchange objective and the Provide Patients Electronic Access to their Health Information measure by adding 5 points to each measure.

For the Health Information Exchange objective, CMS proposes required reporting for both measure, each worth 20 points. CMS notes these measures are weighted heavily to emphasize the importance of sharing health information through interoperable exchange. For the 2019 performance period, CMS acknowledges that these measures may not be fully developed or implemented and proposes an exclusion for the Support Electronic Referral Loops by Receiving and Incorporating Health Information. Any eligible clinician who is unable to implement this measure for the 2019 performance period would be excluded from reporting this measure; the 20 points would be redistributed to the Support Electronic Referral Loops by Sending Health Information and that measure would be worth 40 points. **CMS seeks public comment on whether this redistribution is appropriate or whether the points should be redistributed differently.**

CMS proposes one measure for the Provider to Patient Exchange objective. CMS believes this objective and its measure are the crux of the PI performance category.

Because the measures under the Public Health and Clinical Data Exchange objective are reported using “yes” or “no” responses, CMS proposes to score these measures on a pass/fail basis. Eligible clinicians would receive the full 10 points for reporting two “yes” responses or for submitting a “yes” for one measure and claiming an exclusion for another. If there are no “yes” responses and two exclusions are claimed, the 10 points would be redistributed to the Provide Patients Electronic Access to Their Health Information measure. A MIPS eligible clinician would receive zero points for reporting “no” responses for the measures in this objective.

CMS proposes that the Protect Patient Health Information objective and its associated measure, Security Risk Analysis, would remain part of the requirements for the PI performance category, but would no longer be scored as a measure. CMS proposes that to earn any score in the PI performance category, a MIPS eligible clinician would have to report that they completed the actions in the Security Risk Analysis measure at some point during the performance period.

CMS proposes that in order to earn any for the PI performance category, MIPS eligible clinicians would need to report on all of the required measures across all objectives. Failure to report any required measure, or reporting a “no” response on a “yes or no” response measure, unless an exclusion applies would result in a score of zero. **CMS seeks comment on this requirement or whether reporting on a smaller subset of optional measures would be appropriate.**

Table 38, reproduced below, provides an example of the proposed scoring methodology for the 2019 performance period.

Objectives	Measures	Maximum Points	Numerator/Denominator	Performance Rate	Score
e- Prescribing	e-Prescribing	10 points	200/250	80%	10*0.8=8 points
	<i>Bonus:</i> Query of Prescription Drug Monitoring Program (PDMP)	5 points bonus	150/175	86%	5 bonus points
	<i>Bonus:</i> Verify Opioid	5 points	N/A	N/A	0 points

Objectives	Measures	Maximum Points	Numerator/Denominator	Performance Rate	Score
	Treatment Agreement	bonus			
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points	135/185	73%	20*0.73 = 15 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	20 points	145/175	83%	20*0.83 = 17 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points	350/500	70%	40*0.70 = 28 points
Public Health and Clinical Data Exchange	Immunization Registry Reporting	10 points	Yes	N/A	10 points
	Public Health Registry Reporting		Yes		
Total Score					83 points

If the new scoring methodology is not finalized, for the 2019 performance period, CMS proposes to maintain the current PI scoring methodology with the same objectives, measures, and requirements for the 2018 performance period, except that it would discontinue the 2018 Promoting Interoperability Transition Objectives and Measures. CMS would discontinue the use of the transition measures because they are associated with the 2014 Edition CEHRT and it is requiring 2015 Edition CEHRT.

CMS seeks public comment on the feasibility of the proposed new scoring in 2019 and whether MIPS eligible clinicians would be able to implement the new measures and reporting requirements.

(c) PI/Advancing Care Information Objectives and Measure Specifications for the 2018 Performance Period

CMS refers readers to the 2017 and 2018 QPP final rules (81 FR 77227 through 77229 and 82 FR 53674 through 53680, respectively for detailed information about the requirements for the 2018 performance period. A summary of the 2018 objectives is provided in the proposed rule.

(d) Promoting IP Category Measure Proposals for MIPS Eligible Clinicians

Table 39, reproduced below, provides a summary of the proposals for the PI category measures for the MIPS 2019 performance period. The reader is referred to the discussion in the proposed rule for more specific details about these proposals.

Measure Status	Measure
Measures retained-no modifications*	e-Prescribing
Measures retained with modifications	- Send a Summary of Care (name proposal – Support Electronic Referral Loops by Sending Health Information)

Table 39: Summary of Proposals for the PI Performance Category Objectives and Measures for the MIPS Performance Period in 2019	
Measure Status	Measure
	<ul style="list-style-type: none"> - Provider Patient Access (name proposal – Provide Patients Electronic Access to Their Health Information - Immunization Registry Reporting - Syndromic Surveillance Reporting - Electronic Case Reporting - Public Health Registry Reporting - Clinical Data Registry Reporting
Removed measures	<ul style="list-style-type: none"> - Request/Accept Summary of Care - Clinical Information Reconciliation - Patient-Specific Education - Secure Messaging - View, Download or Transmit - Patient-Generated Health Data
New measures	<ul style="list-style-type: none"> - Query of Prescription Drug Monitoring Program (PDMP) - Verify Opioid Treatment Agreement - Support Electronic Referral Loops – Receiving and Incorporating Health Information
* Security Risk Analysis is retained, but not included as a measure under the proposed scoring methodology	

In addition to seeking comments on the proposals for the PI performance category measures, CMS seeks comments for a potential new measure in the Health Information Exchange objective. Specifically, CMS seeks comments on a potential new measure, CMS Health Information Exchange Across the Care Continuum, in which a MIPS eligible clinician would send an electronic summary of care record, or receive and incorporate an electronic summary of care record, for transitions of care and referrals with a health care provider other than a MIPS eligible clinician. The measure would include health care providers in care settings including but not limited to long term care facilities and post-acute care providers such as SNF, home health, and behavioral health settings.

(e) Improvement Activities Bonus Score Under the PI Performance Category and Future Reporting Considerations

For the 2017 and 2018 performance periods, CMS awards a bonus score to MIPS eligible clinicians who use CEHRT to complete certain activities in the improvement activities performance category. In connection with the proposals for the PI performance category, beginning with the 2019 performance period, CMS proposes not to continue this bonus.

CMS acknowledges that discontinuing this bonus could be viewed as increasing burden and it discusses various ways to align and streamline the different performance categories under MIPS. CMS is interested in linking the quality, improvement activities and PI performance categories to reduce burden and create a more cohesive program. CMS discusses an option to establish several sets of new multi-category measures that would cut across the three performance categories and allow MIPS eligible clinicians to report once for credit in all three performance categories. For example, one possible combined measure could bring together the proposed PI measure, Support Electronic Referral Loops by Sending Health Information, with the improvement activity, Implementation of use of specialists report back to the referring clinician

or group to close referral loop, and the quality measure, Closing the Referral Loop: Receipt of specialists report. CMS notes there are challenges in implementing this concept, including the lack of measures and activities that share identical and aligned requirements across the three performance categories. **CMS seeks comments on this concept as well as measure and activity suggestions to enhance the link between the three performance categories.**

CMS also considers proposing in future rulemaking public health priority sets across all four MIPS performance categories. CMS believes that public health priority sets would allow clinicians to focus on activities and measures that fit within their workflow, address their patient population needs, and encourage increased participation in MIPS. CMS intends to develop the first few public health priority sets around opioids, blood pressure, diabetes, and general health (healthy habits). **CMS seeks public comments on the following:**

- Additional public health priority sets and whether they should be more specialty focused versus condition specific.
- How to implement public health priority sets to minimize burden, such as by offering sets that emphasize use of common health IT functionalities.
- How CMS could encourage or incentivize providers to use public health priority sets

(f) Additional Considerations

Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists. For the 2018 and 2019 performance periods, CMS assigns a weight of zero to this performance category if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. CMS assigns a weight of zero only in the event that these eligible clinicians do not submit any data for any of the measures specified for this performance category. If these clinicians choose to report they will be scored like all other MIPS eligible clinicians,

CMS intended to use the first MIPS performance period to evaluate the participation of these MIPS eligible clinicians to determine policies for future years. Since CMS has not yet analyzed the data for the first MIPS performance period and it believes it would be premature to propose any changes. For the 2019 performance period, CMS proposes to continue the current policy.

Physical therapists, Occupational therapists, Clinical social workers, and Clinical psychologists. CMS proposes to assign a weight of zero to the PI performance category if there are not sufficient measures applicable and available to these new types of MIPS eligible clinicians: physical therapists, occupational therapists, clinical social workers, and clinical psychologists. CMS notes these MIPS eligible clinicians may choose to submit PI measures but if they choose to report, they would be scored on the PI performance category like all other MIPS eligible clinicians.

(6) APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

MIPS eligible clinicians including those participating in MIPS APMs, are subject to MIPS reporting requirements and payments adjustments, unless excluded on another basis. CMS

finalized under §414.1370(f) that, under the APM scoring standard, MIPS eligible clinicians will be scored at the APM entity group level and each MIPS eligible clinician will receive the APM Entity's final MIPS score. CMS proposes to amend §414.1370(f)(2) to state that if the APM Entity group is excluded from MIPS, all eligible clinicians within that APM Entity group are also excluded from MIPS.

(b) MIPS APM Criteria

In the 2017 QPP final rule, CMS established an APM Scoring Standard applicable to MIPS eligible clinicians participating in MIPS APMs. CMS finalized at §414.1370(b) that to be a MIPS APM, an APM must satisfy the following criteria:

- (1) APM Entities participate in the APM under an agreement with CMS or by law or regulation;
- (2) The APM requires that APM Entities include at least one MIPS eligible clinicians on a participation list;
- (3) The APM bases payment incentives on performance (either at the APM Entity or eligible clinician level) on cost/utilization and quality measures; and
- (4) The APM is neither a new APM for which the first performance period begins after the first day of the MIPS performance period for the year nor an APM in the final year of operation for which the APM scoring standard is impracticable.

In response to comments, CMS proposes to revise the third criterion to specify that a MIPS APM must be designed in such a way that participating APM Entities are incented to reduce costs of care or utilization of services, or both. CMS proposes to state that the APM bases payment incentives on performance (either at the APM entity or eligible clinician level) on quality measures and cost/utilization.

CMS clarifies it will review each distinct track of an AMP as to whether it meets the above criteria to be a MIPS APM and that it is possible for an APM to have tracks that are MIPS APMs and tracks that are not MIPS APMs. CMS would not consider whether the individual APM Entities or MIPS eligible clinicians participating within a given track each satisfy all of the MIPS APM criteria. CMS considers the term "track" to refer to a distinct arrangement through which an APM Entity participates in the APM, and that such participation is mutually exclusive of the APM Entity's participation in another "track" within the same APM. For example, CMS would consider the two risk arrangements under OCM to be two separate tracks.

CMS also clarifies its interpretation of the rule at §414.1370(b)(4)(i) for APMs that begin after the first day of the MIPS performance period for the year (currently January 1) but require participants to report quality data for quality measures tied to payment for the full MIPS performance period, beginning January 1. CMS believes it would be counter to the purpose of the APM scoring standard to report duplicative reporting of quality measures for both the APM and MIPS and to create potential conflicting incentives between the quality scoring requirements and payment incentives. Therefore, for the purposes of MIPS APM determinations, CMS considers the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM.

For the 2019 MIPS performance year, CMS expects that ten APMs will satisfy the requirements to be MIPS APMs:

- Comprehensive ESRD Care Model (all Tracks),
- Comprehensive Primary Care Plus Model (all Tracks),
- Next Generation ACO Model,
- Oncology Care Model (all Tracks),
- Medicare Shared Savings Program (all Tracks),
- Medicare ACO Track 1+ Model,
- Bundled Payments for Care Improvement,
- Advanced Independence at Home Demonstration (if extended),
- Maryland Total Cost of Care Model (Maryland Primary Care Program), and
- Vermont Medicare ACO Initiative.

(c) Calculating MIPS APM Performance Category Scores

Quality Performance Category. For the quality performance category, MIPS eligible clinicians in APM Entities will continue to be score only on the quality measures that are required under the terms of their APMs and available for scoring as specified in §414.1370(g)(1).

Web Interface Reporters. In the 2018 QPP final rule, CMS finalized using quality measure data that participating APM Entities submit using the CMS Web Interface and CAHPS surveys as required under the terms of the APMs. When APM benchmarks are not available, CMS uses MIPS benchmarks to score quality for the MIPS eligible clinicians at the APM Entity level under the APM scoring standard.

If a Shared Savings Program ACO does not report quality measures as required, each ACO participant TIN will be treated as a unique APM entity for purposes of the APM scoring standard, and may report data for the MIPS quality performance category according to the MIPS submission and reporting requirements. CMS clarifies that any “partial” reporting through the CMS Web Interface that does not satisfy the requirements of the Shared Savings Program will be considered a failure to report and each ACO participant TIN will also have the opportunity to report quality data to avoid a score of zero for the quality performance category. CMS acknowledges that successfully reporting MIPS according to group reporting requirements may be difficult for solo practitioners and proposes a modification in the exception policy. Beginning with the 2019 performance period, when a Shared Savings Program ACO fails to report complete quality data for all Web Interface measures, CMS proposes it would also allow a solo practitioner (a MIPS eligible clinician who has only one NPI billing through their TIN), to report on any available MIPS measures, including individual measures.

CMS also proposes that, beginning with the 2019 performance period, the complete requirement for Web Interface reporters will be modified to specify that if an APM entity (in this case, an ACO) fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACO survey, it will score the CAHPS survey and apply it towards the APM Entity’s quality performance category score. In this scenario, the Shared Savings Program TIN-level reporting exception would not be triggered and all MIPS eligible clinicians within the ACO would receive the APM Entity score. CMS seeks comments on these proposals.

For the 2019 MIPS performance period, CMS expects there will be four Web Interface Reporter APMs:

- Shared Savings Program,
- Medicare ACO Track 1+ Model,
- Next Generation ACO Model, and
- Vermont ACO Medicare Initiative.

Other MIPS APMs. The MIPS quality performance score for a MIPS performance period is calculated for the APM Entity using the data submitted by the APM Entity based on measures specified by CMS through notice and comment rulemaking.

For the 2019 MIPS performance period, CMS expects there will be up to six Other MIPS APMs and lists each specific measure set in Tables 41 through 46 in the proposed rule:

- Comprehensive ESRD Care Model (Table 41),
- Comprehensive Primary Care Plus Model (Table 42),
- Oncology Care Model (Table 43),
- Bundled Payments for Care Improvement Advanced (Table 44),
- Maryland Total Cost of Care Model (Maryland Primary Care Program (Table 45), and
- Independence at Home Demonstration (Table 46).

Promoting Interoperability Performance Category. For the Shared Savings Program, CMS finalized at §414.1370(g)(4)(i) that ACO participant TINs are required to report on the PI performance category, and it will weight and aggregate the ACO participant TIN scores to determine an APM Entity group score. CMS has found that limiting reporting to the ACO participant TIN creases confusion and restricts PI reporting options for MIPS eligible clinicians participating in the Shared Savings Program. Beginning in the 2019 MIPS performance period, CMS proposes to no longer apply the requirements at §414.1370(g)(4)(i) and instead apply the existing policy at §414.1370(g)(4)(ii) so that MIPS eligible clinicians participating in the Shared Savings Program may report on the PI performance category at either the individual or group level under the APM scoring standard.

(d) MIPS APM Performance Feedback

MIPS eligible clinicians who are scored under the APM scoring standard receive performance feedback. CMS notes that split-TIN APM Entities and their participants can only access their performance feedback at the APM Entity or individual MIPS eligible clinician level. MIPS eligible clinicians participating in the Shared Savings Program, which only includes full-TIN ACOs, will be able to access their performance feedback at the ACO participant TIN level.

i. MIPS Final Score Methodology

(1) Converting Measures and Activities into Performance Category Scores

(a) Background

For the 2021 MIPS payment year (2019 performance period), CMS proposes to keep, with some modifications, the scoring methodology adopted for the transition years. Under that methodology, scores are developed for each of the four performance categories and these scores are used to calculate a final score, which is translated into the MIPS adjustment. The BBA of 2018 provided CMS flexibility to continue to ramp up the QPP, and it proposes to use this authority to extend some transition year policies into the 2019 performance period. The proposed changes also include consideration of on-campus outpatient hospital services in the determination of the facility-based measurement option and delaying calculation of an improvement score for the cost category until the 2024 payment year. CMS notes that unless otherwise stated for purpose of this section of the proposed rule ‘MIPS eligible clinician’ does not include those who are scored by facility-based measurement.

(b) Scoring the Quality Performance Category

While the basic structure would be maintained, CMS proposes a number of changes to the scoring of the quality performance category for 2021 payment.

Quality Measure Benchmarks. Regulatory text at §414.1380(b) would be modified to reflect the changes in terminology with respect to data collection versus data submission. Separate benchmarks would be established for the following collection types: eQCMs; QCDR measures; MIPS CQMs; Medicare Part B claims measures; CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures. For example, the eCQM benchmark would apply regardless of whether the submitter is a MIPS eligible clinician, a group or a third-party intermediary. Benchmarks would be established by collection type from all available sources including MIPS eligible clinicians and APMs, to the extent feasible.

CMS seeks comments on potential future approaches to scoring the quality performance category and is interested in clarifying its benchmarking process and considering ways to align it with Physician Compare benchmarking as has been suggested by some past commenters.

3-Point Floor. CMS proposes to continue the 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period. It plans to revisit this policy in future rulemaking.

CAHPS for MIPS. CMS is concerned that some groups that expect to meet the beneficiary sampling requirements for the CAHPS for MIPS measure will find out late in the performance year that they have failed to do so, and therefore will not receive a score on this measure. It therefore proposes that beginning with the 2021 payment year, the denominator (the total available achievement points) would be reduced by 10 points for groups that register for the CAHPS for MIPS but do not meet the beneficiary sampling requirements. This would effectively remove the impact of the group not receiving a score on this measure, and the group would not

need to find a replacement measure. **CMS seeks comment on whether this proposed policy should be limited to one performance period**, as it does not want groups to register for the CAHPS measure knowing that they will not meet the beneficiary sampling requirements.

Assigning Achievement Points for Topped Out Measures. CMS previously adopted a policy that a measure identified as topped out for two consecutive years would receive a maximum of 7 achievement points. CMS refers readers to the 2018 MIPS Quality Benchmarks file for the measures topped out for 2018; these would be subject to the 7-point cap if also determined to be topped out for 2019. The 2019 file will be available later this year. The 2018 file is available at (<https://www.cms.gov/Medicare/Quality-PaymentProgram/Resource-Library/Resource-library.html>). CMS also seeks feedback on ways to score the CAHPS for MIPS Summary Survey Measures (SSMs), which are not currently subject to the policy for scoring topped out measures. Approaches it might use include scoring all SSMs, effectively meaning there would be no topped out scoring for the CAHPS for MIPS, or capping the SSMs that are topped out and score all the others.

Scoring Measures that Do Not Meet Case Minimum, Data Completeness, and Benchmarks Requirements. Table 47 in the proposed rule summarizes policies for measures that are submitted but cannot be scored because they do not meet case minimum or data completeness requirements, or because they do not have a benchmark. CMS proposes to continue these policies for the 2019 MIPS performance period. In addition, CMS proposes that beginning with the 2020 performance period, it would assign zero points to measures that do not meet data completeness requirements. It says that this is part of its effort to move toward complete and accurate reporting. Small practices would continue to receive 3 points for all future MIPS performance periods, although CMS says it may revisit this policy in the future.

Scoring for Measures with Clinical Guideline Changes During the Performance Period. CMS proposes that if a measure is significantly impacted by clinical guideline changes or other changes that it believes may pose patient safety concerns, it would suppress the measure without rulemaking. It says this would align with policies of the Hospital Value-Based Purchasing (VBP) Program (83 FR 20409) and others. CMS would publish suppressed measures on its website whenever technically feasible, but no later than the beginning of the data submission period. Scoring of suppressed measures would result in zero achievement points and a reduction of the total available achievement points (denominator) by 10 points.

Scoring for MIPS Eligible Clinicians that Do Not Meet Quality Performance Category Criteria. CMS previously adopted a policy to begin with the 2021 payment period under which it will validate the availability and applicability of quality measures only with respect to the collection type that a MIPS eligible clinician uses for the quality performance category for a performance period, and only if the clinician collects via claims only, MIPS CQMs only, or a combination of these two collection types. Consistent with the terminology changes it proposes elsewhere, CMS proposes to revise this policy to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen. For example, the policy would not apply to eCQMs even if they are submitted by a registry.

Small Practice Bonus. For the 2020 payment year, CMS will add a 5 point small practice bonus to the final score for clinicians, groups, APM entities and virtual groups who meet the definition of a small practice (§414.1305) and submit data on at least one performance category for the 2018 MIPS performance period. CMS proposes that for 2021 payment, it would add 3 points to the numerator of the quality performance category score for small practices that submit data on at least one quality measure. CMS says that the 3 points represents about 5 percent of the maximum quality performance category score of 60 for small practices, which generally are not measured on the readmission measure or able to participate in the CMS Web Interface. With a category weight of 85 percent, the 3 bonus points would result in 4.25 bonus points added to the final score for clinicians in small practices. (3 points/60 maximum points X .85 X 100 = 4.25) CMS recognizes that clinicians in small practices who do not receive reweighting for the cost or promoting interoperability performance categories would receive fewer than 4.25 bonus points in the final score, it believes that its proposal is simple and that a larger bonus could potentially over-inflate the quality bonus category score and mask poor performance.

Incentives to Report High-Priority Measures. CMS proposes to maintain for the 2021 payment year the cap on high-priority bonus points, which is set to equal 10 percent of the total possible measure achievement points the MIPS eligible clinician could receive in the quality performance category. However, measure bonus points would be discontinued for CMS Web Interface reporters for reporting high-priority measures. Bonus points were intended as a transition policy, and CMS has found that practices electing to report via the CMS Web Interface generally perform better than other practices, so the benefit of bonus points is limited and CMS believes they would create higher than normal scores. CMS Web Interface reporters who choose to report the CAHPS for MIPS survey in addition to the Web Interface would continue to receive bonus points for reporting that survey. CMS says that it will consider eliminating the high priority bonus points entirely after the 2021 payment year.

Incentives to Use CEHRT to Support Quality Performance Category Submissions. CMS proposes to continue to assign bonus points for end-to-end electronic reporting for the 2021 payment year, but to modify it to reflect the proposed changes in submission terminology. In what is described as a clarification of policy, the end-to-end reporting bonus would only apply to data that were submitted by direct, login and upload, and CMS Web Interface that meet the criteria finalized in the 2017 QPP final rule (81 FT 77297) and not to the claims submission type, which does not meet those criteria. CMS reiterates that it will consider in the future whether to no longer offer bonus points for end-to-end reporting on high-priority bonus points. **CMS invites comment on other ways to encourage use of CEHRT for quality reporting.**

Calculating Total Measure Achievement and Measure Bonus Points. No changes are proposed to the policy for calculating total measure achievements and bonus points for non-CMS Web Interface reporters. Terminology changes and technical changes to the regulatory text would apply. Table 48 in the proposed rule presents an example of assigning points for a clinician who submits measures collected across multiple collection types, which CMS expects would be a rare circumstance. CMS does not encourage clinicians to submit the same measure collected via multiple collection types.

Future Approaches to Scoring the Quality Performance Category. As discussed earlier in this summary, for the future, CMS expects to make changes to the quality performance category to reduce burden and potentially to implement a system where points are awarded based on assigning different values to measures. For example, measures might be classified into gold, silver, and bronze level tiers, where the gold measures (e.g., outcome or high-priority measures) would receive more points than measures in other tiers.

If this approach is adopted, the scoring methodology would be changed accordingly. CMS seeks comment on several possible approaches to simplify scoring, and whether they would encourage more accurate reporting of high value measures. The approaches are:

- Restructuring requirements with a pre-determined denominator (e.g., 50 points) but no specific requirements about the number of measures that must be submitted. Gold or top-tier measures would receive up to 15 or 20 points; up to 10 points would be given for measures in the next tier and up to 5 points for those in the lowest tier. A clinician electing to report top tier measures would not have to submit as many as one choosing measures from the other tiers. CMS may consider limiting the number of lower tier measures that could be submitted or requiring a certain number of highest tier measures.
- Continuing the requirements (6 measures including one outcome measure, all worth up to 10 points) but change the minimum number of measure points available by measure tier. For example, the highest tier measures might have a higher floor or qualify for a high priority bonus.
- Moving to sets of measures and removing the validation process to determine whether the eligible clinician has measures that are available and applicable, which CMS believes would simplify the category significantly. Creating sets of measures would eliminate the need for validation and allow for more robust benchmarks. Moving to a pre-determined denominator and allowing clinicians to determine the best method to achieve points would also eliminate the need for the validation process.
- Developing QCDR measure benchmarks using historical measure data, which CMS believes would encourage reporting of these measures. It understands that some clinicians are reluctant to report QCDR measures without established benchmarks because they are uncertain that a benchmark will be calculated which might limit them to a 3-point score. QCDRs would have to submit historical data in a form and manner that meets CMS' benchmarking needs; the data for this purpose would be submitted at the time of self-nomination of the QCDR measure. CMS seeks comment on whether QCDRs have the capability to extract data only for MIPS eligible clinicians and groups for this purpose, and to provide CMS with additional information it would need to analyze the data to ensure that it meets benchmarking standards (e.g., data sources, data completeness, and collection period).

CMS also invites comment on how to incorporate incentives for the use of ECQMs into the approaches described above, and welcomes comments on other approaches to simplify scoring, incentivize submission of outcome measures and develop data that can distinguish clinician performance and determine clinicians that provide high value care.

Improvement Scoring for the MIPS Quality Performance Category. CMS proposes to continue its policy for improvement scoring in the quality performance category for the 2019 MIPS performance period. Under this policy, 2019 performance would be compared to an assumed 2018 performance category achievement percent score of 30 percent for a clinician who earned a quality performance category score for 2018 that is less than or equal to 30 percent. Technical updates would be made to the regulatory text at §414.1380(b) regarding how improvement scores are incorporated into the quality performance category percent score.

(c) Scoring the Cost Performance Category

The BBA 2018 requires that the cost category improvement score will not take improvement into account until the 2024 MIPS payment year. CMS proposes to codify certain previously adopted policies for scoring the cost performance category and to revise the regulatory text to provide that the maximum cost improvement score for the 2020 through 2023 MIPS payment years is zero points.

(d) Facility-Based Measures Scoring Option for the 2021 MIPS Payment Year for the Quality and Cost Performance Categories

Eligibility for Facility-Based Measurement. Beginning with the 2019 performance period, CMS previously adopted a facility-based measurement scoring option for certain facility-based individual clinicians. Briefly, a MIPS eligible clinician furnishing at least 75 percent of his or her professional services in the inpatient hospital or emergency room settings (POS codes 21 or 23) is eligible for facility-based measurement.

In this rule, CMS proposes four changes to the determination of a facility-based individual.

- Professional services provided in the on-campus outpatient hospital setting (POS code 22) would be considered in determining eligibility for facility-based measurement. Commenters previously encouraged this change, and CMS now agrees that the current policy may prevent some clinicians from appropriate eligibility for facility-based measurement. It believes that the Hospital VBP Program captures quality provided in the outpatient department. Patients in observation status are generally treated by the same staff and clinicians as inpatients, for example.
- A clinician would be required to have at least one single service billed with the POS code used for the inpatient hospital or emergency room settings. This is intended to ensure that the clinicians eligible for facility-based measurement contribute to services that are measured under the Hospital VBP Program. That program relies on inpatient measures and CMS is concerned about making clinicians that provide services in the outpatient department that are unrelated to inpatient care eligible for the facility-based measurement. **Comments are sought on whether a better threshold could be used than the proposed one inpatient or emergency department service.** In analyzing claims data CMS found that only 13.45 percent of anesthesiologists would be eligible for facility-based measurement under the existing policy; this would increase to 72.55

percent under the proposal, including this restriction. The change for family physicians would be limited (11 percent to 14 percent).

- If a facility with a Hospital VBP Program score cannot be attributed to the clinician, the clinician would not be eligible for facility-based measurement. CMS believes this situation would be rare.
- The time period for determining eligibility for facility-based measurement would be aligned with changes to the dates used to determine MIPS eligibility and special status. Data (with a 30-day claims run out) from October 1st 2 years prior to the performance period through September 30 of the year preceding the performance period would be used to determine eligibility for the facility-based measurement.

Scoring of Facility-Based Groups. CMS further proposes changes regarding facility-based groups. Previously, CMS established eligibility for facility-based measurement for those groups in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements for facility-based measurement.

The attribution of groups would be modified to differentiate between how facility-based clinicians and groups receive a facility-based score. Currently, for both individual clinicians and groups, the facility-based measurement score is derived from the VBP score for the hospital at which the clinician or group provided services to the most Medicare beneficiaries (and in the case of a tie, the higher scoring hospital). Under the proposal, a facility-based group would receive a score derived from the VBP score for the facility at which the plurality of clinicians would have had their score determined if they received facility-based scores as individual clinicians. CMS believes this would reinforce the connection between an individual clinician and a facility and is more easily understandable for larger groups.

Election of Facility-Based Measurement. CMS previously adopted a policy that eligible clinicians and groups would elect facility-based measurement although a specific proposal for an attestation submission was not finalized. CMS also considered an alternative under which facility-based measurement would be assumed unless the eligible clinician or group opted out. CMS said that it received comments in favor and opposed to the opt-out approach.

In this rule, CMS proposes a modified policy that does not require an election or opt-out process. CMS would automatically apply facility-based measurement to eligible clinicians and groups and calculate a combined quality and cost performance category score. If CMS receives another MIPS data submission for the clinician or group it would assign the higher combined quality and cost performance category score. No formal process to opt-out of facility-based measurement would be required because the higher score would always be used. Clinicians in MIPS APMs are scored under the MIPS APM standard and would not be scored using facility-based measurement.

In MIPS, clinicians are scored as individuals unless they submit data as a group; this would also be true with respect to facility-based measurement. While there are no submission requirements for the quality performance category under facility-based measurement, a group must submit

data in the improvement activities or promoting interoperability categories to be measured as a group under facility-based measurement. Submitting these data would signal an intent to be scored as a group. If a group does not submit these data, facility-based measurement would be applied to individual clinicians. Virtual groups would have been formed prior to the MIPS performance period and those eligible for facility-based measurement would always be measured as a virtual group. CMS believes its proposal preserves the clinician's choice to be scored as a group without the burden of an election process. **Comments are solicited on other means to achieve the same ends as well as this proposal.**

Facility-Based Measures. In the 2018 rulemaking cycle, CMS adopted a policy that for the 2020 MIPS payment year, facility-based clinicians or groups that were attributed to the facility would be scored on all measures for which the hospital is scored under the Hospital VBP Program. CMS adopted a general facility-based scoring standard for later years but did not finalize specific measures.

In this rule, CMS proposes to continue to use the Hospital VBP Program measures for purposes of MIPS facility-based measurement scoring. The measures used would be for the fiscal year Hospital VBP program for which payment begins during the MIPS performance period. For example, for the 2019 MIPS performance period, the FY 2020 Hospital VBP Program measure set would be used. The performance periods for the measures vary but they all end during 2018. In addition, CMS proposes to use the Hospital VBP Program Total Performance Score for facility-based measurement. For informational purposes, Table 49 in the proposed rule lists the Hospital VBP Program measures for FY 2020.

The proposed regulatory text is written to refer generally to VBP programs and their measures, benchmarks and performance periods, so that in the future CMS could expand the facility-based measurement to other VBP programs.

Scoring Facility-Based Measurement. CMS proposes to modify the determination of the cost and quality performance category scores under facility-based measurement to reflect the proposal for replacing the opt-in process for facility-based measurement. Specifically, the percentile performance of the hospital in the VBP Program for the year would be determined and a score associated with that same percentile performance in the MIPS quality and cost categories awarded to those clinicians *who are not eligible to be scored* under facility-based measurement. The current language references the scores of clinicians *who are not scored* under facility-based measurement. The distinction is necessary to allow percentile performance to be determined independent of those clinicians who in the end may or may not receive the facility-based measurement score.

CMS did not previously address a policy for MIPS-eligible clinicians who are scored in MIPS through facility-based measurement in one year and through another method the following year. After consideration of options, CMS has concluded that it is not possible to assess improvement in this circumstance.

Expansion of Facility-Based Measurement to Other Settings. **CMS is interested in expanding facility-based measurement into post-acute care (PAC) and end-stage renal disease (ESRD)**

settings and seeks comment on how it may do this. Commenters in the past have suggested that clinicians who furnish care in PAC settings and bill Medicare Part B might be measured in the same way as hospital-based clinicians. CMS specifically invites comments on:

- How to attribute the quality and cost of care for patients in PACs to clinicians. Would an approach similar to the Hospital VBP approach work for PACs given the number and variation of settings? What level of influence do MIPS-eligible clinicians have in determining performance on quality measures for programs in PAC settings?
- What PAC quality reporting program measures would best be used to measure clinician performance? Should all measures reported to PAC quality reporting programs be included, or should a subset of measures be identified?⁴³
- Should facility-based measurement be limited to specific PAC settings and programs or should all PAC settings be considered?

For clinicians treating patients with ESRD, CMS says it believes that the ESRD Quality Improvement Program (QIP) methodology could be integrated into its current approach for facility-based measurement, although the structure is different from the Hospital VBP Program. For information on the ESRD QIP for 2020 CMS refers readers to 81 FR 77896-77931 and 82 FR 50760-50767. Comments are sought on the following:

- The extent to which the quality measures of dialysis centers reflect clinician performance.
- Can performance of a specific ESRD facility be attributed to an individual clinician? For the Comprehensive ESRD Care Model CMS ties a beneficiary to a dialysis facility, but clinicians are not linked in the same way.

(e) Scoring the Improvement Activities Performance Category

CMS proposes to retain previously adopted policies regarding scoring for the improvement activities category, with one change. Updates to the regulatory text and clarifications are also provided. The proposed change would require that an eligible clinician or group must attest to their status as a patient-centered medical home or comparable specialty medical practice for a continuous 90-day minimum during the performance period in order to receive the scoring credit. The clarifications are:

- Improvement activities score cannot exceed 100 percent.
- Unless a different scoring weight is assigned by CMS, performance in the improvement activities category comprises 15 percent of a clinician's final score beginning with the 2019 payment year.

⁴³ The proposed rule provides current *Federal Register* references for the various PAC quality reporting program measures for 2020. These are: long-term care hospitals (83 FR 20512-20515); inpatient rehabilitation facilities (83 FR 21001-21002); skilled nursing facilities (82 FR 36570-36594); home health agencies (82 FR 51717-51730); hospice (82 FR 36655-36656 and 83 FR 20956- 20957).

(f) Scoring the Promoting Interoperability Performance Category

No changes are proposed to scoring the promoting interoperability performance category.

(2) Calculating the Final Score

CMS proposes to continue the complex patient bonus for the 2021 MIPS payment year, modify the final score calculation, and refine the reweighting policies.

(a) Accounting for Risk Factors

CMS reviews work it has underway regarding the potential role of social risk factors in the MIPS scoring methodology, and references studies undertaken by the Assistant Secretary for Planning and Evaluation (ASPE) and the National Quality Forum socioeconomic status trial. It plans to continue working with ASPE, the public and key stakeholders on this issue.

Complex Patient Bonus for 2021 MIPS Payment. CMS proposes to continue for 2021 the complex patient bonus of up to 5 percent that was adopted for the 2020 payment year. The adjustment is meant to protect access to services for complex patients and avoid disadvantaging the clinicians who care for them. CMS emphasizes that this is a short-term solution while it continues research into the underlying issues, including the risk factor studies referenced above. It intends to analyze data from the 2017 MIPS performance period to identify performance differences and may in the future shift the complex patient bonus to specific performance categories.

Although no changes are proposed to the complex patient bonus, CMS notes that relevant dates may change as a result of other proposals in this rule. Specifically, the dates for the second 12-month segment of the MIPS determination period, which is used in the complex patient bonus when calculating average risk scores and proportion of dual eligible beneficiaries, would be modified. Under this proposed rule beginning with the 2021 payment year the second 12-month segment of the MIPS determination period would begin on October 1st of the calendar year preceding the performance period and end on September 30th of the year in which the performance period occurs.

(b) Final Score Performance Category Weights

As discussed in section III.H.3.h above, CMS proposes to modify the performance category weights for the 2021 payment year. Table 50, reproduced below, shows the previously adopted weights for the transition year and 2020 payment along with the proposals for 2021 payment. Specifically, the quality category weight would be decreased from 50 percent to 45 percent and the cost category weight concomitantly increased from 10 percent to 15 percent.

TABLE 50: Finalized and Proposed Weights by MIPS Performance Category and MIPS Payment Year

Performance Category	Transition Year (Previously Finalized)	2020 MIPS Payment Year (Previously Finalized)	2021 MIPS Payment Year (Proposed)
Quality	60%	50%	45%
Cost	0%	10%	15%
Improvement Activities	15%	15%	15%
Promoting Interoperability	25%	25%	25%

Flexibility for Weighting Performance Categories. CMS proposes to codify the policies it previously adopted for determining when there are sufficient measures applicable and available for the quality and cost performance categories and to continue them for subsequent payment years. Under the MIPS, CMS has the authority to assign different performance category scoring weights based on the extent to which the category is applicable to the type of clinician involved and the measure or activity is applicable and available to the type of clinician involved. Similarly, policies previously adopted for assigning a zero weight to the promoting interoperability category and redistributing that weight to other categories would be continued. CMS continues to believe that all MIPS eligible clinicians have sufficient activities applicable and available, except in the case of extreme and uncontrollable circumstances.

- Reweightings for Extreme and Uncontrollable Circumstances. A few modifications are proposed to the policies previously adopted regarding clinicians experiencing extreme and uncontrollable circumstances. CMS responds to past comments it received and **invites comments on the specific circumstances under which the extreme and uncontrollable circumstances policy should apply to third party intermediary issues.**
 - Beginning with the 2019 performance period, CMS proposes that if an eligible clinician submits an application for reweighting based on extreme and uncontrollable circumstances and also submits data on quality measures or improvement activities, the clinician would be scored on the submitted data and the categories would not be reweighted. Because data submission occurs after the performance period, CMS believes that clinicians would know about the extreme circumstances. In the case of a clinician submitting quality codes on claims which might occur prior to the extreme circumstance, no total score would be calculated unless they also submitted data for the improvement activities or promoting interoperability categories. In addition, administrative data used to calculate the cost category measures and some quality measures are not included in this proposal as CMS says it would not be appropriate to void a reweighting application based on receipt of administrative data.
 - Another proposed modification is that for groups submitting reweighting applications for extreme and uncontrollable circumstances CMS would apply the policy previously finalized for virtual groups. CMS would evaluate whether sufficient measures and activities are applicable and determine whether to reweight a performance category based on the information provided for the individual clinicians and practice locations affected by the extreme circumstances.

This proposal would apply beginning with the 2018 performance period (2020 payment year).

- Reweighting for Clinicians Joining a Practice in the Final 3 Months of the Performance Year. CMS proposes a new policy for cases in which an eligible clinician joins an existing practice (TIN) during the final 3 months of the MIPS performance period. In the case of a clinician joining in the final 3 months a practice that is not participating in MIPS as a group, CMS proposes that such a clinician would not have sufficient measures applicable and available. In the case of a clinician joining a new practice (new TIN), the clinician would not have sufficient measures applicable and available regardless of whether the clinicians in the practice report as individuals or a group. CMS proposes that in each scenario all four of the performance categories would be reweighted to zero and the clinician would receive a final score equal to the performance threshold and a neutral MIPS payment adjustment. CMS says this policy is proposed because no data on measures and activities from these clinicians are accessible from its data systems. By contrast, in the case of a clinician joining an existing practice that reports as a group, CMS can accept data for the group, and reweighting would not be necessary. Section III. H.3.j.1 below further discusses assigning group scores to MIPS eligible clinicians.
- Automatic Extreme and Uncontrollable Circumstances Policy. CMS proposes to codify the policy adopted for the transition year under which it will automatically reweight the performance categories for eligible clinicians who are affected by natural disasters or other extreme and uncontrollable circumstances affecting entire regions or locales. Although the transition policy did not include the cost performance category because it then had a zero weight, this proposal would include all four performance categories. Even if administrative claims data were received and a cost category score could be calculated, CMS would assign a zero weight to this category. This proposed policy would be effective beginning with the 2018 performance period/2020 payment year. CMS continues to believe that an automatic policy is not needed for groups; if it receives data for a group or virtual group, it will be scored, even if individual clinicians in the group are affected by an event that would be included in the automatic extreme and uncontrollable circumstances policy. CMS says that instead of creating an artificial threshold for groups to be eligible for the automatic policy, it is preferable that a group sufficiently impacted by an event apply for consideration for reweighting under the regular extreme and uncontrollable circumstances policy. CMS notes that if not all clinicians in a group are affected by an event but the practice location responsible for data submission was impacted, reweighting might be appropriate.

Redistributing Performance Category Weights. CMS proposes to codify previously adopted policies for redistributing performance category weights under the flexibilities discussed above. In general, where possible weights would be redistributed to the quality performance category. Table 51 in the proposed rule shows the performance category reweighting policies proposed for the 2021 payment determination, and an alternative weighting is offered for comment in Table

52. The table below combines the information in these tables. The alternative is based on previous comments stating that the policy places undue weight on the quality category.

Performance Category Redistribution Policies Proposed for the 2021 MIPS Payment Year and An Alternative (From Proposed Rule Tables 51 and 52)

Alternative shown in italics

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	45%	15%	15%	25%
Reweight One Performance Category				
-No Cost	60%	0%	15%	25%
-No Promoting Interoperability	70%	15%	15%	0%
-No Quality	0%	15%	40%	45%
-No Improvement Activities	60%	15%	0%	25%
<i>Alternative:</i>				
<i>-No Cost</i>	<i>55%</i>	<i>0%</i>	<i>20%</i>	<i>25%</i>
<i>-No Promoting Interoperability</i>	<i>60%</i>	<i>15%</i>	<i>25%</i>	<i>0%</i>
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	50%	50%
-No Cost and no Improvement Activities	75%	0%	0%	25%
-No Promoting Interoperability and no Quality	0%	15%	85%	0%
-No Promoting Interoperability and no Improvement Activities	85%	15%	0%	0%
-No Quality and no Improvement Activities	0%	15%	0%	85%
<i>Alternative:</i>				
<i>-No Cost and no Promoting Interoperability</i>	<i>70%</i>	<i>0%</i>	<i>30%</i>	<i>0%</i>

(c) Final Score Calculation

CMS proposes to revise the formula for calculating the final score to reflect its proposal (discussed above) to eliminate the small practice bonus from the final score calculation beginning with the 2021 payment year. Under that proposal, the bonus would apply to the quality performance category score instead. **CMS requests public comment on this proposal.**

CMS discusses comments it received in 2018 rulemaking, which it says it will take into consideration in the future. Responding to suggestions that the total number of points available for a category should be the category’s weight in the final score, CMS notes that the number of points for the quality and cost performance categories may vary based on whether all the measures apply. In addition, the reweighting of categories would make this simplification impossible. However, CMS says it values simplicity in MIPS scoring and **seeks comments on approaches to simplify calculation of the final score** that take these considerations into account.

j. MIPS Payment Adjustments

(1) Final Score Used in Payment Adjustment Calculation

Under previously adopted policies, for groups submitting data using the TIN identifier, CMS applies the group final score to all the TIN/NPI combinations that bill under the TIN during the performance period. CMS proposes to modify the timeline under this policy beginning with the 2019 performance period (2021 payment). Specifically, CMS proposes a 15-month window that starts with the second 12-month determination period (October 1 prior to the MIPS performance period through September of the MIPS performance period) and also includes the final 3 months of the performance period year (October 1 through December 31 of the performance period year). For groups submitting data using the TIN identifier, the group final score would be applied to all TIN/NPI combinations that bill under that TIN during the proposed 15-month window. CMS believes that partially aligning with the second 12-month determination period creates consistency with its eligibility policies. MIPS determination periods are discussed in section III.H.2.b. of this summary. CMS notes that if a MIPS eligible clinician's TIN/NPI combination was not part of the group practice during the MIPS determination period, the TIN/NPI combination would not be identified in CMS' system at the start of the MIPS data submission period; however, if the MIPS eligible clinician qualifies to receive the group final score under the proposal, CMS would apply the group final score to the MIPS eligible clinician's TIN/NPI combination as soon as the information becomes available.

(2) Establishing the Performance Threshold

The Secretary is required to annually compute a performance threshold for purposes of determining the MIPS payment adjustment factors. The threshold is either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. The statute provides for special rules for the initial 2 years of the MIPS, and as a result of the BBA of 2018, an additional special rule applies for the third year through the fifth year (payment in 2021 through 2023). The new additional special rule requires the Secretary to increase the performance threshold for each of the three specified years to ensure a gradual and incremental transition to the performance threshold specified for year six (2024).

For purposes of the proposed rule, CMS relied on data from the 2017 QPP final rule regulatory impact analysis (81 FR 77514-77536). CMS considered using final scores for the 2017 MIPS performance period (2019 payment year) but final scores were not available in time to use for the proposed rule. If technically feasible, CMS would consider using these scores to estimate a performance threshold for 2024 in the final rule. CMS performed analyses based on two assumptions regarding the percent of eligible clinicians who will submit quality performance data. One analysis assumed 90 percent participation and the other assumed 80 percent participation. Using these assumptions CMS found the estimated mean final score for 2019 to be between 63.50 and 68.98 points and the median between 77.83 and 82.5 points. For purposes of estimating the 2024 payment year performance threshold, CMS used the mean final score range. **Comments are sought on the approach to estimating the 2024 performance threshold, including whether the median should be used instead of the mean, and whether in the future final scores from another payment year should be used.** CMS notes that its modeling

has shown that mean scores are lower than the median, and it would expect a larger proportion of clinicians to have final scores above the mean, rather than the median.

For 2021 payment, CMS proposes a performance threshold of 30 points, which it says would represent a modest increase over the 15 points established for the 2020 payment year and would provide for the required gradual and incremental transition to the estimated 2024 performance threshold of 63.5 to 68.98 points.

CMS discusses how to encourage MIPS participation and the collection of meaningful data from eligible clinicians. A higher threshold would encourage more complete reporting and better performance in anticipation of the 2025 payment year, but if too high would create a performance barrier, especially for clinicians that did not participate in previous quality reporting and promoting interoperability programs. CMS says stakeholders have offered differing views on this issue; it believes that 30 points for 2021 represents a gradual yet meaningful increase. Examples of different ways in which a MIPS-eligible clinician may achieve 30 points are discussed. **CMS seeks comment on alternative numerical values for the 2021 performance threshold, such as 25 points or 35 points.**

In addition, CMS seeks comment on whether to establish a path forward to a performance threshold for the 2024 MIPS payment year. Such a path would provide certainty to clinicians while ensuring a gradual and incremental increase from the performance threshold for the 2021 MIPS payment year to the estimated performance threshold for the 2024 MIPS payment year. CMS offers the example of setting a performance threshold of 30 points for the 2021 payment year, 50 points for 2022, and 70 points for 2023. Slightly lower values could be used if the estimated performance threshold for 2024 remains similar to the current estimate. CMS sees value to MIPS eligible clinicians in knowing the performance threshold in advance for the 2022 and 2023 MIPS payment years. However, CMS also believes that its estimates for the 2024 MIPS payment year performance threshold may change in the future as it obtains actual MIPS data and, therefore, it may be appropriate to propose the performance threshold annually.

(3) Additional Performance Threshold for Exceptional Performance

CMS proposes that for the 2021 payment year the additional performance threshold for exceptional performance would be set at 80 points. For 2020 payment the threshold was previously set at 70 points. Clinicians with final scores at or above this threshold are eligible to share in the \$500 million available for additional payments for exceptional performance. The 80-point threshold for 2021 payment is proposed under the special rule authority provided in the statute. CMS says that because it does not yet have MIPS final scores for a prior performance period, without using the special rule it would be required to set the threshold at the 25th percentile of possible final scores above the performance threshold, which in this case would be 47.5 points, a level that it believes is too low to be recognized as exceptional performance. CMS believes this proposed additional performance threshold level is appropriate because to achieve 80 points, a clinician would have to perform well on at least two performance categories and would have to submit data for the quality performance category. (That is because perfect scores on the other performance categories would only total 55 points.) CMS may consider additional increases to the additional performance threshold for future years.

(4) Application of the MIPS Payment Adjustment Factors

(a) Application to the Medicare Paid Amount for Covered Professional Services

CMS proposes changes to how the MIPS payment adjustment factor is applied in order to conform to changes enacted in the BBA of 2018. Specifically, instead of continuing to apply the factor to the Medicare paid amount for Part B items and services furnished by the MIPS eligible clinician during the year, beginning with the 2019 payment year the factor would be applied to Part B payments for covered professional services (defined as those services for which payment is made under or based on the Medicare Physician Fee Schedule) and which are furnished by an eligible professional. Conforming changes to the regulatory text would be made. The proposed formula would multiply the amount otherwise paid under Part B for covered professional services provided by a MIPS eligible clinician for a payment year by 1 plus the sum of: the MIPS payment adjustment factor divided by 100, and if applicable, the additional MIPS payment adjustment factor divided by 100.

(b) Application for Non-Assigned Claims for Non-Participating Clinicians

CMS proposes for the first time a policy regarding application of the MIPS payment adjustment for non-assigned claims for non-participating clinicians. Beginning with the 2019 MIPS payment year, the MIPS payment adjustment would not apply for non-assigned claims for non-participating clinicians, an approach consistent with the policy for application of the value modifier. A non-assigned claim is one where non-participating clinicians choose not to accept assignment for a claim, Medicare makes payment directly to the beneficiary, and the physician collects payment from the beneficiary. If the MIPS payment adjustment was applied to non-assigned claims it would not affect payment to the MIPS eligible clinician; it would only affect Medicare payment to the beneficiary. CMS notes that in this case Medicare payment to a beneficiary would be increased when the MIPS payment adjustment is positive and decreased when the MIPS payment adjustment is negative. CMS believes that beneficiary liability should not be affected by the MIPS payment adjustment, which should be applied to the amount that Medicare pays to MIPS eligible clinicians. CMS does not expect that this proposal would affect a clinician's decision to participate in Medicare or to otherwise accept assignment for a particular claim. **However, CMS seeks comment on whether stakeholders and others believe clinician behavior would change as a result of this policy.**

(c) Waiver of the Requirement to Apply the MIPS Payment Adjustment to Certain Payments in Section 1115A Models

CMS proposes that beginning in the 2019 payment year the MIPS payment adjustment factors (including the additional payment adjustment for exceptional performance) would not apply to certain payments made under a Center for Medicare & Medicaid Innovation (CMMI) model for the duration of the model's testing. CMS makes this proposal using the waiver authority under section 1115A(d)(1) of the Act; it is concerned that without the waiver, the testing and evaluation of the payment and savings impacts of model-specific payments made under CMMI models may not be possible. The waiver would not apply to payments made outside of a CMMI model. In the proposed rule the Monthly Enhanced Oncology Services (MEOS) payment in the Oncology Care Model (OCM) is discussed as an example of why the waiver is needed. Briefly, CMS is

concerned that if the MIPS payment adjustment factors are applied and OCM practices therefore receive differential MEOS payment amounts it would interfere with the model payment incentives and make it difficult to discern the appropriate monthly payment amount. CMS proposes to provide public notice when new model-specific payments subject to the waiver are announced on the QPP website (www.qpp.cms.gov) and in a *Federal Register* notice.

(d) Exclusion of MIPS Eligible Clinicians Participating in the MAQI Demonstration

CMS proposes waiving MIPS reporting and payment adjustment requirements for certain eligible clinicians participating in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration. CMS announced the MAQI Demonstration in conjunction with the release of this proposed rule; the demonstration is contingent on the proposed waivers being finalized. The MAQI Demonstration is created using authority under section 402 of the Social Security Amendments of 1968 (as amended). The demonstration announcement is available at: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-07-12.html>.

The MAQI Demonstration is designed to test whether excluding MIPS eligible clinicians who participate in certain payment arrangements with Medicare Advantage Organizations (MAOs) from the MIPS reporting requirements and the MIPS payment adjustment will increase or maintain participation in these payment arrangements, which are similar to Advanced APMs.

In this rule CMS proposes to use the authority in section 402(b) of the Social Security Amendments of 1968 to waive requirements of section 1848(q)(6)(E) of the Act and the associated implementing regulations to waive the payment consequences of the MIPS and to waive the associated MIPS reporting requirements in 42 CFR part 414, subject to conditions outlined in the demonstration.

Using the proposed waivers, the MAQI Demonstration would allow certain participating clinicians to be excluded from the MIPS reporting requirements and payment adjustment. To qualify for the exclusion for a payment year, clinicians would be required to participate to a sufficient degree in a combination of Qualifying Payment Arrangements with MAOs and Advanced APMs with fee-for-service Medicare during the performance period for that year without meeting the criteria to be QPs or otherwise meeting a MIPS exclusion criterion under the QPP. For purposes of the MAQI Demonstration, requirements for Qualifying Payment Arrangements would be consistent with the criteria for Other Payer Advanced APMs under the QPP.

In order to attain waiver of the MIPS reporting requirement and payment adjustment, CMS proposes that the combined thresholds for Medicare payments or patients through Qualifying Payment Arrangements with MAOs and Advanced APMs that a participating clinician would have to meet would match the thresholds for participation in Advanced APMs under the Medicare Option of the QPP. In 2018, those thresholds are 25 percent for the payment amount threshold and 20 percent for the patient count threshold. Under the MAQI Demonstration, aggregate participation in Advanced APMs and Qualifying Payment Arrangements will be used,

without applying a specific minimum threshold to participation in either type of payment arrangement.

The threshold for a clinician to qualify for the waivers using participation in these specific payment arrangements could be met with respect to a certain percentage of payments or a certain percentage of patients tied to participation in a combination of Advanced APMs and Qualifying Payment Arrangements. As noted above, the thresholds would be those used under the Medicare Option of the QPP. CMS proposes to begin the MAQI Demonstration in 2018, with the 2018 Performance Period, and operate the project for a total of 5 years.

The proposed waivers would also prohibit reporting under the MIPS by eligible clinicians who participate in the MAQI demonstration. CMS says this is necessary to prevent a potential gaming opportunity for participating clinicians to intentionally report artificially poor performance under the MIPS while they are operating under waivers from MIPS payment consequences, then later receive artificially inflated quality improvement points under MIPS when the waivers have expired. Clinicians who participate in the demonstration but are not excluded from MIPS (whether through participation in the demonstration or otherwise) would continue to be MIPS eligible clinicians who are subject to the MIPS reporting requirements and payment adjustment as usual.

Because of the requirement to ensure budget neutrality with regard to the MIPS payment adjustments, removing MIPS eligible clinicians from the MIPS payment adjustment calculations may affect the payment adjustments for other MIPS eligible clinicians. It is for this reason that CMS says it has made proceeding with the demonstration contingent on its finalizing the proposed waivers.

(e) Example of MIPS Adjustment Factors

Figure A⁴⁴, copied below from the proposed rule, illustrates how scores would be converted into adjustment factors as proposed for 2021 payment. The proposed performance threshold is 30 points, and the applicable percentage is 7 percent. As shown, clinicians with a final score of 30 would receive a 0 percent adjustment. The scale for other scores is not completely linear for two reasons. First, all clinicians with a final score between 0 and $\frac{1}{4}$ of the performance threshold (0 and 7.5 in the example) would receive the lowest negative adjustment of -7 percent. Second, the linear sliding scale line for the positive adjustment factor is affected by the budget neutrality scaling factor. If the budget neutrality scaling factor is greater than 0 and less than or equal to 1.0, then the adjustment factor for a final score of 100 would be less than or equal to 7 percent. If the scaling factor is above 1.0, but less than or equal to the specified limit of 3.0, then the adjustment factor for a final score of 100 would be higher than 7 percent. CMS anticipates that with a performance threshold of 30 points, the scaling factor would be less than 1.0 and the payment adjustment for clinicians with a final score of 100 would be less than 7 percent.

⁴⁴ In the July 12th *Federal Register* display copy of the proposed rule, Figure A was missing information. The corrected July 18th version is shown here.

CMS indicates that for Figure A, the illustrative budget neutrality scaling factor is 0.229; MIPS eligible clinicians with a final score of 100 would receive an adjustment factor of 1.6 percent (7.0 percent X 0.229).

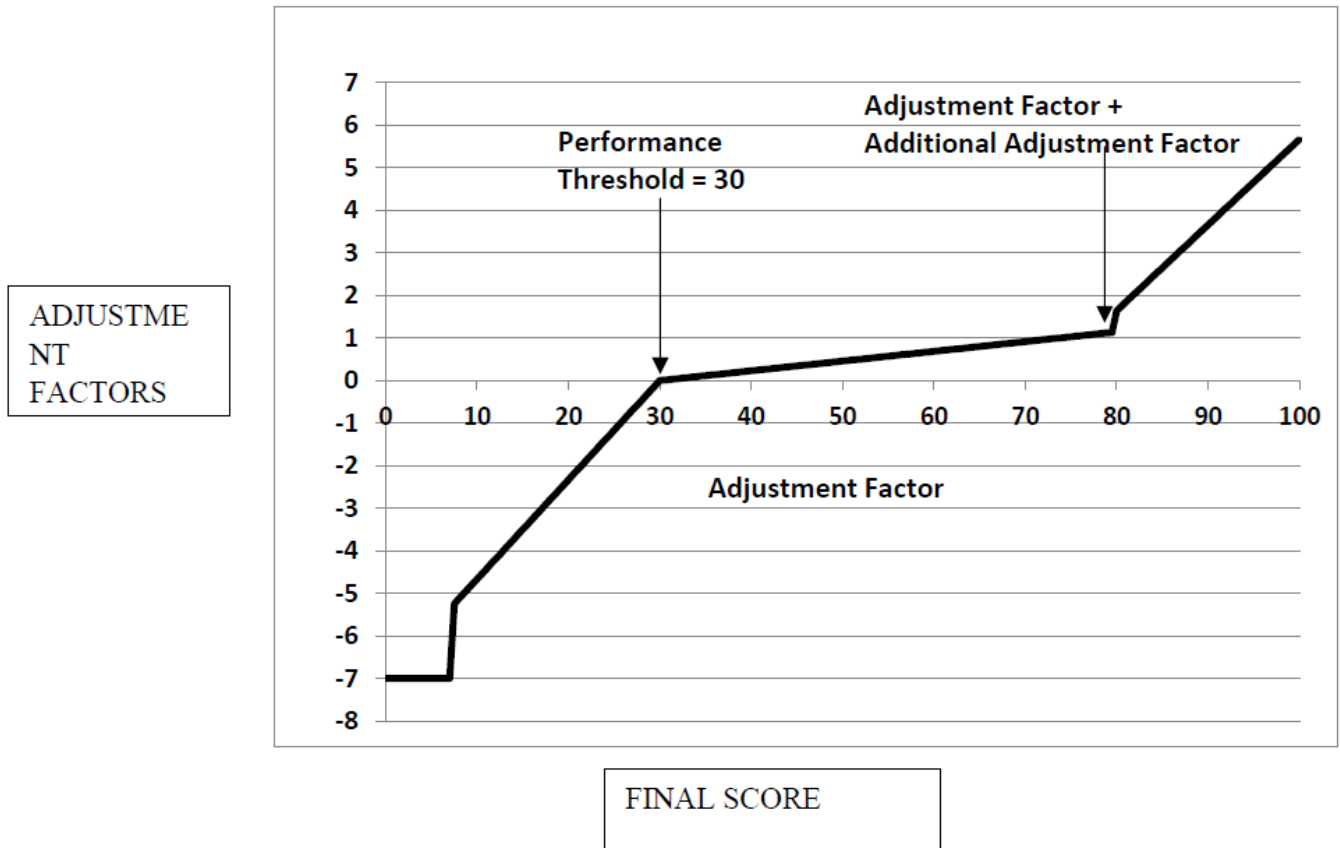
The additional performance threshold is 80. A score of 80 would receive an additional adjustment factor of 0.5 percent and the factor would increase to the statutory maximum of 10 percent for a perfect final score of 100, with a separate scaling factor applied to ensure distribution of the \$500 million payments. CMS also indicates that for Figure A, the illustrative scaling factor for the additional adjustment is 0.407; a clinician with a final score of 100 will receive an additional adjustment factor of 4.07 percent (10 percent X 0.407), and therefore a total adjustment of 5.67 percent (1.6 percent + 4.07 percent).

CMS notes that the actual MIPS payment adjustments will be determined by the distribution of performance scores; the greater the number of clinicians above the threshold, the more the scaling factors will decrease, and vice versa.

Table 53 in the proposed rule compares the point system and associated adjustment adopted for the transition year and for the 2020 MIPS payment year to the proposals for 2021 payment.

The proposed rule also includes three examples of how MIPS eligible clinicians can achieve a final score at or above the finalized 15-point performance threshold. The examples are for a clinician in a small practice with one quality measure and one improvement activity; a medium size group; and a non-patient facing clinician.

FIGURE A: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2021 MIPS Payment Year



k. Third Party Intermediaries⁴⁵

(1) General Considerations

To better reflect the function and purpose of §414.1400, CMS proposes to change the section’s heading from “Third party data submissions” to “Third party intermediaries” and proposes to define the term “third party intermediary” as an entity that has been approved under §414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the Quality, Improvement Activities, or Promoting Interoperability performance categories.

CMS proposes to require that a third party intermediary’s principal place of business and retention of associated CMS data must be within the U.S. CMS believes that a non-U.S.-based intermediary would encounter substantial barriers to the identity proofing that is needed to gain access to CMS IT systems. However, CMS emphasizes that those intermediaries authorized by

⁴⁵ Previously finalized policies are found at (82 FR 53806 through 53819).

the agency to submit data to MIPS have not been evaluated for the capabilities, quality, or any other features or its products; also, neither the federal government nor CMS endorses or recommends any third party intermediary or its products.

Finally, CMS proposes to update its certification requirements for data submission by intermediaries to state that all data submitted to CMS by a third party intermediary must be certified as true, accurate, and complete to the best of its knowledge and that such certification must be made in a form and manner and at such time as specified by CMS. CMS proposes these changes because it has determined that it is not operationally feasible to fully implement the existing requirements. (CMS also refers readers to proposed modifications to data submission terminology found in section III.H.3.h of the rule.)

(2) Modifications to QCDR Requirements

Definition. QCDR self-nominations and their measure submissions have been increasing. Through recent interactions with QCDRs, CMS has found that some of these entities have predominantly technical backgrounds and are limited in their clinical quality measurement expertise. As a result, measures submitted by those QCDRs often have not undergone the same consensus development, scientific rigor, and clinical assessment that is needed for developing measures, compared to those QCDR measures that are developed by entities with clinical expertise (e.g., specialty societies). To ensure that QCDR owners remain focused on the goals of improving the quality of clinical care and providing reliable quality reporting options for use by clinicians, CMS proposes to update the definition of a QCDR to read “an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.” CMS would follow-up directly with those entities as needed to assure uniform standards are being met by all QCDRs. CMS also proposes to support collaboration of entities with complementary expertise (e.g., technical versus clinical) provided that the collaborators have a signed, written agreement detailing each partner’s responsibilities.

CMS notes that less broadly-skilled entities considering self-nomination as QCDRs may wish to consider qualifying instead as a clinical registry. CMS has also become aware that some QCDRs may not be prepared to accept data from MIPS eligible clinicians starting with January 1 of a performance period which may impair a clinician’s ability to report required quality data via that QCDR and thereby diminish the potential for care improvement. To address this challenge, CMS proposes that beginning with the 2020 performance year, a QCDR must have at least 25 participants by January 1 of the year prior to the performance period rather than the current requirement of January 1 of the performance year.

QCDR Self-Nomination Period. CMS proposes to update the self-nomination period and the information required at the time of self-nomination. Currently QCDRs must self-nominate between September 1 and November 1 of the year prior to the performance year and must provide all CMS-requested information coincident with self-nomination. This timeline is structured to allow CMS to publish the approved list of QCDRs and their approved measures before the performance period starts. CMS has learned from self-nominees that they need more

time to respond to CMS requests for more information; further, CMS believes that the agency itself needs more time to properly review and process all the measure submissions before the performance period start date. Accordingly, CMS proposes to change the self-nomination period to run for 60 days, from July 1 until September 1 of the year preceding the performance period; the proposed change would take effect with performance year 2020. All required information must be submitted at the time of self-nomination as well as any CMS-requested information.

QCDR Measure ID Use. CMS assigns a QCDR measure ID to each approved QCDR measure. Stakeholder feedback has suggested confusion about proper use of the measure ID. In response, CMS proposes to specify that QCDRs must include their assigned measure ID number when posting their approved QCDR measure's specifications and when submitting data on the QCDR measures to CMS. CMS also notes that the same assigned ID must be used by all other QCDRs that also have received approval to report that measure.

QCDR Measure Requirements. To facilitate selection and approval of QCDR measures, CMS previously finalized a policy that measure submissions must provide specifications for each measure, activity, or objective for which the QCDR will seek approval as well as provide descriptions and narrative specifications for each measure, activity, or objective. All information must be submitted to CMS no later than November 1 of the applicable performance period for which the QCDR wishes to submit data for the Quality, Improvement Activities, or Promoting Interoperability performance category, starting with the 2018 performance period and in future program years. CMS now proposes to consolidate the finalized standards and criteria at §414.1400(b)(3) and to adopt into the QCDR measure approval process some criteria currently used in the MIPS Call for Measures Process. The latter change is proposed by CMS as an adjunct to improving the reliability and validity of new measures and to accelerating movement towards using consistent selection standards and criteria for all MIPS quality measures. Specifically, in addition to the QCDR measure criteria at proposed §414.1400(b)(3), CMS proposes to apply the following criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS:

- Measures that are beyond the measure concept phase of development.
- Preference given to measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.
- Measures that address the payment for patient and caregiver experience.
- Measures that address efficiency, cost and resource use.
- Measures that address significant variation in performance.

CMS notes that further alignment of criteria for QCDR and MIPS quality measures likely will be judged to be appropriate in future years.

Shared Measure Use by Multiple QCDRs. CMS has previously established a policy for the 2018 performance year (and future program years) that allows one or more QCDRs to request permission from another QCDR to use an existing measure owned by the latter entity. This policy was intended to reduce overlap and duplication among QCDR measures and could

potentially enhance benchmark reliability and clinician performance by allowing reporting of a measure by a larger cohort of clinicians. CMS reports learning of an unanticipated and unintended consequence in which some measure owners are charging fees to other QCDRs who seek permission to report on the owner's measure. CMS states that all MIPS quality measures are generally freely available for use by MIPS eligible clinicians and third party intermediaries. CMS further states its belief that QCDR measures approved for MIPS reporting should likewise be freely available for MIPS reporting by other QCDRs. CMS, therefore, proposes to condition QCDR approval for MIPS reporting on the execution of a license agreement by the measure's owner with CMS. The agreement would permit any approved QCDR to submit data on the shared measure (without modification) to MIPS for each applicable payment year. Refusal to enter into a license agreement would trigger rejection by CMS of the owner's measure and, potentially, approval by CMS of a similar measure instead. CMS further proposes to codify that the same CMS-assigned QCDR measure ID must be used by all QCDRs reporting on a shared measure.

(3) Qualified Registries: Self-Nomination⁴⁶

CMS proposes several policy updates regarding self-nomination by qualified registries. First, beginning with the 2020 performance year, a qualified registry would be required to have at least 25 participants by January 1 of the year prior to the performance period rather than the current requirement of January 1 of the performance year. The updated requirement is designed to ensure that the registry would be ready to accept data submissions in time for the beginning of the applicable performance year and would align with the analogous proposed requirement for QCDRs. Lack of preparedness may reduce clinician engagement in quality improvement activities.

Second, CMS proposes to update the period for self-nomination by qualified registries, currently from September 1 until November 1 of the year prior to the performance year to July 1 until September 1 of the year preceding the performance period. The registry must provide all required materials as well as CMS-requested information coincident with self-nomination. The new timeline would take effect with performance year 2020.

(4) Health IT Vendors

Policies have been established by CMS regarding health IT vendors (or other authorized third parties) that obtain data from MIPS eligible clinicians, including through the clinicians' CEHRT systems. Health IT vendors, as a type of third party intermediary, are subject to CMS' requirements for intermediaries (discussed previously in this summary). CMS now proposes to codify the definition of a health IT vendor at §414.1305 to read: "an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT)." CMS also proposes to indicate at §414.1400(d) that a health IT vendor seeking approval as a third party intermediary would be required to submit data in the form and manner specified by CMS.⁴⁷

⁴⁶ Established policies are described at 82 FR 53815-53818.

⁴⁷ CMS also notes that a health IT vendor may also be a health IT developer under the ONC Health IT Certification Program. Vendors may maintain a range of data transmission, aggregation, and calculation services or functions

(5) CMS-Approved Survey Vendors

CMS proposes that entities seeking to be survey vendors for any CMS-approved MIPS performance period would be required to submit a survey vendor application, in a form and manner specified by CMS, for each MIPS performance period in which the vendor wishes to transmit data. Entities would be required to meet all CMS' deadlines for submitting their applications and all supplemental materials. CMS proposes the following additional criteria that a potential vendor must demonstrate; the vendor must:

- Have sufficient experience, capability, and capacity to accurately report CAHPS data, including:
 - At least 3 years of experience administering mixed-mode surveys including mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);
 - At least 3 years of experience administering surveys to a Medicare population;
 - At least 3 years of experience administering CAHPS surveys within the past 5 years;
 - Experience administering surveys in English and one of the following languages: Cantonese, Korean, Mandarin, Russian, or Vietnamese;
 - Use equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and
 - Employ a program manager, information systems specialist, call center supervisor, and mail center supervisor to administer the survey.
- Have certified it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data.
- Have successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors.
- Have submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts.
- Have agreed to participate and cooperate, and has required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors.
- Have sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

(6) Auditing of Third Party Intermediaries Submitting MIPS Data

CMS does not propose any changes to previously finalized policies concerning audit processes for third party intermediaries submitting MIPS data.

(e.g., facilitating health information exchange).

(7) Remedial Actions and Termination of Third Party Intermediaries

Policies for probation and disqualification of third party intermediaries were established by CMS for performance year 2017. CMS now proposes to consolidate and restructure those and other third party remediation policies in a section to be titled “Remedial actions and termination of third party intermediaries” at §414.1400(f). CMS believes that the revised title would better describe the section’s functions: 1) identifying noncompliance with third party intermediary criteria, and 2) recognizing issues potentially impacting CMS’ ability to accurately use the data submitted by the intermediaries. CMS proposes to take one or more remedial actions upon determining that a third party intermediary (i.e., a QCDR, health IT vendor, qualified registry, or CMS approved survey vendor) no longer meets one or more of the applicable criteria for approval by CMS, or has submitted data that is inaccurate, unusable, or otherwise compromised. CMS could determine data to be inaccurate, unusable, or otherwise compromised if the data were found to include TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and to affect more than three percent (but less than 5 percent) of the total number of MIPS eligible clinicians for which data were submitted by the third party intermediary.

CMS proposes that the potential remedial actions available to CMS, after providing written notice to the intermediary, would include (i) requiring submission to CMS of a Corrective Action Plan that addresses identified deficiencies or data issues and details efforts to prevent recurrent problems, and (ii) public disclosure of the intermediary’s data error rate if that rate is 3 percent or greater, and not removing the error rate from the CMS website until the rate falls below 3 percent.

CMS further proposes to terminate (immediately or with advance notice) a third party intermediary from MIPS data submission for one or more of the following reasons:

- CMS has grounds for remedial action.
- CMS has not received a CAP within the CMS-specified time.
- The intermediary fails to correct the deficiencies or data errors by the CMS-specified date.

Finally, CMS proposes to remove its probation policy along with its definition of probation and all references to probation.

I. Public Reporting on Physician Compare

(1) General Considerations

CMS intends to continue a phased approach to public reporting of MIPS and APM related data for QPP year 3 on the Physician Compare Initiative website; it plans to report 2019 data, as available, in late 2020. Utilization data (information related to items and services furnished to Medicare beneficiaries) also are added annually to the Physician Compare downloadable database. (<https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/>) To be reported, all data must first meet CMS’ established reporting standards (see §414.1395(b)), and clinicians are provided with an opportunity for data review and correction before the data are released publicly. CMS notes that

while all information submitted under MIPS is available for public reporting (i.e., meets standards and is provided to clinicians for review and correction, limited only by technical feasibility constraints), not all data actually will appear on either the public-facing profile pages or in the database, in order to avoid overwhelming website users. CMS makes decisions about how and where measures are reported on the website through statistical testing and website user testing plus consultation with the Physician Compare Technical Expert Panel. CMS believes that Physician Compare data reporting encourages quality improvement by clinicians and assists beneficiaries with healthcare decision-making.

(2) MIPS Reporting on Physician Compare by Performance Category

In General. As finalized for CY 2018 and all future years, MIPS final scores along with results for each MIPS category (Quality, Cost, Improvement Activities, and Promoting Interoperability) are reported publicly by CMS for all MIPS eligible clinicians. Further, aggregate information for all eligible clinicians is added to the website periodically, including ranges for final scores and ranges for performance by category.

Quality. CMS reaffirms its existing policy that all MIPS Quality performance category measures are available for public reporting on Physician Compare, including all available measures across all collection types for MIPS eligible individual clinicians and groups. (Hereafter clinicians will be used to mean individuals and groups.) For each measure listed in the downloadable database, the total number of patients for whom data were submitted is provided. Current policy also provides that results of a “first year quality measure” (in its first year of use within the Quality performance category) will not be reported. CMS proposes two changes for performance year 2019 intended to encourage the reporting of new measures, as follows:

- Revise §414.1395(c) so that results of newly introduced quality measures will not be publicly reported for the first two years that the measure is in use; and
- Update the terminology for public reporting standards from “submission mechanisms” to “collection types” at §414.1395(b).

Cost. In keeping with previously finalized policies, CMS currently includes all available MIPS Cost performance category measures on Physician Compare and does not publicly report the results of first year cost measures. CMS proposes a single change for performance year 2019 for Cost category reporting: to revise §414.1395(c) so that results of newly introduced cost measures will not be publicly reported for the first two years that the measure is in use (analogous to the change proposed for the Quality performance category).

Improvement Activities. Existing policies provide that successful completion of the Improvement Activities performance category requirements is reflected on Physician Compare as an indicator. In contrast to the Quality and Cost categories, first year activities are publicly reported for this category. CMS does not propose any changes to the MIPS Improvement Activities performance category for performance year 2019.

Promoting Interoperability (formerly Advancing Care Information). CMS reprises policies previously finalized for the Promoting Interoperability performance category, as follows:

- Successful performance is defined as achieving the base score of 50 percent and is reported publicly with an indicator on Physician Compare. Beginning with performance year 2018, performance is to be indicated as “high” for scores of 100 percent (2018 data to be available for reporting in late 2019).
- Objectives, activities, and measures as specified in the CY 2018 QPP final rule for all available collections types and all MIPS-eligible clinicians are also reported on the website.
- First year objectives, activities, and measures are publicly reported for this category.

CMS now proposes not to include the “high” performance indicator, keeping only the indicator for “successful.” This change would be implemented beginning with the reporting of performance year 2018 data (available for reporting in late 2019), reversing the change adopted in the CY 2018 final rule. CMS bases this proposal on website testing that showed accurate differentiation of “successful” and “high” was problematic for users. **CMS solicits comment on the type of EHR utilization performance information stakeholders would like CMS to consider adding to Physician Compare. This information would be considered for possible future inclusion with other Promoting Interoperability data on the website.**

(3) Benchmarking

In General. CMS asserts that benchmarks provide important reference points facilitating comparisons across clinicians by Physician Compare users. For performance year 2018, CMS finalized a policy implementing the Achievable Benchmark of Care (ABC™) methodology for annual use with all MIPS categories to set benchmarks by measure and collection type using the most recently available data for each year. CMS also finalized using the ABC™ benchmarks in combination with the equal ranges method in creating 5-star ratings for all available measures. More information about the ABC™ and equal ranges methodologies, including the Benchmark and Star Rating Fact Sheet, is available on the Physician Compare website.

Historical Data-Based Benchmarks. CMS believes that star ratings and their underlying benchmarks aid beneficiary understanding of the Physician Compare data and assist clinicians with understanding their own data, as well as allowing comparing themselves to peers. CMS initially established that benchmarks for each performance year would be constructed using only the most recently available data (from the performance year itself). This approach assured that benchmarks would reflect current measure specifications, since measures were expected to change frequently during the early years of MIPS implementation. However, this approach also prevents release of the benchmark to clinicians before the performance year starts.

Believing that measure stability has increased over time, CMS now proposes that benchmarks be built by incorporating historical data (rather than the most recent) into the ABC™ methodology, beginning with QPP Year 3 (2019 data for 2020 public reporting). Each measure would use data from a baseline period, defined as the 12-month calendar year that is two years prior to the performance period. For example, performance year 2019 benchmarks would be calculated using 2017 performance year data and published by January 1, 2019. CMS would substitute current performance year data for baseline period data in calculating the benchmark if the baseline period data were unavailable (e.g., 2019 performance data would be used to build

benchmarks for CY 2019 performance period measures where benchmark period data were unavailable). The historical benchmarks would be published before the beginning of the relevant performance period, permitting clinicians to understand the performance required to receive a 5-star rating before data collection begins.

QCDR Measure Benchmarks. Presently on Physician Compare, star ratings are shown for MIPS measures but not QCDR measures; the latter are publicly reported as percent performance rates. CMS notes that QCDR data suitable for public reporting is proliferating and the number of QCDR measures is growing. CMS believes that creating star ratings for QCDR measures would add to their value, enhancing website user experience by aligning performance reporting formats and expanding the information available to beneficiaries for healthcare decision-making. CMS, therefore, proposes to determine a benchmark and 5-star rating by measure and collection type for QCDR measures by using the ABC™ and equal ranges approaches. CMS proposes a two-step implementation, first using the most recent data (2018 performance data, (available for reporting in late 2019) and then transitioning to historical benchmarking (as proposed above) beginning with 2019 data (available reporting in late 2020) and continuing for subsequent years.

Voluntary Reporting. CMS does not propose to change its policy for publicly reporting data that are voluntarily submitted for any MIPS category by clinicians not subject to MIPS payment adjustments (e.g., those who meet the low-volume threshold). Any voluntarily submitted data are considered available for public reporting after clinicians are offered a 30-day preview period. During the preview period, the clinicians may opt out of public reporting; their data will be posted should they not opt out during the preview period.

APM Data Reporting. CMS proposes no changes to existing policies. Data will continue to be publicly reported on Physician Compare including the names of eligible clinicians in Advanced APMs, the names and performances of Advanced APMs, and the names and performances of APMs that are not considered “Advanced” (e.g., Medicare Shared Savings Program Track 1). CMS also will continue to link clinicians and their APMs on the website.

3. Overview of the Alternative Payment Model (APM) Incentive

(a) QPP Context and Advanced APM Criteria

CMS introduces their discussion of the APM pathway for payment of eligible clinicians as proposed for 2019 by reprising some current aspects of the APM Incentive program.

- For payment years 2019 and 2020, eligible clinicians can become Qualifying APM Participants (QPs), and thereby be excluded from MIPS, based only upon their extent of Advanced APM participation (i.e. payments or patient counts, through the Medicare Option). All Advanced APMs are sponsored by CMS.
- For payment years 2021 and later, QP status can be reached by combining Advanced APM participation with Other Payer Advanced APM participation (i.e., through the All-Payer Combination Option). Payment arrangements that may qualify as Other Payer Advanced APMs include those between eligible clinicians and Medicare Health Plans, Title XIX programs, CMS Multi-Payer Models, and what CMS terms “Remaining Other Payers”.

- In payment years 2019 through 2024, QPs receive a lump sum incentive payment annually equal to 5 percent of their prior year’s estimated aggregate payments for Part B covered professional services. Beginning in 2026, QPs receive a higher annual fee schedule update than non-QPs.⁴⁸

CMS goes on to describe the criteria for defining an Advanced APM. The criteria are based on statutory requirements from MACRA and all must be met.

- Participants are required to use CEHRT.
 - All APM Entities within an Advanced APM must require at least 50 percent of eligible clinicians to use CEHRT to document and communicate clinical care.
- Payment for covered professional services must be based at least in part on quality measures comparable to those of the MIPS Quality performance category.
- Participating APM Entities must bear risk for more than nominal monetary losses or be an expanded Medical Home Model (under section 1115A(c) of the Act).⁴⁹

(b) Increasing CEHRT Usage

Currently, all APM Entities within an Advanced APM must require at least 50 percent of eligible clinicians to use CEHRT to document and communicate clinical care with patients and other healthcare professionals. CMS proposes to increase the required CEHRT usage for performance year 2019 and succeeding years to at least 75 percent at §414.1415(a)(i). CMS believes that the change would be consistent with their Promoting Interoperability initiative, that EHR availability has become widespread, and that most existing Advanced APMs already require 75 percent or more CEHRT usage. **CMS invites comment on this proposal.**

(c) Clarifying MIPS-Comparable Quality Measures

Advanced APMs are required to base payment to eligible clinicians on at least one quality measure, and CMS has previously set criteria for such measures at §414.1415(b).⁵⁰ Having learned of unintended interpretations, CMS proposes to revise the criteria, retaining those that clearly emphasize the overarching requirement for measures to be evidence-based, reliable, and valid. The revised criteria for a quality measure upon which Advanced APMs base payment are: finalized on the MIPS final list of measures; endorsed by a consensus-based entity (e.g., NQF); or otherwise determined by CMS to be evidenced-based, reliable, and valid. The revised criteria would become effective beginning on January 1, 2020, to avoid interference with the 2019 QP Performance Period already underway. CMS notes that MIPS-comparability of QCDR measures also would be subject to the revised criteria.

At least one measure upon which Advanced APMs base payment also must be an outcome measure unless CMS determines that an applicable outcome measure is not available. To add

⁴⁸ Beginning in CY 2026, the update to the “qualifying APM conversion factor” is set at 0.75% for QPs and the update to the nonqualifying APM conversion factor is set at 0.25% for non-QPs.

⁴⁹ As yet, no medical home models have been expanded under Section 1115A(c) of the Act.

⁵⁰ The criteria are: used in the MIPS quality performance category; endorsed by a consensus-based entity); developed under the QPP; submitted in response to an annual MIPS Call for Quality Measures; or any other measures so determined by CMS (§414.1415(b)). At least one criterion must be met.

clarity and align measures, CMS proposes that the required outcome measure would be evidence-based, reliable, and valid, according to the revised criteria described above. This change also would become effective beginning on January 1, 2020.

(d) Financial Risk Standard Setting for QP Performance Periods 2021-2024

Advanced APMs are required to bear more than nominal risk for monetary losses. The generally applicable revenue-based nominal amount standard initially was set at 8 percent or greater for QP Performance Periods 2017-2018 and later extended through 2020.⁵¹ CMS proposes to retain the 8 percent standard for QP Performance Periods 2021-2024; the standard applies to models that express risk in terms of revenue. The total expenditure-based nominal amount standard was set at 3 percent or greater beginning with 2017 without a specified date for expiration or increase, and no change is being proposed by CMS. CMS states that maintaining the current standards would continue a gradual implementation trajectory for the QPP, offer predictability to participants, and allow CMS to better assess the effects of the standards on the APM Entities. **CMS seeks comment on whether it should consider raising the revenue-based nominal amount standard to 10 percent, and the expenditure-based nominal amount standard to 4 percent starting for QP Performance Periods in 2025 and subsequent years.**

(e) QP and Partial QP Determinations: Operational Changes

CMS performs QP determinations at three snapshot dates during each performance year (March 31, June 30, and August 31). A clinician meeting any QP threshold (e.g., patient count) at any snapshot date earns QP status for the entire performance year. QP determinations currently include a 90-day claims run-out period; thus, QP results are not available to clinicians until about 4 months after the snapshot dates. The August 31 snapshot date is most problematic, as results are not released until very shortly before the start of the upcoming MIPS data submission period (the following January 1). Based on recent operational experience, CMS now proposes to reduce the claims run-out period from 90 days to 60 days, decreasing clinician burden by shortening the interval from snapshot to final determination. Claims analysis showed that the percentage of claims completely processed declined by only a 0.5 percent with the shorter run-out period.

CMS also addresses a Partial QP operational issue. Although Partial QPs are not eligible for the 5 percent APM incentive payment, they may elect to be MIPS-exempt. When an APM Entity's clinicians achieve Partial QP status, the entity conveys the group's decision for or against MIPS participation to CMS. For determinations made at the individual clinician level, however, the same decision instead is inferred by CMS. Reporting of any of the individual's MIPS data to CMS is interpreted as electing MIPS participation and the absence of reporting as an election to be MIPS-exempt. Based on recent operational experience, CMS now proposes to align the group and individual processes; an individual Partial QP who opts for MIPS participation would make an explicit election to do so. Absent such election, the individual would be treated as MIPS-exempt. CMS perceives that an explicit election for MIPS participation protects individuals from being opted into MIPS inadvertently through unanticipated reporting of their data by others (e.g., one of multiple billing TINs to which an individual Partial QP belongs).

⁵¹ The standard is based on the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities.

(f) Continued Implementation of the All-Payer Combination Option

(1) General Considerations

For 2019, CMS continues building on the processes finalized in 2018 to support implementation of the All-Payer Combination Option. Under this option, groups and individual clinicians may achieve QP status by reaching pre-defined levels of participation (e.g., patient counts) in both Medicare's Advanced APMs and Other Payer Advanced APMs.⁵² The All-Payer option is available starting with performance year 2019. CMS has direct access to all information needed to determine if an APM meets criteria to be an Advanced APM and to make QP status determinations under the Medicare option, but requires input from external sources to make Other Payer Advanced APM and QP status determinations under the All-Payer option. In 2018, CMS finalized the Payer Initiated and Eligible Clinician Initiated processes and timelines for obtaining and using information about payment arrangements involving Title XIX, Medicare Health Plans, or CMS Multi-Payer Models.⁵³ For 2019, CMS proposes to address analogous issues for the Remaining Other Payers category (e.g., commercial payers). CMS reaffirms their continuing commitment to maximizing policy and process alignment between the Medicare and All-Payer Combination options whenever feasible.

(2) Other Payer Advanced APM Criteria

Increasing CEHRT Usage. Currently, all APM Entities within an Other Payer Advanced APM must require at least 50 percent of their eligible clinicians to use CEHRT to document and communicate clinical care with patients and other healthcare professionals. CMS now proposes to increase the required CEHRT usage for 2020 and later to at least 75 percent, paralleling their proposal for Medicare-sponsored Advanced APMs.

Documenting CEHRT Usage. CMS also seeks to modify how CEHRT participation is documented by clinicians for 2019 and later years. Currently, CMS presumes that the CEHRT standard is being met when clinicians submit payment arrangement materials that explicitly require CEHRT usage (e.g., payer-clinician contract). Feedback to CMS has indicated that CEHRT usage is common under Other Payer Advanced APMs but not always specified contractually. CMS proposes that evidence of sufficient CEHRT usage would now be submitted by clinicians or payers and that evidence must be submitted even when CEHRT is not explicitly required by their payment arrangements. CMS proposes to allow flexibility as to the form and content of the evidence (e.g., commercial payer materials describing CEHRT adoption rates within their networks).

⁵² Tables 57 and 58 of the proposed rule show the pre-defined levels ("thresholds"); Figures 1 and 2 of the rule depict the QP determination decision trees for both the Medicare and All-Payer Combination options.

⁵³ Some operations to implement the All-Payer option began in 2018 (e.g., submission of information by states to CMS about their Title IX payment arrangements for Other Payer Advanced APM determinations). The eligible clinician initiated process may be used by both APM Entities and individual clinicians. The 2018 final All-Payer Combination policies are available at 82 FR 53874-53876 and 82 FR 53890-53891.

MIPS-Comparable Quality Measures. Other Payer Advanced APMs are required to base clinician payment on at least one MIPS-comparable quality measure. CMS proposes to modify the comparability criteria to parallel those proposed for usage by Medicare Advanced APMs. A measure must be finalized on the MIPS final list of measures; endorsed by a consensus-based entity (e.g., NQF); or otherwise determined by CMS to be evidenced-based, reliable, and valid. The revised criteria would become effective beginning on January 1, 2020. CMS also notes that at least one measure upon which Other Payer Advanced APMs condition payment must be an outcome measure.⁵⁴ To align measures, CMS proposes that the required outcome measure would be evidence-based, reliable, and valid, adopting the revised criteria proposed for Medicare-sponsored Advanced APMs. This change would become effective starting on January 1, 2020. The change is not retroactive; models determined to be Other Payer Advanced APMs for prior performance years would not be affected. CMS states that MIPS-comparability of QCDR outcome measures also would be assessed using the revised criteria.

Financial Risk Standard Setting. Other Payer Advanced APMs are required to bear more than nominal risk for monetary losses. The Other Payer generally applicable revenue-based nominal amount standard initially was finalized at 8 percent or greater for QP Performance Periods 2019-2020 and only applied to models that expressly define risk in terms of revenue. CMS proposes to extend the 8 percent revenue-based standard through performance period 2024. The expenditure-based nominal amount standard for Other Payer Advanced APMs initially was set at 3 percent or greater beginning with 2017 and without a specified date for expiration or increase, and no change is proposed by CMS.⁵⁵ CMS reiterates that “business risk” costs associated with Other Payer Advanced APM participation (e.g., adding patient navigators) are not counted towards meeting the risk standards. CMS does note that payment arrangements might be structured to recognize these costs, such as partial pre-payment of expected shared savings (analogous to the Medicare ACO Investment Model). **CMS seeks comment on the proposal to maintain the 8 percent nominal amount standard for Other Payer Advanced APMs for QP performance periods through 2024.**

(3) Other Payer Advanced APM Multi-Year Determinations

CMS has previously established that individuals or APM Entities are responsible for submitting the information necessary to perform Other Payer Advanced APM determinations; the involved payers may voluntarily submit the information. Determinations are valid for one year only, whether based on information submitted through the Eligible Clinician Initiated or the Payer Initiated process.⁵⁶ Stakeholders have told CMS that annual information submission is burdensome and that other payers often execute multi-year contracts. CMS now proposes to retain annual submission for both processes but with modifications that would begin with performance year 2020. Under the proposal, once CMS initially determines that a payment arrangement meets Other Payer Advanced APM criteria, requesters (payers, APM Entities, and eligible clinicians) submitting multi-year arrangements would be required only to annually

⁵⁴ The requirement does not apply if CMS determines that an applicable outcome measure is not available.

⁵⁵ The Other Payer Advanced APM generally applicable nominal financial risk standard also mandates a marginal risk of at least 30 percent and a minimum loss rate of no more than 4 percent. No changes are proposed to these requirements for 2019.

⁵⁶ The Eligible Clinician Initiated and Payer Initiated processes are described in detail at 82 FR 53814-53873.

submit information about changes related to the Other Payer Advanced APM criteria. If no such payment arrangement changes are made, CMS would extend the initial Advanced APM determination for each successive year for five years or until the end date of the arrangement, whichever occurs earlier. As part of the information submission for the initial determination, the requester would be required to certify that revised information would be provided to CMS about any material change. Further, the requester's certifying official would be required to agree to review the initial submission at least annually to identify any material changes and to submit updated APM information to CMS. CMS believes that these modifications would align Medicare's processes with those of other payers, reflect more accurately the typical timeline on which payers revise APM arrangements, and encourage the development of stable, multi-year, Other Payer Advanced APMs.

(4) Remaining Other Payers Process and Timeline

In 2018, CMS finalized processes and timelines for making Advanced APM determinations for payment arrangements involving Title XIX, Medicare Health Plans, and CMS Multi-Payer Models. However, CMS deferred establishing policies for the Remaining Other Payers (e.g., commercial and private plans) until 2019, except to finalize that those payers could seek determinations before the beginning of the 2020 QP performance period begins (January 1, 2020) and in subsequent years. CMS now proposes details for use of the Payer Initiated process for the remaining payers.

- The process would be voluntary.
- The Payer Initiated Submission Form would be adapted for use by the remaining payers and would be required for requesting an Other Payer Advanced APM determination.⁵⁷
- The Submission Period would open on January 1 and close on June 1 of the calendar year preceding the relevant QP performance period.
- The requesting payer would be notified by CMS if the information submitted is incomplete and given 15 business days to respond.
- Determinations would be final. Payers would be notified promptly once determinations are made.
- CMS would add Remaining Other Payer Advanced APMs to the Other Payer Advanced APM List maintained on the CMS website.

CMS summarizes Other Payer Advanced APM determination timelines for Medicaid and Medicare Health Plans (finalized) and for the Remaining Other Payers (proposed) in Table 59 of the proposed rule, reproduced with modifications at the end of this summary section.

(5) CMS Multi-Payer Models Process Change

For the initial QP performance period of the All-Payer option (beginning January 1, 2019), CMS previously established that payers having payment arrangements aligned with a CMS Multi-Payer Model could request an Advanced APM determination regarding the aligned arrangements through the Payer Initiated process from January 1 until June 1, 2018. CMS now proposes to end this submission option for performance year 2020 and subsequent years. Instead, the aligned

⁵⁷ A single form could be used for multiple tracks within a single payment arrangement.

payers would use the proposed Remaining Other Payer process or the established Title XIX or Medicare Health Plans processes, whichever is most applicable to their specific payment arrangement. CMS states that the process policies that would be available to aligned payers are substantially similar or identical to the multi-payer policies proposed for elimination.

(6) Threshold Scores for QP Status Determinations under the All-Payer Combination Option

Background. CMS previously finalized that under the All-Payer option, clinicians may request their QP determinations to be made at the individual level while APM Entities may request assessment at the APM Entity (group) level. QP status will be determined at both levels when the individual and the entity submit requests; QP status will be awarded based upon the higher of the two threshold scores.⁵⁸ However, eligible clinicians for whom QP status is assessed individually under the Medicare Option also will be assessed only at the individual level under the All Payer Combination Option.⁵⁹ QP calculations are performed for three snapshot dates (March 31, June 30, and August 31 of the performance year) for clinician groups on Advanced APM Participant Lists and for individual clinicians on Affiliated Practitioner Lists.⁶⁰ Entities and individuals must submit all payment and patient count information by December 1 of the relevant performance year. At both the individual and entity level, CMS performs sequential determinations in the following order, using only those methods for which complete data are available: Medicare Option payment method then patient count method followed by All-Payer Combination option payment method then patient count method. An individual or group can reach QP status by meeting the threshold score for any one of these determinations.

TIN level QP Determinations. Responding to stakeholder input, CMS proposes to add an alternative under which TIN level determinations could be requested in addition to those at group or individual levels. The TIN level alternative would only apply when all clinicians who have reassigned their billing rights under the TIN participate in the same (single) APM Entity. Use of the TIN level alternative would be further restricted to those instances in which the entire TIN (not just the individual) has met the Medicare threshold for the All-Payer option based upon its participation in a single Medicare-sponsored Advanced APM entity. CMS proposes to utilize the most advantageous QP outcome (individual, TIN, or APM Entity level). CMS believes this alternative would add to QP determination flexibility, increase the number of QPs, better reflect non-Medicare payer contracting practices, and reduce reporting burden.

Relationship between Payment and Patient Count Calculations. CMS asserts that some stakeholders remain confused, believing that the same method (payment or patient count) must be used for both the Medicare and Other Payer parts of the All-Payer option determination. CMS, therefore, reiterates the following existing policy requirements:

⁵⁸ Threshold Score calculations are discussed in detail at 81 FR 77453-77458, 81 FR 77474-77478, and 82 FR 53876-53892.

⁵⁹ These are clinicians in Advanced APMs for which QP determinations are guided by an Affiliated Practitioner List, and those participating in multiple Advanced APMs entities when no single entity achieves QP status through group-level assessments.

⁶⁰ Affiliated Practitioner Lists are used in lieu of APM Participant Lists when the APM participants are hospitals (e.g., Comprehensive Care for Joint Replacement, CJR).

- The minimum Medicare threshold needed to qualify for an All-Payer option QP determination may be calculated using either payments or patient counts.
- The subsequent Other Payer calculation also may use either payments or patient counts, regardless of the method used for the minimum Medicare calculation.
- For both the minimum Medicare and subsequent Other Payer threshold calculations, the method most advantageous to the clinician will be utilized in QP calculations.

CMS proposes to reaffirm the above policy by adding clarifying language at §414.1440(d)(4).

Weighting Methodology. CMS previously established a methodology under the Medicare Option to handle when a clinician’s individual level threshold score is equal to or less than the score calculated at the entity level, disadvantaging those clinicians whose individual scores are equal to or less than their entity scores. CMS asserts that the weighting methodology ensures that the Medicare portion of a clinician’s All-Payer Option QP threshold score would not be less than the Medicare Option QP score received by that clinician when calculated at the entity level.⁶¹ CMS proposes to extend the same weighting approach to TIN level All-Payer QP determinations. When a TIN is assessed as a part of an APM Entity group and receives an entity level Medicare score lower than its TIN level score, CMS would apply a weighting methodology so that the TIN level Medicare score to be used in the All-Payer calculation is at least equal to entity level Medicare score. The proposed methodology multiplier formula is shown below, and CMS describes some example calculations in the rule (Table 59 and the following text).

$$\frac{(\text{APM Entity Medicare Threshold Score} \times \text{TIN Medicare Payments or Patients}) + \text{TIN Other Payer Advanced APM Payments or Patients}}{\text{TIN Payments or Patients (All Payers except those excluded by statute, e.g., Department of Defense)}}$$

TIN Payments or Patients (All Payers except those excluded by statute, e.g., Department of Defense)

Applying the methodology, CMS would calculate the TIN’s Medicare QP threshold score twice (for use in the All-Payer calculation), with and without the weighting multiplier, and use the result that is most advantageous for the TIN. The weighting methodology only applies to a TIN when that TIN is a subset of the eligible clinicians in the APM Entity.

Other Payer Advanced APM (OP AAPM) Determination Process Timeline for Payment Arrangements by Payer Type for QP Performance Period 2020 (modified from Table 59 of the proposed rule)				
Payer Type	Payer Initiated	Date	Eligible Clinician (EC) Initiated	Date
Medicaid Title XIX <i>Status: Finalized</i>	Guidance sent to STATES Submission Opens STATES	Jan 2019	Guidance to ECs Submission Opens ECs	Sept 2019
	Submission Closes STATES	April 2019	Submission Closes ECs	Nov 2019

⁶¹ A full explanation of the methodology is provided at 82 FR 53881-53882.

Other Payer Advanced APM (OP AAPM) Determination Process Timeline for Payment Arrangements by Payer Type for QP Performance Period 2020 (modified from Table 59 of the proposed rule)				
Payer Type	Payer Initiated	Date	Eligible Clinician (EC) Initiated	Date
	CMS Notifies STATES CMS Posts OP AAPM List	Sept 2019	CMS Notifies STATES & ECs CMS Posts OP AAPM List	Dec 2019
Medicare Health Plans (MHP) <i>Status: Finalized</i>	Guidance available for MHP Submission Opens MHP	April 2019	Guidance available to ECs Submission Opens ECs	Sept 2020
	Submission Closes MHP	June 2019	Submission Closes ECs	Nov 2020
	CMS Notifies MHP CMS Posts OP AAPM List	Sept 2019	CMS Notifies ECs CMS Posts OP AAPM List	Dec 2020
Remaining Other Payers (ROP) <i>Status: Proposed</i>	Guidance available to ROP Submission Opens ROP	Jan 2019	Guidance available to ECs Submission Opens ECs	Sept 2020
	Submission Closes ROP	June 2019	Submission Closes ECs	Nov 2020
	CMS Notifies ROP CMS Posts OP AAPM List	Sept 2019	CMS Notifies ECs & ROP CMS Posts OP AAPM List	Dec 2020

Collection of Information Requirements

Pursuant to Paperwork Reduction Act requirements, a detailed discussion for the QPP is provided regarding the information collection requirements included in this proposed rule. In addition, CMS provides new baseline estimates of pre-existing QPP information collection requirements. Table 62 in the proposed rule provides a framework for how organizations permitted or required to submit data on behalf of clinicians varies across the types of data and whether the clinician is a MIPS eligible clinician, MIPS APM participant, or an Advanced APM participant. CMS used this information for calculation of the burden associated with the various information collection requirements.

Tables 63 through 88 in the proposed rule provide specific estimates on the burden associated with proposed changes to program requirements as well as with pre-existing program requirements.

Table 89 in the proposed rule summarizes all of those estimated changes on the burden for the QPP. For the 2019 QPP performance year, CMS estimates total annual burden of 5,581,492 hours, a reduction of 2,008,096 hours from current total burden hours. That reduction is the net impact of changes attributable to proposed rule changes and to changes to estimates of the underlying baseline burden for the program. In calculating this estimate CMS assumes

1,064,982 respondents (a decrease from the current number of approved respondents of 229,467 respondents). Table 90 in the proposed rule provides the reasons for this estimated change in burden.

IV. RFIs on Promoting Interoperability and Price Transparency

CMS makes two requests for information (RFIs) as part of this proposed rule; these requests have appeared in other Medicare provider payment proposed rules issued this year. The usual procedures and disclaimers associated with RFIs are included (e.g., proprietary or confidential information should not be included; CMS may post the comments received or a summary of them.)

A. Request for Information on Promoting Electronic Interoperability

CMS discusses the status of adoption of health IT among Medicare and Medicaid participating providers. It says that as of 2015, 96 percent of hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care, yet significant obstacles to electronic exchange of health information remain. It reviews CMS and Office of National Coordinator (ONC) initiatives and regulatory activities aimed at advancing health information exchange. The January 2018 ONC draft Trusted Exchange Framework and Common Agreement (TEFCA)⁶² is highlighted.

CMS is interested in feedback from stakeholders on how it should use the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities to advance electronic exchange of health information in support of care transitions between hospitals and community providers. As an example, CMS says it might consider revising the hospital CoPs to require that hospitals electronically transfer medically necessary patient information to the other facility when a patient is transferred. Similarly, it might require that hospitals electronically send discharge information to a patient's community provider when possible, and to provide discharge instructions electronically to patients or a third-party application, if requested.

Relevant provisions of proposed CoP regulations are discussed including the November 3, 2015 proposed rule to implement provisions of the IMPACT Act (80 FR 68126), June 16, 2016 proposed changes to CoPs for hospitals and CAHs (81 FR 39448), and an October 4, 2016 final rule on requirements for LTC facilities (81 FR 68688).

In this rule, CMS requests stakeholder feedback on the following questions:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?

⁶² The draft is available at <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>

- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, HIPAA, and implementation of relevant policies in the 21st Century Cures Act?
- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?
- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?
- Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?
- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements, should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP including CEHRT hardship or small practices be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

In addition, CMS discusses the MyHealthEData initiative to promote patient access to their medical records and the Blue Button 2.0 initiative for beneficiary access to Medicare claims information through API technology.

CMS seeks ideas from the public on how best to accomplish the goal of fully interoperable health IT and EHR systems for providers and suppliers and how to advance the MyHealthEData initiative for patients. In particular, it would like to identify fundamental barriers to interoperability and patient access and how they might be reduced through revisions to the CoPs, CfCs, and RfPs for hospitals and other Medicare providers and suppliers. CMS has a particular interest in hearing about issues for providers and suppliers who are ineligible for the Medicare

and Medicaid EHR Incentives program, such as long-term care and post-acute care providers, behavioral health providers, clinical laboratories and social service providers.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

The Affordable Care Act established section 2718(e) of the Public Health Service Act. This provision requires each hospital operating within the United States to make public a list of its standard charges for items and services including for diagnosis-related groups according to guidelines established by the Secretary. In the FY 2015 IPPS/LTCH rule (79 FR 50146), CMS reminded hospitals of their obligation to comply with this provision by making public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry. In the FY 2019 IPPS/LTCH proposed rule, CMS updated its guidelines effective January 1, 2019 to require hospitals to make available a list of their current standard charges via the internet in a machine-readable format and to update this information at least annually. All providers are encouraged to engage in consumer-friendly communication of their charges to help patients understand their potential financial liability for services and to enable comparison of charges across providers, and to update this information at least annually.

The proposed rule describes CMS' concern that challenges continue to exist for patients due to insufficient price transparency. Such challenges include surprise billing for out-of-network physicians and chargemaster data that are not helpful in estimating what a patient is likely to pay for a service.

CMS is considering ways to improve the accessibility and usability of current charge information, and seeks comments from providers and suppliers on the following:

- How should “standard charges” be defined in various provider and supplier settings? Should it be defined as average or median rates for the items on the chargemaster; average or median rates for groups of services commonly billed together, as determined by the provider or supplier based on its billing patterns; or the average discount off the chargemaster, price list or charge list amount across all payers, either for each item on the chargemaster or for groups of services commonly billed together? Should “standard charges” be defined and reported for both some measure of the average contracted rate and the chargemaster? Or is the best measure of a provider or supplier’s standard charges its chargemaster?
- What types of information would be most beneficial to patients, how can providers and suppliers best enable patients to use charge and cost information in their decision-making, and how can CMS and providers and suppliers help third parties create patient-friendly interfaces with these data?
- Should providers and suppliers be required to inform patients how much their out-of-pocket costs for a service will be before those patients are furnished that service? How can information on out-of-pocket costs be provided to better support patients’ choice and decision making? What changes would be needed to support greater transparency around

patient obligations for their out-of-pocket costs? How can CMS help beneficiaries to better understand how co-pays and co-insurance are applied to each service covered by Medicare? What can be done to better inform patients of their financial obligations? Should providers and suppliers play any role in helping to inform patients of what their out-of-pocket obligations will be?

- Can CMS require providers and suppliers to provide patients with information on what Medicare pays for services? If so, what changes would providers and suppliers have to make? What burden would such a requirement add?

In addition, CMS seeks comment on the following questions involving how to improve a Medigap patient's understanding of his or her out-of-pocket costs prior to receiving services:

- How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care?
- What challenges do providers face in providing information about out-of-pocket costs to patients with Medigap?
- What changes would be needed to support providers sharing out-of-pocket cost information with patients that reflects the patient's Medigap coverage?
- Who is best situated to provide patients with Medigap coverage clear information on their out-of-pocket costs prior to receipt of care?
- What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service?
- What state-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

V. Regulatory Impact Analysis

A. RVU Impacts

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, CMS makes adjustments to preserve budget neutrality.

CMS estimates of changes in Medicare allowed charges for PFS services compare payment rates for 2018 with proposed payment rates for 2019 using 2017 Medicare utilization for all years. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. As usual, CMS asserts that the average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

Prior to 2015, the annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula (the Sustainable Growth Rate methodology that was largely overridden each year by Congressional action). MACRA established the update factor for calendar years 2015 through 2025. For 2019, the specified update is 0.5 percent, before applying other adjustments. In addition to the update factor, the CF calculation for 2019 takes into account an RVU budget neutrality adjustment.

The proposed CF for 2019 is \$36.0463, which reflects the 0.25 percent update adjustment factor specified under BBA of 2018 and a budget neutrality adjustment of -0.12 percent (2018 conversion factor of \$35.9996*1.025*0.9988).⁶³ The 2019 proposed anesthesia conversion factor is \$22.2986, which reflect the same adjustments and an additional adjustment due to an update to the malpractice risk factor for anesthesia specialty. See Tables 92 and 93 from the proposed rule, which are reproduced below.

Table 92: Calculation of the Proposed 2019 PFS Conversion Factor

Conversion Factor in effect in 2018		\$35.9996
Statutory Update Factor	0.25 percent (1.0025)	
2019 RVU Budget Neutrality Adjustment	-0.12 percent (0.9988)	
2019 Conversion Factor		\$36.0463

TABLE 93: Calculation of the Proposed 2019 Anesthesia Conversion Factor

2018 National Average Anesthesia Conversion Factor		\$22.1887
Update Factor	0.25 percent (1.0025)	
2019 RVU Budget Neutrality Adjustment	-0.12 percent (0.9988)	
2019 Practice Expense and Malpractice Adjustment	0.365 percent (1.00365)	
2019 Conversion Factor		\$22.2986

Table 94 (included at the end of this section) shows the estimated impact of changes in the components of the RVUs on total allowed charges, by specialty. The allowed charges shown in the table are the Medicare PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary).

2019 PFS Impact Discussion

The most widespread specialty impacts of the RVU changes are generally related to proposed changes to RVUs for specific services resulting from the Misvalued Code Initiatives, including the establishment of proposed RVUs for new and revised codes. CMS states that much of the specialty level impacts in this proposed rule are being driven by CMS' proposal related to office/outpatient E/M codes, which comprise a large volume of services in the PFS. CMS proposal establishes a single E/M payment rate for new patients and a single PFS rate for

⁶³ As required by section 53106 of the Bipartisan Budget Act of 2018, the update adjustment factor is 0.25 percent before applying any other adjustments. The adjustment factor had been 0.5 percent for 2019 under MACRA before this statutory change.

established E/M visits levels 2-5 as well as other adjustments. In addition, CMS also proposes to systematically update prices of over 1,300 supplies and 750 equipment items used in the calculation of practice expense, which also contributed to specialty level impacts. The phase-in of previously finalized policies is another factor contributing to differences among specialties (e.g., allocation of indirect PE for some office-based services), particularly the increases among behavioral health specialties.

Some specialties, including, for example, obstetrics/gynecology, urology, independent labs, and clinical psychologists would see increases relative to other specialties. CMS attributes these changes to proposed increases in value for particular services, proposed updates to supply and equipment pricing, and the proposed valuation of E/M office visits that had a positive impact on specialties reporting a higher proportion of level 2 and 3 office visits. Other specialties, including allergy/immunology, diagnostic testing facilities, hematology/oncology, radiation therapy centers, and podiatry would experience decreases in payments relative to other specialties for similar reasons as well as continued implementation of code-level reductions being phased-in over several years.

Column F of Table 94 shows the estimated 2019 combined impact on total allowed charges by specialty of all the proposed RVU and other changes. These impacts range from an increase of 4 percent for obstetrics/gynecology and independent laboratories, increase of 3 percent for psychiatry, to a decrease of 5 percent for allergy/immunology and a decrease of 4 percent for diagnostic testing facility, hematology/oncology, and rheumatology.

TABLE 94: 2019 PFS Proposed Rule 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	\$92,173	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	\$238	1%	-6%	0%	-5%
ANESTHESIOLOGY	\$1,889	0%	0%	0%	0%
AUDIOLOGIST	\$67	0%	0%	-1%	-1%
CARDIAC SURGERY	\$293	-1%	-1%	1%	-1%
CARDIOLOGY	\$6,590	0%	-1%	0%	-1%
CHIROPRACTOR	\$749	0%	1%	0%	0%
CLINICAL PSYCHOLOGIST	\$770	0%	2%	0%	2%
CLINICAL SOCIAL WORKER	\$725	0%	2%	0%	2%
COLON AND RECTAL SURGERY	\$165	0%	1%	0%	1%
CRITICAL CARE	\$340	-1%	0%	0%	0%
DERMATOLOGY	\$3,477	1%	-2%	0%	-1%
DIAGNOSTIC TESTING FACILITY	\$728	0%	-4%	0%	-4%
EMERGENCY MEDICINE	\$3,110	0%	0%	0%	0%
ENDOCRINOLOGY	\$480	0%	-1%	0%	-1%
FAMILY PRACTICE	\$6,176	0%	1%	0%	1%
GASTROENTEROLOGY	\$1,750	-1%	1%	0%	1%
GENERAL PRACTICE	\$423	0%	1%	0%	1%
GENERAL SURGERY	\$2,079	0%	0%	0%	1%
GERIATRICS	\$196	-2%	1%	0%	-1%
HAND SURGERY	\$213	2%	1%	0%	2%
HEMATOLOGY/ONCOLOGY	\$1,737	-1%	-3%	0%	-4%
INDEPENDENT LABORATORY	\$640	0%	4%	0%	4%
INFECTIOUS DISEASE	\$645	-1%	1%	0%	0%
INTERNAL MEDICINE	\$10,698	0%	1%	0%	1%
INTERVENTIONAL PAIN MGMT	\$863	2%	1%	0%	3%
INTERVENTIONAL RADIOLOGY	\$384	1%	-1%	0%	0%
MULTISPECIALTY CLINIC/OTHER PHYS	\$148	-1%	0%	0%	-1%
NEPHROLOGY	\$2,182	-1%	0%	0%	-1%
NEUROLOGY	\$1,521	-1%	-1%	0%	-2%
NEUROSURGERY	\$798	0%	0%	1%	1%
NUCLEAR MEDICINE	\$50	-1%	-1%	0%	-1%
NURSE ANES / ANES ASST	\$1,163	0%	0%	0%	0%
NURSE PRACTITIONER	\$4,043	1%	2%	0%	2%
OBSTETRICS/GYNECOLOGY	\$635	3%	1%	0%	4%
OPHTHALMOLOGY	\$5,437	0%	-1%	0%	-1%
OPTOMETRY	\$1,301	1%	0%	0%	1%
ORAL/MAXILLOFACIAL SURGERY	\$67	1%	-2%	0%	-1%
ORTHOPEDIC SURGERY	\$3,730	1%	0%	0%	1%

(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*
OTHER	\$31	0%	5%	0%	4%
OTOLARNGOLOGY	\$1,206	2%	-3%	0%	-1%
PATHOLOGY	\$1,158	0%	-1%	0%	-1%
PEDIATRICS	\$61	-1%	0%	0%	-1%
PHYSICAL MEDICINE	\$1,102	-1%	0%	0%	-1%
PHYSICAL/OCCUPATIONAL THERAPY	\$3,930	0%	-1%	0%	-1%
PHYSICIAN ASSISTANT	\$2,447	1%	0%	0%	1%
PLASTIC SURGERY	\$373	1%	0%	0%	1%
PODIATRY	\$1,958	-1%	0%	0%	-2%
PORTABLE X-RAY SUPPLIER	\$98	0%	1%	0%	1%
PSYCHIATRY	\$1,177	0%	2%	0%	3%
PULMONARY DISEASE	\$1,709	-2%	0%	0%	-2%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	\$1,760	0%	-2%	0%	-2%
RADIOLOGY	\$4,891	0%	0%	0%	0%
RHEUMATOLOGY	\$540	-1%	-3%	0%	-4%
THORACIC SURGERY	\$356	-1%	-1%	1%	-1%
UROLOGY	\$1,733	2%	1%	0%	3%
VASCULAR SURGERY	\$1,144	0%	-2%	0%	-1%

** Column F may not equal the sum of columns C, D, and E due to rounding.

The following is an explanation of the information for Table 94:

- Column A (Specialty): Identifies the specialty for which data is shown.
- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on 2017 utilization and 2018 rates. Allowed charges are the Medicare fee schedule amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all specialties to arrive at the total allowed charges for the specialty.
- Column C (Impact of Work RVU Changes): This column shows the estimated 2019 impact on total allowed charges of the proposed changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- Column D (Impact of PE RVU Changes): This column shows the estimated 2019 impact on total allowed charges of the proposed changes in the PE RVUs.
- Column E (Impact of MP RVU Changes): This column shows the estimated 2019 impact on total allowed charges of the proposed changes in the MP RVUs.
- Column F (Combined Impact): This column shows the estimated 2019 combined impact on total allowed charges of all the changes in the previous columns

B. Impacts of Other Proposals

The expected impacts of some of the proposed changes in this rule (other than those associated with changes in RVUs or the update factor) are discussed in previous sections of this summary. This includes the effect of changes related to telehealth, payments to provider-based departments of hospitals paid under the PFS, WAC-based payments for Part B drugs, regulations associated with the ambulance fee schedule, clinical laboratory fee schedule, AUC criteria for advanced diagnostic imaging services, and the physician self-referral law, among other proposals.

C. Changes Due to the Quality Payment Program

CMS estimates that approximately 43 percent of the nearly 1.5 million clinicians billing to Part B (650,165) will be assigned a MIPS score for 2021 because others will be ineligible for or excluded from MIPS. Table 96, reproduced below, provides the details of clinicians' MIPS eligibility status for 2021 MIPS payment year. CMS notes it is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the proposed policy; CMS assumes 33 percent of the opt-in eligible clinicians that participated in PQRS will elect to opt-in to the MIPS program.

Eligibility Status	Predicted Participation Status in MIPS Among Clinicians*	Number of Clinicians	Cumulative Number of Clinicians
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Participate in MIPS	186,549	186,549
	Do not participate in MIPS	31,921	218,470
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low- volume threshold in all 3 criteria and submit as a group)	Submit data as a group	389,670	608,140
Opt-In eligibility (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low- volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	42,025	<u>650,165**</u>
Not MIPS eligible Potentially MIPS eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: 1) meet group eligibility or 2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	482,574	1,132,739
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	88,070	1,220,809
Excluded for other reasons	Not applicable	302,172	1,522,981

(Non-eligible clinician type, newly- enrolled, QP)			
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*Participation in MIPS defined as previously submitting quality or EHR data for PQRS. Our assumptions for group reporting are based on 2016 PQRS group reporting.

**Estimated MIPS Eligible Population

*** Facility-based eligible clinicians are not modeled separately in this table and are captured in the individual eligible category. This table does not consider the impact of the MAQI Demonstration waiver.

In the aggregate, CMS estimates that for the 2021 payment year, it would redistribute about \$372 million in payment adjustments on a budget neutral basis. The maximum positive payment adjustments are 5.6 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. CMS estimates that 96 percent of eligible clinicians will have a positive or neutral payment adjustment and 3.9 percent will have a negative payment adjustment. Table 98, reproduced below, shows the impact of payments by practice size and whether clinicians submitting data to either PQRS or the Medicare or Medicaid EHR Incentive program. CMS estimates that clinicians in small practices (1-15 clinicians) participating in MIPS would perform as well as or better than mid-size practices.

Table 98: MIPS Estimated Payment Year 2021 Impact on Total Estimated Paid Amount by Participation Status and Practice Size*

Practice Size*	Number of MIPS eligible clinicians	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount**
Among those submitting data***					
1) 1-15	110,284	92.5%	46.4%	7.5%	1.9%
2) 16-24	27,798	89.1%	35.5%	10.9%	1.3%
3) 25-99	128,988	93.2%	44.2%	6.8%	1.5%
4) 100+	351,174	98.8%	65.3%	1.2%	2.5%
Overall	618,244	96.1%	56.2%	3.9%	2.0%
Among those not submitting data					
1) 1-15	28,096	0.0%	0.0%	100.0%	-6.1%
2) 16-24	1,282	0.0%	0.0%	100.0%	-6.0%
3) 25-99	1,871	0.0%	0.0%	100.0%	-5.9%
4) 100+	672	0.0%	0.0%	100.0%	-6.1%
Overall	31,921	0.0%	0.0%	100.0%	-6.1%

** 2014, 2015 and 2016 data used to estimate 2019 payment adjustments. Payments estimated using 2015 and 2016 dollars.

***Includes facility-based clinicians whose quality data is submitted through hospital programs.

CMS estimates that approximately 160,000 to 215,000 clinicians will become QPs for the 2021 and a total of \$600 to \$800 million in incentive payments will be made.

Limitations of CMS Analysis

Importantly, CMS describes several limitations to the analysis underlying the tables. CMS bases its analyses on the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility, participant lists using the APM Participation List and historical PQRS data, the Medicare/Medicaid Incentive Program data, including CAHPS for PQRS, and the VM. CMS plans to update the analysis of actual MIPS performance data if it is available in time for the final rule. CMS notes the scoring model does not reflect the growth in Advanced APM participation between 2018 and 2019 because that data are not available at the detailed level needed for the scoring analysis. CMS also notes that given these limitations and others, there is considerable uncertainty around its estimates.

D. Impact on Beneficiaries

CMS notes that there are a number of changes in this proposed rule that would have an effect on beneficiaries. In general, CMS believes that many of the proposed changes will have a positive impact and improve the quality and value of care provided to beneficiaries.

Most of the proposed policy changes could result in a change in beneficiary liability as relates to coinsurance. For example, the 2018 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is \$109.80 which means in 2018 a beneficiary would be responsible for 20 percent of this amount, or \$21.96. Based on this proposed rule, using the estimated 2019 CF, the 2019 national payment amount in the nonfacility setting for CPT code 99203 is \$134.45 which means that in 2019, the proposed beneficiary coinsurance would be \$26.89.

E. Estimating Regulatory Costs

Because regulations impose administrative costs on private entities, CMS estimates the cost associated with regulatory review, such as the time needed to read and interpret the proposed rule. CMS assumes that the total number of unique reviewers for this year's rule will be comparable to the number of unique commenters on last year's proposed rule. CMS also assumes that each reviewer reads approximately 50 percent of the rule. CMS estimates that the cost of reviewing this rule is \$107.38 per hour, including overhead and fringe benefits. In addition, CMS assumes that it would take about 8 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is \$859 (8.0 hours x \$107.38) and the total cost of reviewing this regulation is \$5,102,275 (\$859 x 5,943 reviewers).