

A Summary of the CY 2019 Physician Fee Schedule Proposed Rule

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Overview

On July 12, 2018, the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2019 Physician Fee Schedule (MPFS) proposed rule. This major proposed rule addresses changes to the Medicare physician fee schedule and other Medicare Part B payment policies, including the Quality Payment Program (QPP) and the Medicare Shared Savings Program (MSSP).

Page numbers in the summary refer to the public display version of the proposed rule, filed on July 12, 2018,¹ which can be viewed [here](#).

Comments will be accepted through **September 10, 2018**. The final rule will be released in early November 2018.

Executive Summary ([p. 6](#))

This major proposed rule proposes to revise payment policies under the MPFS and make other policy changes, including proposals to implement certain provisions of the Bipartisan Budget Act of 2018 (BBA of 2018), related to Medicare Part B payment, applicable to services furnished in CY 2019. CMS includes discussions and proposals regarding the following major provisions in this proposed rule:

- Potentially Misvalued Codes
- Communication Technology-Based Services
- Valuation of New, Revised, and Misvalued Codes
- Payment Rates under the PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital
- E/M Visits
- Therapy Services
- Clinical Laboratory Fee Schedule
- Ambulance Fee Schedule – Provisions in the BBA of 2018
- Appropriate Use Criteria for Advanced Diagnostic Imaging Services
- Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)
- Medicare Shared Savings Program Quality Measures
- Physician Self-Referral Law
- CY 2019 Updates to the QPP
- Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers
- Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

CMS has determined that this major proposed rule is economically significant. **CMS is requesting public comments on all of the proposals being made in this proposed rule.**

¹ Note that on July 18, 2018, CMS posted an updated version of the rule to reflect a minor technical issue found in the original public display version. The only change made in the updated version is a correction to [Figure A](#), which is a chart illustrating the Merit-Based Incentive Payment System (MIPS) Payment Adjustment factors based on final scores for the 2021 Payment Year. This chart was not rendering correctly in the original display version.

Provisions of the Proposed Rule for PFS ([p. 9](#))

Determination of Practice Expense (PE) Relative Value Units (RVUs) ([p. 15](#))

CMS reviews the step-by-step PE RVU methodology beginning on [p. 21](#).

Specialty-Specific PE/HR Data ([p. 18](#))

In calculating practice expense values for specialties, CMS uses AMA survey data, most recently from 2007 and 2008 as part of the Physician Practice Expense Information Survey (PPIS). CMS used this data to provide transitional updates to PE/HR beginning in CY 2010 for the specialties that participated in the survey.²

In the past, for those specialties without SMS or supplemental survey data, CMS crosswalks the specialty to “similar specialties” to estimate a proxy PE/HR value. For newly recognized specialties without available data, **CMS proposes the following crosswalks ([p. 18](#)):**

- **Hospitalists (crosswalked to Emergency Medicine)**
- **Advanced Heart Failure and Transplant Cardiology (crosswalked to Cardiology).**

The PE/HR values for all specialties and, where applicable, crosswalks for these and other specialties are posted on the CMS website in the [CY 2019 PFS Proposed Rule PE/HR](#) file.

Low Volume Codes ([p. 22](#))

CMS makes special changes for service codes that it determines have low Medicare volumes because the specialty mix assignment (which impacts the PE levels) can fluctuate so much from year to year on a low volume code. To avoid this for low volume codes, CMS assigns an “expected specialty” to prevent large year-to-year fluctuations. **CMS proposes to add 28 additional low volume codes to the list and makes “expected specialty” assignments for them ([p. 23](#)).** The list and proposed “expected specialty” assignments can be found in [Table 22](#).³

Equipment Costs ([p. 32](#))

Equipment Utilization Rate Assumption. In order to incorporate costs associated with equipment, CMS sets an equipment utilization rate assumption for distributing the costs associated with the equipment. In past rulemaking, CMS set an equipment utilization rate assumption of 50 percent for most equipment and a 90 percent equipment utilization rate assumption for expensive diagnostic equipment (as required by statute). CMS revisited past stakeholder complaints that a 50 percent utilization rate assumption is inaccurate and should be reduced. CMS declined to do so in the absence of “robust, objective, auditable data,” but **CMS requested stakeholder submission of data to illustrate an alternative equipment utilization rate assumption ([p. 32](#)).**

Equipment Maintenance. CMS previously set an annual maintenance factor for all equipment of 5 percent. CMS reiterated its past belief that the 5 percent rate understates the cost of maintaining some equipment while overstates the maintenance cost for other equipment. While CMS received some data, the agency states that it does not believe “that voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs” ([p. 33](#)). CMS has identified no publicly available datasets on which to reconfigure the equipment maintenance factor. **CMS states that it will continue to “investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.” ([p. 33](#)).**

² CMS reiterated that it does not use the PPIS data for endocrinology or spine surgery because “these specialties currently are not separately recognized by Medicare, and CMS has no method to blend PPIS data with Medicare-recognized specialty data ([p. 17](#)).”

³ “Expected Specialties” on the list include Diagnostic Radiology, Gastroenterology, Urology, Ob/Gyn, Pathology, Cardiology, and Neurology ([p. 24](#)).

Interest Rates. CMS proposes no changes to equipment interest rates ([p. 33](#)). The interest rates can be found in [Table 4](#).

Direct PE Inputs for Specific Services ([p. 34](#))⁴

Standardization of Clinical Labor Tasks ([p. 34](#)). CMS previously finalized standard times for clinical labor tasks associated with [digital imaging \(\[p. 35\]\(#\)\)](#):

- “Availability of prior images confirmed”: 2 minutes
- “Patient clinical Information and questionnaire reviewed by technologist, order from physician confirmed and exam protocolled by radiologist”: 2 minutes
- “Review examination with interpreting MD”: 2 minutes
- “Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue”: 1 minute
- “Technologist QC images in PACS, checking for all images, reformats, and dose page”:
 - Simple case: 2 minutes
 - Intermediate case: 3 minutes
 - Complex case: 4 minutes
 - Highly complex case: 5 minutes

CMS also previously finalized standard times for clinical labor tasks associated with [pathology services \(\[p.36\]\(#\)\)](#):

- “Accession specimen/prepare for examination”: 4 minutes
- “Assemble and deliver slides with paperwork to pathologists”: 0.5 minutes
- “Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation”: 0.5 minutes
- “Clean room/equipment following procedure”: 1 minute
- “Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste”: 1 minute
- “Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable)”: 1 minute

CMS stated that it does not believe that clinical labor tasks associated with pathology services would be depending on number of blocks or batch size, and **CMS continues to believe these values “accurately reflect the typical time it takes to perform these clinical labor tasks.”** ([p. 36](#)).

CMS notes that the RUC has mandated use of a new PE worksheet that assists in making recommendations for standardized clinical labor tasks. **CMS believes the new worksheet will assist CMS in simplifying and standardizing the clinical labor tasks listed in its direct PE database** ([p. 36](#)).

In CMS’ review, it concluded that there were some corrections that needed to be made with regard to other activities. In particular, CMS identified instances where 3 minutes of clinical labor time that was traditionally assigned to “Prepare room, equipment and supplies” were inappropriately split into 2 minutes for “Prepare room, equipment and supplies” activity and 1 minutes for “Confirm order, protocol exam” for certain services where the RUC-reviewed codes should not have time assigned for “Confirm order, protocol exam.” Therefore, **CMS proposes to maintain the clinical labor time of 3 minutes for “Prepare room, equipment and supplies” and remove the clinical labor time for “Confirm order, protocol exam” wherever CMS identified this happening** ([p. 37](#)).

CMS lists [labor task public use file on the CMS website](#).

⁴ CMS also included a comment solicitation for balloon sinus surgery kits ([p. 42](#)) because of concerns stated by stakeholders that marketing firms and sales reps are advertising related CPT codes “as a method for generating additional profits due to the payment for the procedure exceeding the resources typically needed to furnish the services) ([p. 43](#)).

Equipment Recommendation for Scope Systems ([p. 37](#)). In previous rulemaking, CMS implemented a methodology that separates scopes, the associated video system, and scope accessories typical as distinct equipment for each code ([p. 38](#)).

Scope Equipment: CMS divides the scopes into the following types:

- Non-video scopes
- Flexible scopes (typically paired with one of the scope video systems)
 - Diagnostic (or non-channelled)
 - Therapeutic (or channelled)
 - Multi-channelled
- Semi-rigid scopes (typically paired with one of the scope video systems)
- Rigid scopes (typically paired with one of the scope video systems)

While CMS had instituted this process previously, it did not complete development of all of the pricing inputs. In 2017, CMS stated that it did not make recent changes regarding existing scope equipment because it was awaiting input from the RUC PE Subcommittee, while the RUC PE subcommittee stated that “no further action was required” after CMS previously finalized the policy ([p. 39](#)). Therefore, CMS made additional proposals for CY 2018. CMS did not finalize its proposal to create and price a single scope equipment code for each of the categories identified, but rather, finalized creation of scope equipment codes on a per-specialty basis ([p. 40](#)). ***CMS continues to seek input on recommendations regarding scope equipment times that would be typically required for each scope category and proper pricing for each scope*** ([p. 40](#)).

Scope Video System: CMS previously defined a scope video system as ([p. 40](#)):

- A monitor
- A processor
- A form of digital capture
- A cart
- A printer

CMS did not finalize its 2018 pricing update for scope video systems with the intent to address changes in CY 2019 with input from stakeholders ([p. 41](#)).

Scope Accessories: CMS recognizes that there can be other accessories for use with scopes and finalized a proposal to separately price scope accessories (other than the scope video system) and individually evaluate whether to include as direct PE inputs for particular codes ([p. 41](#)).

CMS is delaying general proposals for further changes to scope equipment until CY 2020 because it states that the RUC Scope Equipment Reorganization Workgroup did not convene in time to make recommendations for CY 2019 rulemaking ([p. 41](#)). ***CMS proposes several specific updates:***

- ***Scope Video System (ES031):*** Increase price to \$36,306 (from \$33,391) (Rationale: addition of the LED light and miscellaneous small equipment associated with the system)
- ***Video System, Endoscopy (processor, digital capture, monitor, printer cart) (ES031):*** Changing name to *Scope Video System (monitor, processor, digital capture, cart, printer, LED Light)* (Rationale: code not limited to endoscopy)

Technical Directions to Direct PE Input Database and Supporting Files ([p. 44](#)). CMS received input that there were “clerical inconsistencies” in the direct PE database. ***CMS proposes to correct these inconsistencies in the direct PE database.*** This includes:

- 165 RUC-identified CPT codes billed with an office E/M visit more than 50 percent of the time in the non-facility setting with more minimum multi-specialty visit supply packs than post-op visits in the global period. The CMS revisions to the quantity of minimum multi-specialty visit supply packs by code in [Table 6](#).
- Potential Rank Order Anomaly in direct PE inputs for the “*Shaving of Epidermal or Dermal Lesions*” code family (from CY 2013 rulemaking). CMS believes there were clerical inconsistencies in the assignment of lower nonfacility PE RVUs for CPT 11311 (*Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.6 to 1.0 cm*). **CMS proposes to revise the direct PE inputs to align with the direct PE inputs finalized in rulemaking for CPT 11311** ([p. 49](#)).
- CMS states that it inadvertently assigned too many minutes of clinical labor time for “Obtain vital signs” in 3 therapy codes **and proposes to refine the “obtain vital signs” clinical labor task times to their previous times** ([p. 49](#)):
 - CPT 97124 (*Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)*): Restoring to 1 minute
 - CPT 97750 (*Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes*): Restoring to 1 minute
 - CPT 97755 (*Assistive technology assessment (eg, to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes*): Restoring to 3 minutes
- CMS received input of an anomaly in the direct PE inputs for CPT 52000 (*Cystourethroscopy (separate procedure)*). **CMS proposes to add the endoscope disinfectant (ES005) to CPT 52200 and add 22 of equipment time to match the equipment time of other non-scope items included in that code** ([p. 50](#)).

Updates to Prices for Existing Direct PE Inputs: Market-based Supply and Equipment Pricing Update ([p. 50](#)).

For CY 2019, CMS proposes to update the price of four supplies and one equipment item in response new analysis, as detailed in [Table 16: Invoices Received for Existing Direct PE Inputs](#). CMS notes that because all of the changes are in a single code family that the new pricing will take place completely in CY 2019 instead of a four year phase-in ([p. 50](#)).

However, in addition to these specific changes, CMS reviewed its market research process and contractor activity beginning on [p. 51](#). After reviewing the information provided and new data from the contractor,

- **CMS proposes to adopt the updated direct PE input prices for supplies and equipment as recommended in the report** ([p. 53](#)) **and moving away from pricing data “that is more than a decade old.”**
- **CMS proposes to phase in use of new direct PE input pricing over a four year period:**
 - **CY 2019: 25/75 blend**
 - **CY 2020: 50/50 blend**
 - **CY 2021: 75/25 blend**
 - **CY 2022: 100/0 blend**
- **For new supply and equipment codes priced during the transition years base on public submission of invoices, CMS proposes to fully implement those prices with no transition (because there is no current price)** ([p. 54](#)).
- As mentioned above, **for existing supply and equipment codes when prices are based on invoices submitted as part of a revaluation or comprehensive review of a code or code family, CMS proposes it will be fully implemented in the year adopted without being phased-in** ([p. 54](#)).
- **For existing codes not part of a comprehensive review and valuation of a code family where prices are established based on publicly-submitted invoices, CMS proposes to implement the established invoice**

price as the updated price and phase in the new price over the remaining years of the 4 year transition (p. 55).

- ***CMS proposes to phase in any updated pricing established during the 4 year transition for very commonly used supplies and items included in 100 or more codes (e.g. sterile gloves (SB024) or exam tables (EF023)) even when invoices are provided as part of a formal code family review (p. 55).***
- ***CMS continues to encourage stakeholders to provide input including additional invoices (p. 56).***
- ***CMS seeks comments specifically on two allergy/immunology codes because of the disproportional impact of the new pricing on the codes (even when assuming a 4 year phase-in) (p. 56):***
 - CPT 95165 (*Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)*)⁵
 - CPT 95004 (*Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report by a physician, specify number of tests*)

CMS has posted the updated supply and equipment pricing data on [the CMS website under the file CY 2019 PFS Proposed Rule Direct PE Inputs](#).

Updates to Prices for Existing Direct PE Inputs: Breast Biopsy Software (EQ370) (p. 57). CMS received a request to update the pricing for Breast Biopsy software (EQ370) equipment. In the past, CMS has not created new direct PE inputs for this equipment because, even though they received an invoice⁶ during CY 2014 rulemaking, CMS believes that the items services clinical functions similar to other items already included in the Magnetic Resonance (MR) room equipment (EL008) affiliated with the relevant CPT codes (p. 57).

The stakeholder requested that EQ370 be renamed to “*Breast MRI computer aided detection and biopsy software*” and be added to the following CPT codes:

- CPT 19085 (*Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance*)
- CPT 19086 (*Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including magnetic resonance guidance*)
- CPT 19287 (*Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance*)
- CPT 19288 (*Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including magnetic resonance guidance*)
- CPT 77X51 (new) (*Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD- real time lesion detection, characterization and pharmacokinetic analysis) when performed; unilateral*)
- CPT 77X52 (new) (*Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD- real time lesion detection, characterization and pharmacokinetic analysis) when performed; bilateral*)

CMS does not propose to update the price or add the software to these CPT codes citing its previous rationale that the current equipment attributed to the codes serves a similar clinical function. However, **CMS proposes to change the name of EQ370 from “Breast Biopsy software” to “Breast MRI computer aided detection and**

⁵ CMS states: “The direct PE costs for CPT code 95165 would go down from \$8.43 to \$8.17 as a result of the updated supply and equipment pricing information. This would result in the PE RVU for CPT code 96165 to decrease from 0.30 to 0.26.” (p. 56) (Note: CMS appears to make a typographical error by referring to 96165.)

⁶ The stakeholder also submitted a new invoice for this equipment for \$52,275 (p. 58).

biopsy guidance software” (p. 57). CMS also noted that the RUC did not include EQ370 in its recommendations for CPT 77X51 and 77X52.

Updates to Prices for Existing Direct PE Inputs: Invoice Submission: CMS noted that it has received invoices after the February 10th deadline to be included for consideration in the CY 2019 proposed rule. ***CMS stated that it would consider invoices received after the February 10th deadline and invoices submitted as public comments to this rule as part of its annual process for requests to update supply and equipment prices (p. 59).***

Adjustment to the Allocation of Indirect PE for Some Office-based Services (p. 59)

CMS referred to CY 2018 MPFS rulemaking where it established criteria for identifying services affected by the indirect PE allocation anomaly “that does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in nonfacility settings” as well as the finalized methodology for allocating indirect PE RVUs to more accurately assign PE indirect resources for these services. ***CMS proposes to continue its second year transition to this process for allocating indirect PE (p. 59).***

Determination of Malpractice Relative Value Units (RVUs) (p. 60)

To calculate the malpractice (MP) RVUs for paying physician fee schedule services, CMS relies on a methodology based on three factors:

- (1) Specialty-level risk factors derived from data on specialty-specific MP premiums incurred by practitioners;
- (2) Service level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service; and
- (3) An intensity/complexity of service adjustment to the service level risk factor based on either the higher of the work RVU or clinical labor RVU

Under statute, CMS is required to review, and if needed, adjust MP RVUs every five years with CY 2020 being the next deadline for update (p. 60). CMS had previously finalized that specialty-specific risk factors would be updated every 5 years with updated premium data and remain unchanged between the 5 year reviews (p. 61). CMS reviewed the CY 2018 proposal to update the specialty-specific prior to the next 5 year review. CMS did not finalize the proposal after pushback from stakeholders, and CMS acknowledged differences it saw in the descriptions of the raw rate filings (compared with how the data were categorized to conform with CMS-identified specialties). ***CMS continues to seek input on the next MP RVU update due to occur in CY 2020. CMS specifically requests comment on how it can improve how specialties in the state-level raw rate filings data are crosswalked for categorization into CMS specialty codes in order to develop the specialty-level risk factors and the MP RVUs (p. 62).***

Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services (p. 63)

Background

CMS reviewed the criteria under which Medicare is statutory allowed to pay for “telehealth” services (p. 63).

CMS states that through its information collection efforts, stakeholders have made clear that the barriers to Medicare payment for remote services like those described by the office visit codes include the statutory restrictions on “Medicare telehealth services,” but also include limitations on appropriate payment for “evolving physicians’ services that are inherently furnished via communication technology” (p. 65). CMS acknowledges the concerns about the statutory restrictions and goes on to state:

We have come to believe that 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, we believe that section 1834(m) of the Act 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 (p. 65).

As such, ***CMS proposes to pay for 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" (p. 66).*** This set of services would not be subject to the "Medicare telehealth services" statutory restrictions because CMS does not consider them to be "Medicare telehealth services." CMS states that "they would be paid under the PFS like other physicians' services" and reminded stakeholders that practitioners must continue to comply with privacy and security laws including HIPAA.

Proposed Communication Technology-Based Services

Brief Communication Technology-based Service (e.g. Virtual Check-in) (GHC11). CMS recognizes that as technology has evolved "a broader range of services can be furnished by health care professionals via communication technology as compared to 20 years ago" (p. 67). CMS recognizes that many practices are able to use communication technology to evaluate whether an office visit (or other service) is needed. If this results in an office visit, the remote check-in would be bundled into the visit. However, if there is no resulting office visit (or other service) there is no billable service into which the check-in can be bundled. Effective January 1, 2019, ***CMS proposes to separately pay for the service of a physician or other qualified health care professional when that physician or other 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" when it does not result in a follow-up visit (p. 67).*** CMS proposes it would be paid at a lower rate than in-person E/M services to reflect the low work time and intensity and to account for resource costs and efficiencies associated with the use of communication technology (p. 69).

- The proposed code is GVC11 (*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*) (p. 68)
- ***CMS proposes the code values in the Valuation of Specific Codes section of the proposed rule.***
- ***CMS proposes that if the communication originates from a related E/M service within the previous 7 days by the same physician or other qualified health professional (QHP) that the service is bundled in the previous E/M (p. 68).***
- ***CMS proposes that if the communication leads to an in-person E/M service with the same physician or QHP that the service would be considered bundled into that E/M service and not separately billable.***
- ***CMS proposes that this could only be used for established patients (p. 69). CMS seeks specific comment on the appropriateness of a time limit and whether, for example, setting the time limit at 24 hours would lead to a spike in the number of follow-up visits occurring 25 hours later.***
- CMS highlights that the service could be used as part of treatment for opioid use and other substance use disorders (p. 68).
- **Additional comment requests:**
 - ***CMS seeks comment on what types of communication technology are utilized by physicians or other qualified health care professionals furnishing these services (including the necessity of video and other kinds of data transmission or simply audio-only telephone interactions) (p. 68)***
 - ***CMS seeks comment on whether it should require verbal patient consent in the medical record for the service given that beneficiaries would be financially liable for cost-sharing (p. 69).***

- **CMS seeks comment on whether it would be clinically appropriate to set a frequency limitation on the use of the code and what would be a reasonable limit (p. 69).**
- **CMS seeks comment on how clinicians can best document the medical necessity of this service (consistent with documentation requirements of any other service under the MPFS) (p. 70).**

Remote Evaluation of Pre-Recorded Patient Information (GRAS1). CMS states that it has received requests that CMS make separate payments for physician use of recorded video and/or images captured by a patient to evaluate a patient's condition (p. 70).⁷ Because the use of this images is not meant to replace an in-person service, it is not a "Medicare telehealth service." Effective, January 1, 2019, **CMS proposes a specific code that describes remote professional evaluation of patient-transmitted information conducted via pre-recorded "store and forward" video or image technology (p. 71).**

- 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) (p. 71).
- Similar to the previous code proposal, **CMS proposes that this would be a stand-alone service "that could be separately billed to the extent 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" (p. 71).**
- **CMS proposes the code values in the [Valuation of Specific Codes section](#) of the proposed rule.**
- **Additional comment requests:**
 - **CMS seeks comment on whether these services should be limited to established patients**
 - **CMS seeks comment on whether there are certain services where it is appropriate for new patients to receive the services (e.g. dermatology or ophthalmology) (p. 72)**

Interprofessional Internet Consultation. The AMA RUC previously forwarded recommendations for CPT codes describing interprofessional consultations for which CMS declined to make separate payment (p. 72):

- CPT 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)
- CPT 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)
- CPT 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)
- CPT 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)

The CPT Editorial Panel also created (and the RUC recommended values for) two (2) new codes to describe additional consultative services:

⁷ CMS states that these services are referred to as "store-and-forward" communication technology that provides for the "asynchronous transmission of health care information" under [Social Security Act §1834\(m\)](#) (p. 70).

- CPT 994X0 (*Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes*)
- CPT 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 describes that the codes are intended to reflect work when a professional “requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise to assist with the diagnosis and/or management of the patient’s problem without the need for the patient’s face-to-face contact with the consulting physician or qualified health professional” (emphasis added) (p. 74). **CMS proposes to begin separately paying for these codes. CMS proposes the code values in [the Valuation of Specific Codes section](#) of the proposed rule.** CMS states that because the resource costs associated with seeking or providing consultative advice is considered bundled, CMS believes “specialist input is often sought through scheduling a separate visit for the patient when a phone or internet-based interaction between the treating practitioner and the consulting provider would have been sufficient” (p. 74).

CMS proposes to require the treating practitioner to obtain verbal beneficiary consent in advance of these services (documented in the medical record) given that billing for this service would trigger beneficiary cost-sharing (p. 76).

Additional Comment Requests:

- **CMS seeks comment on its assumption that these are separately identifiable services attributable to a single beneficiary (as opposed to information shared as a professional courtesy or as continuing education) (p. 75)**
- **CMS seeks comment on how best to minimize program integrity issues given concerns about CMS and contractor ability to whether an interprofessional consultation is “reasonable and necessary” (p. 75)**
- **CMS seeks comment on whether there are similar services paid by private payers and what controls or limitations those payers use to ensure appropriate billing (p. 76)**

Medicare Telehealth Services⁸ (p. 76)

CMS previously had a deadline of no later than December 31 of each calendar year to add services to the list of Medicare telehealth services or the next rulemaking cycle. **CMS states that beginning in CY 2019 it intends to accept requests through February 10th (which aligns with the deadline for receipt of code valuation recommendations from the RUC) (p. 78).** Thus, to be considered for CY 2020 rulemaking, requests must be received by February 10, 2019. The following requests were received as “services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services” in CY 2017 for inclusion in 2019:

- **G0513 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service).** CMS believed this service was sufficiently similar to services currently on the telehealth list. **CMS proposes to add G0513 to the telehealth list on a Category 1 basis for 2019 (p. 79).** CMS believes all components of the service

⁸ Note that CMS makes a technical proposal to follow up on a previously finalized change regarding the list of telehealth services. CMS previously finalized that it would not list the approved telehealth services in regulation, but rather reference in regulation the location on the CMS website where the approved services were listed. **CMS proposes to delete the previous descriptions of individual services and exceptions (p. 91).**

can be furnished via interactive telecommunications technology and aligns with the provision of the underlying preventive health service that can be reported via telehealth.

- G0514 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code G0513 for additional 30 minutes of preventive service) CMS believed this service was sufficiently similar to services currently on the telehealth list. **CMS proposes to add G0514 to the telehealth list on a Category 1 basis for 2019** (p. 79). CMS believes all components of the service can be furnished via interactive telecommunications technology and aligns with the provision of the underlying preventive health service that can be reported via telehealth.

CMS also **declined to add** the following requests to the list of telehealth services:

- Chronic Care Remote Physiologic Monitoring: CMS reiterated past rationale for not including the services on the Medicare telehealth list: the codes already inherently describe non face-to-face services so there is no need to add them to the list (p. 81).
 - CPT 990X0 (Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment)
 - CPT 990X1 (Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days).
 - CPT code 994X9 (Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month)
- Interprofessional Internet Consultation: As discussed in the previous section, CMS does not believe that these are “Medicare telehealth services” and separately proposes them for payment as communication technology-based services (and therefore will not be subject to the “Medicare telehealth restrictions”) (p. 81).
 - CPT 994X0 (Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes)
 - CPT 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)
- Initial Hospital Care Services: CMS previously considered these codes for addition to the Medicare telehealth list. Initial hospital *consultation* services are on the telehealth list, but no services that resemble initial hospital for an acutely ill patient by the admitting practitioner who will have ongoing responsibility for the patient during the hospital stay (p. 82). CMS believes it is “critical that the initial hospital visit by the admitting practitioner be conducted in person to ensure that the practitioner with ongoing treatment responsibility comprehensively assesses the patient’s condition upon admission to the hospital through a thorough in-person examination.” (p. 83).
 - CPT 99221 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the

problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity.)

- CPT 99222 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity.)
- CPT 99223 (Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity.)

CMS also **declined to change the requirements** for the following codes:

- **Subsequent Hospital Care Services:** These codes are currently on the Medicare telehealth list but are only allowed to be billed via telehealth once every 3 days ([p. 84](#)). CMS received a request to remove the frequency limitation. CMS continues to believe “that admitting practitioners should continue to make appropriate in-person visits to all patients who need such care during their hospitalization. Therefore, ***CMS declines to remove the telehealth frequency limitations for subsequent hospital care services*** ([p. 85](#)).
- CPT 99231 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.)
- CPT 99232 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; an expanded problem focused examination; medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit.)
- CPT 99233 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; a detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.)
- **Subsequent Nursing Facility Care Services:** These codes are currently on the Medicare telehealth list but are only allowed to be billed via telehealth once every 30 days ([p. 86](#)). CMS received a request

that CMS remove the frequency limitation when the services are provided for psychiatric care. CMS states that because the codes are used to report care for patients with a variety of diagnoses (including psychiatric diagnoses) and because CMS continues to have concerns about potential acuity and complexity of SNF patients, **CMS does not believe it would appropriate to remove the frequency limitation (p. 87)**.

- CPT 99307 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 10 minutes are spent at the bedside and on the patient's facility floor or unit.)
- CPT 99308 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; an expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 15 minutes are spent at the bedside and on the patient's facility floor or unit.)
- CPT 99309 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; a detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient has developed a significant complication or a significant new problem. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.)
- CPT 99310 (Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A comprehensive interval history; a comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 35 minutes are spent at the bedside and on the patient's facility floor or unit.)

Expanding the Use of Telehealth Under the Bipartisan Budget Act of 2018⁹ (p. 87)

CMS outlined that the Bipartisan Budget Act of 2018 (BBA 18) modified limitations related to geography and patient setting for certain telehealth services, including:

Certain home dialysis end-stage renal disease (ESRD)-related services (via [BBA 18 Section 50302](#)): There are several requirements related to providing this service via telehealth included in the new statutory provisions:

- This section request that the individual must receive a face-to-face visit without the use of telehealth at least monthly for the initial 3 months of home dialysis and at least once every 3 consecutive 3 months after the initial 3 months ([p. 88](#)).

⁹ Note that in the introduction to the “Communications-based Technology Services” section CMS also lists the BBA 2018 provision that is directed at expanding telehealth for services furnished by practitioners in certain Accountable Care Organizations (ACOs) (via [BBA 18 Section 50324](#)). However, CMS does not address this provision in this section.

- It includes a renal dialysis facility and the home of an individual as telehealth originating sites but *only* for the purposes of the monthly ESRD-related clinical assessments furnished through telehealth.
- The telehealth geographic requirements do not apply to telehealth services (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.
- It requires that no originating site facility fee is paid if the home of the individual is the originating site.

CMS proposes to revise its regulations to implement these statutory requirements (p. 89).

Acute Stroke-Related Services (via [BBA 18 Section 50325](#)). These statutory provisions allow for telehealth services to be delivered for the purposes of “diagnosis, evaluation, or treatment of acute stroke.” There are several provisions included in the statute:

- The statute removes the restrictions on the geographic locations and types of originating sites where acute stroke telehealth services can be furnished.
- The statute specifies that acute stroke telehealth services can be furnished in any hospital, critical access hospital, mobile stroke units, or any other site determined appropriate by the Secretary (in addition to current eligible telehealth originating sites).
- The statute limits payment of an originating site facility fee to acute stroke telehealth services furnished in sites that meet the usual telehealth restrictions.

To implement these provisions, ***CMS proposes a new modifier to identify acute stroke telehealth services (p. 90).*** The modifier would be added to the clinically appropriate HCPCS code when billing for an acute stroke telehealth service or an originating site facility fee.

In addition, ***CMS 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 (p. 90).*** ***CMS also seeks comment on other possible originating sites for telehealth services furnished “for the diagnosis, evaluation, or treatment of symptoms of an acute stroke” (p. 91).***

Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders (p. 91)

CMS cites evidence that routine counseling can increase the effectiveness of treatment for substance abuse disorders (both with or without medication assisted treatment (MAT)) ([p. 92](#)). CMS believes that creating a bundled episode of care for components of MAT (e.g. management and counseling treatment, including opioid use disorder, treatment planning and medication management or observing drug dosing) could provide “opportunities to better leverage services furnished with communication technology while simultaneously expanding treatment for substance abuse disorders, as well as prevent the need for more acute services ([p. 92](#)).

CMS seeks public comment on creating of a bundled payment of this type, including (pp. 93-94):

- Whether it would be appropriate to develop a separate bundled payment for an episode of care for substance abuse disorders
- Whether such a bundled episode-based payment would be beneficial to improve access, quality and efficiency for SUD treatment
- Development coding and payment for a bundled episode of care for treatment for substance abuse disorders that could include overall treatment management, any necessary counseling, and components of a MAT program
- What assumptions CMS should make about the typical number of counseling sessions
- What assumptions CMS should make about the duration of the service period

- What assumptions CMS should make about which types of practitioners could furnish these services
- What assumptions CMS should make about 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
- Whether the concept of a global period (similar to the existing globals for surgical procedures) might be applicable to treatment for substance abuse disorders
- 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 overall care (and supervise any other counselors participating in treatment)
- Regulatory and subregulatory changes to prevent opioid use disorder and improve access to treatment under the Medicare program
- Methods for identifying non-opioid alternatives for pain treatment and management along with identifying barriers that inhibit access to non-opioid alternatives for pain treatment and management (including payment or coverage barriers)
- Suggestions to improve existing requirements in order to more effectively address the opioid epidemic.

Potentially Misvalued Services under the PFS ([p. 95](#))

As part of CMS' ongoing RVU refinement process, CMS plans to continue its review of potentially misvalued codes of the upcoming years. CMS reviewed its process and states that it requests recommendations from the RUC and other public commenters. In addition to the codes CMS identifies, the RUC also identifies misvalued codes for review. CMS also identifies potentially misvalued codes via its public nomination process. CMS notes that it plans to continue its work to examine potentially misvalued codes. CMS states that since CY 2009 it has reviewed approximately 1,700¹⁰ potentially misvalued codes and assigned appropriate work RVUs and Direct PE inputs as a result of the review ([p. 99](#)).

CY 2019 Identification and Review of Potentially Misvalued Services ([p. 100](#))

Public Nomination. CMS reviewed its public nomination process for potentially misvalued codes ([p. 100](#)). CMS stated that it received submissions on several codes for review under the potentially misvalued code initiative. The codes are as follows:

Submission 1

CMS stated that one submitter submitted several codes for review under the Potentially Misvalued Services initiative.

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

The submitter provided the following rationale for adding the codes to the potentially misvalued code initiative:

- The codes are high volume;

¹⁰ Note that this is the same exact number that CMS uses in the CY 2018 proposed rule on [p. 103](#).

- “a systemic overvaluation of work RVUs in certain procedures and testes based ‘on a number of Government Accountability Office (GAO) and Medicare Payment Advisory Commission (MedPAC) reports, media reports regarding time inflation of specific services, and the January 19, 2017 Urban Institute report for CMS”;
- The times built into the work RVUs are inaccurate (citing “substantial overestimates of preservice and postservice time, including follow-up inpatient and outpatient visits that do not take place” and “time estimates for tests and some other procedures are primarily overstated as part of the intraservice time”); and
- “that previous RUC reviews of these services did not result in reductions in valuation that adequately reflected reductions in surveyed times.”

CMS does not state whether it proposes to add the codes to the list of potentially misvalued codes- just that the codes were submitted via public nomination. Even in CMS’ description of the process for Potentially Misvalued Codes, CMS states, “[w]e publish the list of nominated codes and indicate whether we proposed each nominated code as a potentially misvalued code.” (p. 101).

Submission 2

CMS received a request to add the following CPT codes to the list of Potentially Misvalued Code initiative:

- CPT 92992 (Atrial septectomy or septostomy; transvenous method, balloon (eg, Rashkind type) (includes cardiac catheterization))
- CPT 92993 (Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)).

CMS notes that the codes are current priced by the MACs. ***CMS does not state whether it proposes to add the codes to the list of potentially misvalued codes- just that the codes were submitted via public nomination. Even in CMS’ description of the process for Potentially Misvalued Codes, CMS states, “[w]e publish the list of nominated codes and indicate whether we proposed each nominated code as a potentially misvalued code.” (p. 101).***

Code Screens. In past years, CMS had prioritized the following codes screens for identifying codes for the misvalued code initiative:

- Codes with low work RVUs commonly billed in multiple units per single encounter
- Codes with high volume and low work RVUs
- Codes with site-of-service-anomalies
- E/M codes
- PFS high expenditure services
- Services with standalone PE procedure time
- Services with anomalous time
- Contractor Medical Director identified potentially misvalued codes
- Codes with higher total Medicare payments in office than in hospital or ASC
- Publicly nominated potentially misvalued codes
- 0-day global services that are typically billed with an evaluation and management (E/M) service with modifier 25

CMS makes no mention of adding any additional screens or codes via its screens to the Potentially Misvalued Code initiative.

Update on the Global Surgery Data Collection (p. 102). CMS reviewed its global payment policy, noting that CMS does not typically collect data on how many post-op visits are performed during the global period. As

required by MACRA, CMS implemented a process for collecting data on the number and level of post-op visits. In CY 2017, CMS finalized the use of CPT 99024 (*Postoperative follow-up visit, normally excluded 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*) for reporting post-operative services for codes that are reported annually by more than 100 practitioners and are reported more than 10,000 times or have allowed charges in excess of \$10 million annually. While CMS encouraged broad utilization of the code, the use of 99024 was only required by practices in groups of 10 or more practitioners in the following states:

- Florida
- Kentucky
- Louisiana
- Nevada
- New Jersey
- North Dakota
- Ohio
- Oregon
- Rhode Island

In this rule, CMS provided several reporting statistics from the states where reporting was required, including:

- Post-op visits (99024) reported: 990,581
- Percentage of practitioners (assumed to be in practices that met the group size requirement) who furnished one of the identified procedures that reported at least one or more visit with 99024: 45%
- Reporting rates by specialty: See [Table 9](#)
- Reporting rates by state: See [Table 10](#)
- Percentage of 10-day globals (where possible to match post-op visit to specific procedure) with one or more post-op visits reported: 4% (By specialty, see [Table 11](#)).
- Percentage of 90-day globals (where possible to match post-op visit to specific procedure) with one or more post-op visits reported: 67% (By specialty, see [Table 12](#))

CMS believes one potential explanation for the results is that practitioners are not consistently reporting the post-up visits ([p. 110](#)).

- **CMS seeks input on how it can encourage reporting to ensure the validity of the data “without imposing an undue burden.”**
- **CMS seeks input on whether it needs to “do more to make practitioners aware of their obligation.”**
- **CMS seeks input on whether it should consider implementation of an “enforcement mechanism.”**
- **CMS requests comment on whether it is reasonable to assume that many visits are not being furnished (or whether there is an alternate explanation)**
- **CMS seeks comment on whether it can infer from the data that the post-op visits are not being delivered (or if the post-op visit is being furnished by a different practitioner)**
- **CMS seeks comment on whether the post-op visits are being delivered after the end of the global period and being reported and paid for separately**

CMS also identified “robust reporters.” CMS defined these practitioners as those who

- Furnished 10 or more procedures with 90-day global periods where it is possible to match specific procedures to reported postoperative visits without ambiguity; and
- Reported a post-operative visit using CPT 99024 for at least half of these 90-day global procedures

For these “robust reporters”:

- Percent of procedures (90-day global) with one or more reported post-op visits: 87%
- Percent of procedures (10-day global) with one or more reported post-op visits: 16%

CMS states that this is evidence that, for 10-day globals, post-op visits are not being furnished rather than that post-op visits are not being reported ([p. 111](#)). **CMS seeks comment on how to approach 10-day globals for which the preliminary data suggests post-op visits are rarely performed ([p. 111](#)). In this context, CMS also requests comment on whether it should consider changing the global period and reviewing the code valuation ([p. 111](#)).**

- **Transfers of Care:** CMS also discusses the potential impact of transfers of care ([p. 111](#)). Under Medicare payment policy, if the surgeon transfers the patient to another practitioner for post-op care, the surgeon will bill for only the surgical care by appending modifier ~54 to the CPT code for the procedure; the practitioner who furnishes the post op care bills using modifier ~55 to designate “postoperative management only.” However, this is only required if there is a “formal transfer of postoperative care.” **CMS seeks comment on whether it should consider requiring the use of modifiers regardless of whether a transfer of care is formalized** ([p. 111](#)).
- **Level of Visit:** CMS reminds stakeholders that the reporting of 99024 is intended to collect data on the frequency of post-op visits but not the level. CMS noted that it will begin (“in the near future”) distribution a survey-based data collection effort on the level of post-op visits which include collecting information on:
 - Time involved in furnishing post-op visits
 - Staff involved in furnishing post-op visits
 - Activities involved in furnishing post-op visits
 - Non-face-to-face services

CMS notes that RAND developed a survey to accomplish this that was piloted but yielded a low response rate. CMS states that it refocused the survey “to collect information on post-operative visits and non-face-to-face services associated with a small number of high-volume procedures” ([p. 112](#)). CMS also notes that future survey-based data collection could focus on a broader range of procedures with 10- and 90-day globals.

Radiologist Assistants ([p. 113](#))

In accordance with §410.32(b)(3), except as otherwise provided, all diagnostic X-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under at least a general level of physician supervision. In addition, some of these tests require either direct or personal supervision. CMS lists the required minimum physician supervision level for each diagnostic X- ray and other diagnostic test service along with the codes and relative values for these services in the PFS Relative Value File, which is posted on the [CMS website](#). For most diagnostic imaging procedures, this required physician supervision level applies only to the technical component (TC) of the procedure.

In response to the Request for Information on CMS Flexibilities and Efficiencies (RFI) that was issued in the CY 2018 PFS proposed rule, many commenters recommended that CMS revise the physician supervision requirements at §410.32(b) for diagnostic tests with a focus on those that are typically furnished by a radiologist assistant under the supervision of a physician. Specifically, the commenters stated that all diagnostic tests, when performed by radiologist assistants (RAs), can be furnished under direct supervision rather than personal supervision of a physician, and that CMS should revise the Medicare supervision requirements so that when RAs conduct diagnostic imaging tests that would otherwise require personal supervision, they only need to do so under direct supervision.

After consideration stakeholder input, ***CMS is proposing to revise its regulations to specify that all diagnostic imaging tests may be furnished under the direct supervision of a physician when performed by an RA in***

accordance with state law and state scope of practice rules. Stakeholders representing the radiology community have provided CMS with information showing that the RA designation includes registered radiologist assistants (RRAs) who are certified by The American Registry of Radiologic Technologists, and radiology practitioner assistants (RPAs) who are certified by the Certification Board for Radiology Practitioner Assistants. ***CMS is proposing to revise its regulation at §410.32 to add a new paragraph (b)(4) to state that diagnostic tests performed by an RRA or an RPA require only a direct level of physician supervision, when permitted by state law and state scope of practice regulations.*** CMS notes that for diagnostic imaging tests requiring a general level of physician supervision, this proposal would not change the level of physician supervision to direct supervision. Otherwise, the diagnostic imaging tests must be performed as specified elsewhere under §410.32(b). CMS includes additional detail on its considerations in making this proposal on [p. 114](#).

Payment Rates under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital ([p. 115](#))

Background

CMS has continued to monitor concerns that the trends in hospital acquisition of physician practices and increased delivery of physician services in a hospital setting have led to total higher Medicare payments. When care is delivered in a hospital Provider Based Department (PBD), Medicare makes two payments: one for the facility fees (under the OPPS) and the other for the physician's professional services (under the Physician Fee Schedule). Medicare and other stakeholders have been concerned that the total of those two payments are higher for many services when billed out of a PBD than they were when they were previously provided in the physician office setting.

The Bipartisan Budget Act of 2015 included a provision that “applicable items and services”¹¹ furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, will not be considered OPD service . . . for purposes of payment under the OPPS and will instead be paid ‘under the applicable payment system; under Medicare Part B.” ([p. 115](#)). The statute defines “off-campus outpatient department of a provider” as “a department of a provider . . . that is not located on the campus of such provider, or within the distance from a remote location of a hospital¹² facility.” The statute also excepts from that definition “an off-campus PBD that was billing . . . with respect to covered OPD services furnished prior to” November 2, 2015.” CMS previously finalized that the “applicable payment system” for the provisions covered by the Bipartisan Budget Act of 2015 would be the Medicare Physician Fee Schedule (MPFS). That is, most nonexcepted items and services furnished by off-campus PBDs will be paid under the MPFS. CMS previously finalized a policy in which nonexcepted off-campus PBDs would continue to bill for nonexcepted items and services on the institutional claim using the claim line modifier ~PN to indicate that an item or service is a nonexcepted item or service ([p. 116](#)).

Payment Mechanism & PFS Relativity Adjuster ([p. 115](#))

In creating the new payment mechanism, CMS sought to ensure that the relativity in OPPS payment rates was maintained under the relative payment system of the MPFS. Therefore, ***CMS had established a transitional policy of site-specific rates under the MPFS for the TC of nonexcepted “items and services” furnished by nonexcepted off-campus PBDs based on the OPPS payment for those services and scaled down by “the PFS Relativity Adjuster”*** ([p. 116](#)). For CY 2017, CMS had implemented a PFS Relativity Adjuster of 50 percent of the OPPS rate ([p. 117](#)). In CY 2018, CMS finalized a PFS Relativity Adjuster of 40 percent of the OPPS rate ([p. 117](#)).

¹¹ The statutory definition of “applicable items and services” specifically excludes items and services furnished by a dedicated emergency department. Therefore, these items and services will continue to be paid under the OPPS.

¹² Current regulation defines “remote location of a hospital” as “a facility or an organization that is either created by, or acquired by a hospital that is the main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider . . .”

based on its calculations that that yielded a 35 percent relative difference in payment rates between the OPPS and MPFS ([p. 120](#)) (based on the points of reference that were included in the CMS analysis as explained on [pp. 118-120](#)).

CMS originally set the PFS Relativity Adjuster based on claims data received after providers were required to begin using the ~PO modifier in CY 2016 to signal that it was a service billed by an off-campus department of a hospital because it did not yet have data available based on the use of the ~PN modifier. As it continues to explore other options to improve payment accuracy, ***CMS proposes to continue instructing nonexcepted off-campus PBDs to bill for nonexcepted items and services on an institutional claim to bill using the ~PN modifier*** ([p. 120](#)). CMS notes that this will continue until it can find “a workable alternative mechanism that would improve payment accuracy.” ([p. 121](#)).¹³

CMS is proposing to make several CY 2019 adjustments to its PFS Relativity Adjuster methodology based on having had access to a full year of claims data submitted with use of the ~PN modifier. This data showed that:

- The single most frequently reported service furnished in a nonexcepted PBD is G0463 (*Hospital outpatient clinic visit for assessment and management of a patient*)
- In CY 2017, 49 percent of all claims lines for separately payable or conditionally packaged services furnished by nonexcepted off-campus PBDs included G0463 (which was 30 percent of total Medicare payments for separately payable or conditionally packaged services)
- The top 30 code combinations accounted for 80 percent of all claim lines and about 60 percent of Medicare payments for services that are separately billable.
- The largest differences between the number of claims lines and the number of claims units are for injections and immunizations (not typically separately payable or conditionally packaged under the OPPS).

In order to set the CY 2019 PFS Relativity Adjuster, CMS established site-specific rates under the PFS to reflect the TC of items and services furnished by nonexcepted off-campus PBDs in CY 2017 ([p. 122](#)). Where CMS cannot make a direct comparison (because the code under the PFS does not calculate a separate TC), CMS estimated the site-specific rate as:

- The difference between the PFS nonfacility rate and the PFS facility rate; or
- In instances where payment would have been made only to the facility or only to the physician, the full nonfacility rate ([p. 122](#)).

CMS goes into further detail on the methodology beginning on [p. 122](#), which is based on the same methodology used in CY 2017 and CY 2018. ***CMS found that its updated analysis supports maintaining a PFS Relativity Adjuster of 40 percent for CY 2019.*** In addition, ***CMS proposes to maintain the PFS Relativity Adjuster of 40 percent “for future years until updated data or other considerations indicate that an alternative adjuster or a change to our approach is warranted”*** ([p. 123](#)). CMS also states that it believes that maintaining its policy of applying the overall scaling factor to OPPS payments to implement these provisions of the Bipartisan Budget Act of 2014 “allows hospitals to continue billing through a facility claim form and permits continued use of the packaging rules and cost report-based relative payment rate determinations for nonexcepted services” ([p. 129](#)).

CMS proposes to maintain its previously finalized policies for nonexcepted off-campus PBDs for supervision rules, beneficiary cost-sharing, and geographic adjustments ([p. 124](#)).

Future Years ([p. 127](#))

CMS states that it intends to continue to examine claims data to determine whether a different PFS Relativity Adjuster is warranted and whether it should make additional methodology changes ([p. 127](#)).

¹³ See also, [CMS Transmittal 3941, Change Request 10417 \(December 22, 2017\)](#).

- CMS will continue to monitor claims for shifts in mix of services that could affect the relativity between the OPPS and PFS.
- CMS will continue to monitor whether there is an increase over time in the share of nonexcepted items and services with lower TC rates under the PFS compared with APC rates under the OPPS (that would require a lower PFS Relativity Adjuster)
- CMS will assess annual payment updates to the PFS and OPPS fee schedule rules (e.g. expanded OPPS packaging or an increase in the number of codes with PFS global periods) ([p. 128](#)).
- CMS will analyze PFS claims to identify patterns of services furnished together on the same day¹⁴
- CMS will continue to look for alternatives for its current estimates to better reflect the TC of services furnished in nonexcepted off campus PBDs.
- ***CMS is seeking feedback on how CMS can improve pricing and transparency with regard to the differences in the payment rates across sites of service ([p. 128](#)).***

Valuation of Specific Codes ([p. 130](#))

Background: Process for Valuing New, Revised, and Potentially Misvalued Codes ([p. 130](#))

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS, and CMS notes it remains a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. CMS will continue to engage with stakeholders, including the RUC, with regard to its approach for accurately valuing codes, and as the agency prioritizes its obligation to value new, revised, and potentially misvalued codes. CMS continues to welcome feedback from all interested parties regarding valuation of services for consideration through its rulemaking process.

Methodology for Establishing Work RVUs ([p. 133](#))

For each code identified in this section, CMS conducted a review that included the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. CMS' reviews of recommended work RVUs and time inputs generally included, but were not limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. Multiple other approaches have also been used when reviewing and establishing work RVUs, such as survey data (collected by specialty societies), building block, crosswalks to key reference or similar codes, and magnitude estimation.

CMS explains that the agency has been particularly concerned with the RUC's and various specialty societies' objections to its approach given the significance of the RUC's recommendations to CMS' process for valuing services and since much of the information CMS has used to make the adjustments is derived from the RUC survey process. CMS requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, the agency did not receive any specific potential alternatives. CMS looks forward to continuing to engage with stakeholders and commenters, including the RUC, as the agency prioritizes its obligation to value new, revised, and potentially misvalued codes, and will continue to welcome feedback from all interested parties regarding valuation of services for consideration through the PFS rulemaking process.

¹⁴ Note the potential impact that the expansion of the MPPR to Modifier ~25 situations could have here.

Methodology for the Direct PE Inputs to Develop PE RVUs (p. 138)

Like its review of recommended work RVUs, CMS' review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. CMS' review and refinement of RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. In this proposed rule, CMS addresses several refinements that are common across codes, and refinements to particular codes are addressed in the portions of this section that are dedicated to particular codes.

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. Nearly half of the refinements listed in [Table 14](#) result in changes under the \$0.30 threshold and are unlikely to result in a change to the RVUs.

Common Refinements

In this section, CMS discusses common refinements, including:

- Changes in Work Time
- Equipment Time
- Standard Tasks and Minutes for Clinical Labor Tasks
- Recommended Items that are not Direct PE Inputs
- New Supply and Equipment Items
- Service Period Clinical Labor Time in the Facility Setting
- Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

Proposed Valuation of Specific Codes for CY 2019 (p. 145)

[Table 13](#) outlines proposed work RVUs for new, revised and potentially misvalued codes for CY 2019, where [Table 14](#) outlines proposed direct practice expense refinements for CY 2019. CMS provides more detail on the proposed valuation for the following codes in the proposed rule:

- [Fine Needle Aspiration \(CPT codes 10021, 10X11, 10X12, 10X13, 10X14, 10X15, 10X16, 10X17, 10X18, 10X19, 76492, 77002 and 77021\)](#)
- [Biopsy of Nail \(CPT code 11755\)](#)
- [Skin Biopsy \(CPT codes 11X02, 11X03, 11X04, 11X05, 11X06, and 11X07\)](#)
- [Injection Tendon Origin-Insertion \(CPT code 20551\)](#)
- [Structural Allograft \(CPT codes 209X3, 209X4, and 209X5\)](#)
- [Knee Arthrography Injection \(CPT code 27X69\)](#)
- [Application of Long Arm Splint \(CPT code 29105\)](#)
- [Strapping Lower Extremity \(CPT codes 29540 and 29550\)](#)
- [Bronchoscopy \(CPT codes 31623 and 31624\)](#)
- [Pulmonary Wireless Pressure Sensor Services \(CPT codes 332X0 and 93XX1\)](#)
- [Cardiac Event Recorder Procedures \(CPT codes 332X5 and 332X6\)](#)
- [Aortoventriculoplasty with Pulmonary Autograft \(CPT code 335X1\)](#)
- [Hemi-Aortic Arch Replacement \(CPT code 33X01\)](#)
- [Leadless Pacemaker Procedures \(CPT codes 33X05 and 33X06\)](#)
- [PICC Line Procedures \(CPT codes 36568, 36569, 36X72, 36X73, and 36584\)](#)
- [Biopsy or Excision of Inguinofemoral Node\(s\) \(CPT code 3853X\)](#)
- [Radioactive Tracer \(CPT code 38792\)](#)

- [Percutaneous Change of G-Tube \(CPT code 43760\)](#)
- [Gastrostomy Tube Replacement \(CPT codes 43X63 and 43X64\)](#)
- [Diagnostic Proctosigmoidoscopy – Rigid \(CPT code 45300\)](#)
- [Hemorrhoid Injection \(CPT code 46500\)](#)
- [Removal of Intraperitoneal Catheter \(CPT code 49422\)](#)
- [Dilation of Urinary Tract \(CPT codes 50X39, 50X40, 52334, and 74485\)](#)
- [Transurethral Destruction of Prostate Tissue \(CPT codes 53850, 53852, and 538X3\)](#)
- [Injection Digital Nerves \(CPT code 64455\)](#)
- [Removal of Foreign Body – Eye \(CPT codes 65205 and 65210\)](#)
- [X-Ray Spine \(CPT codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120\)](#)
- [X-Ray Sacrum \(CPT codes 72200, 72202, and 72220\)](#)
- [X-Ray Elbow-Forearm \(CPT codes 73070, 73080, and 73090\)](#)
- [X-Ray Heel \(CPT code 73650\)](#)
- [X-Ray Toe \(CPT code 73660\)](#)
- [X-Ray Esophagus \(CPT codes 74210, 74220, and 74230\)](#)
- [X-Ray Urinary Tract \(CPT code 74420\)](#)
- [Fluoroscopy \(CPT code 76000\)](#)
- [Ultrasound Elastography \(CPT codes 767X1, 767X2, and 767X3\)](#)
- [Ultrasound Exam – Scrotum \(CPT code 76870\)](#)
- [Contrast-Enhanced Ultrasound \(CPT codes 76X0X and 76X1X\)](#)
- [Magnetic Resonance Elastography \(CPT code 76X01\)](#)
- [Computed Tomography \(CT\) Scan for Needle Biopsy \(CPT code 77012\)](#)
- [Dual-Energy X-Ray Absorptiometry \(CPT code 77081\)](#)
- [Breast MRI with Computer-Aided Detection \(CPT codes 77X49, 77X50, 77X51, and 77X52\)](#)
- [Blood Smear Interpretation \(CPT code 85060\)](#)
- [Bone Marrow Interpretation \(CPT code 85097\)](#)
- [Fibrinolysis Screen \(CPT code 85390\)](#)
- [Electroretinography \(CPT codes 92X71, 92X73, and 03X0T\)](#)
- [Cardiac Output Measurement \(CPT codes 93561 and 93562\)](#)
- [Coronary Flow Reserve Measurement \(CPT codes 93571 and 93572\)](#)
- [Peripheral Artery Disease \(PAD\) Rehabilitation \(CPT code 93668\)](#)
- [Electrocorticography \(CPT code 96X00\)](#)
- [Chronic Care Remote Physiologic Monitoring \(CPT codes 990X0, 990X1, and 994X9\)](#)
- [Interprofessional Internet Consultation \(CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99449\)](#)
- [Chronic Care Management Services \(CPT code 994X7\)](#)
- [Wound Closure by Adhesive \(HCPCS code G0168\)](#)
- [Structured Assessment, Brief Intervention, and Referral to Treatment for Substance Use Disorders \(HCPCS codes G0396, G0397, and G5BR1\)](#)
- [Prolonged Services \(HCPCS code GPRO1\)](#)
- [Remote pre-recorded services \(HCPCS code GRAS1\)](#)
- [Brief Communication Technology-based Service, e.g. Virtual Check-in \(HCPCS code GVC11\)](#)
- [Visit Complexity Inherent to Certain Specialist Visits \(HCPCS code GCG0X\)](#)
- [Visit Complexity Inherent to Primary Care Services \(HCPCS code GPC1X\)](#)
- [Podiatric Evaluation and Management Services \(HCPCS codes GPD0X and GPD1X\)](#)
- [Comment Solicitation on Superficial Radiation Treatment Planning and Management](#)

Evaluation & Management (E/M) Visits ([p. 323](#))

Background

CMS provides a review of the current evaluation and management (E/M) coding and payment structure, including the three components of history, exam, and medical decision making (MDM) beginning on [p. 323](#). CMS also highlights that while it differs by specialty, overall:

- All E/M visits make up approximately 40 percent of allowed charges for physician fee schedule services; while
- Office/outpatient E/M visits make up approximately 20 percent of allowed charges for physician fee schedule services.

CMS notes that E/M visits represent a greater share of total allowed services for those clinicians who do not routinely “furnish procedural interventions or diagnostic tests” including:

- Primary care practitioners; and
- Specialists such as neurologists, endocrinologists, and rheumatologists.

CMS also states that some specialties tend to furnish lower level E/M visits more often than higher level E/M visits, specifically citing podiatry.

CMS then states that some specialties bill more E/M visits on the same day as they bill minor procedures, citing:

- Dermatology
- Otolaryngology

CMS also summarizes some of its past activities and concerns regarding the valuation of E/M visits ([p. 324](#)).

E/M Documentation Guidelines

Citations. CMS cites the currently used [1995 E/M Documentation Guidelines](#) and the [1997 E/M Documentation Guidelines](#).¹⁵ While CMS references the AMA’s CPT codebook for E/M visits and some similarities to the E/M documentation guidelines, CMS points out that the AMA’s CPT codebook:

- Does not include examples of clinical work that comprise different levels of medical decision-making
- Does contain references to preventive care.

Time. CMS states that (according to both Medicare billing and CPT coding rules), “when 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) the duration of the visit can be used as an alternative basis to select the appropriate E/M visit level)” and provide citations from the various controlling documents ([p. 327](#)).

Critiques. CMS reviewed the input that it has received regarding the E/M documentation guidelines beginning on [p. 328](#), including:

- “administratively burdensome and outdated with respect to the practice of medicine”
- “outdated material (on history, exam and MDM) that can be found within all versions of the E/M guidelines”
- “too complex, ambiguous, fail to meaningfully distinguish differences among code levels”
- “not updated for changes in technology, especially electronic health record (EHR) use”
- “lack of stakeholder consensus (with widely varying views among specialties)”¹⁶

¹⁵ CMS notes substantial similarities between the 1995 and 1997 E/M documentation guidelines, but includes a comparison of the differences in how the 1995 and 1997 guidelines distinguish between level 2 and level 3 visits in [Table 18](#).

¹⁶ CMS states that as part of its request for input, it received “substantially different recommendations by specialty” ([p. 330](#)).

- “differing perspectives on whether code revaluation would be necessary under the PFS as a result of revising the guidelines”
- “variation in how Medicare’s own contractors (Medicare Administrative Contractors (MACs) interpret and apply the guidelines as part of their audit processes”
- “E/M visit codes themselves need substantial updating and revaluation to reflect changes in the practice of medicine, and that revising the documentation guidelines without addressing the codes themselves simply preserves an antiquated framework for payment of E/M services”

CY 2019 Proposals ([p. 331](#)). CMS proposes several changes for E/M documentation and payment. ***The CMS proposals are limited to office/outpatient visit codes (CPT 99201 – 99215) unless otherwise specified*** ([p. 331](#)).¹⁷ ***CMS proposes the policies would be effective January 1, 2019, but CMS is open to input on whether it should consider a multi-year process or delayed implementation date (e.g. January 1, 2020) which would allow for practitioner education, workflow changes, time for the AMA to develop changes to the CPT coding definitions and guidance (including changes to MDM or code definitions that CMS could consider for adoption), and time for other payers to react and potentially readjust policies*** ([p. 376](#)).

- ***“Lifting Restrictions Related to E/M Documentation”*** ([p. 332](#)):
 - ***Eliminating Extra Documentation Requirements for Home Visits (CPT Codes 99341 – 99350)*** ([p. 332](#)): While the beneficiary need not be confined to the home, the current Medicare Claims Processing manual requires that the medical record must document the medical necessity of the home visit (as opposed to why it was not done in as an office or outpatient visit). CMS agreed with stakeholder concern that whether it is done in the home or in an office is best determined without additional rules. Therefore, ***CMS proposes removing the requirement that the medical record document the medical necessity of furnishing the visit in the home rather than the office*** ([p. 333](#)).
 - ***Public Comment Solicitation on Eliminating Prohibition on Billing Same-Day Visits by Practitioners of the Same Group and Specialty*** ([p. 333](#)): CMS’s concern relates to the Medicare Claims Processing Manual language that states, “As for all other E/M services except where specifically noted, the Medicare Administrative Contractors (MACs) may not pay 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 in the office, off campus-outpatient hospital, or on campus outpatient hospital setting which could not be provided during the same encounter.” CMS is concerned that the specialty enrollment of clinicians does not always reflect the clinical expertise of the clinicians (providing an example of a physician enrolled in Medicare as a geriatrician but that is also an endocrinologist ([p. 334](#))). ***CMS solicits comment on whether it should remove the manual provision given the change in the practice of medicine or whether eliminating it could have unintended consequences for practitioners and beneficiaries*** ([p. 334](#)). ***CMS also seeks input on whether it should alternatively create exceptions or otherwise modify the manual provision rather than eliminate it*** ([p. 335](#)). ***CMS requests examples of where the current instruction is not clinically appropriate*** ([p. 335](#)).
- ***“Documentation Changes for Office or Other Outpatient E/M Visits and Home Visits”*** ([p. 335](#)):
 - ***Providing Choices in Documentation – Medical Decision Making, Time, or Current Framework*** ([p. 335](#)): ***In order to determine the appropriate level of E/M visit, CMS proposes to allow practitioners to between:***
 - ***Medical Decision Making (MDM);***

¹⁷ CMS notes however that it “may consider expanding our efforts more broadly to address sections of the E/M code set beyond the office/outpatient codes in future years.” ([p. 332](#)).

- **Time; or**
- **1995 or 1997 Guidelines**

CMS states that this would “allow different practitioners in different specialties to choose to document the factor(s) that matter most given the nature of their clinical practice” and reduce Medicare’s impact on the standardized recording of history, exam, and MDM data ([p. 335](#)).¹⁸

In addition, ***generally speaking, CMS retains the current CPT coding structure for E/M visits*** ([p. 336](#)).¹⁹

For medical review, CMS proposes to apply “a minimum documentation standard” whereby practitioners would “only need to meet documentation requirements associated with a level 2 visit for history, exam and/or MDM” except when using time to document the service ([p. 337](#)). CMS notes however that for other reasons (clinical, legal, operational, etc.), clinicians would generally continue to document medical record information consistent with the level or service provided.

- **Current Framework:** CMS’ proposed documentation for any level 2 through 5 visit would include:
 - A problem-focused history that does not include a review of systems or a past, family, or social history;
 - A limited exam of the affected body area or organ system; and
 - Straightforward MDM measured by minimal problems, data review, and risk (two of these three)
- **MDM Only:** Medicare will require only documentation supporting straightforward MDM measured by minimal problems, data review, and risk (two of these three). ***CMS is soliciting comments on whether and how guidelines for MDM might be changed in subsequent years*** ([p. 338](#)).
- **Time:** CMS proposes to allow a time-based standard even when counseling and/or care coordination do no account for more than 50 percent of the face-to-face practitioner/patient encounter. That is, ***CMS proposes “the amount of time personally spent by the billing practitioner face-to-face with the patient could be used to document the E/M visit regardless of the amount of counseling and/or care coordination furnished as part of the face-to-face encounter.”*** ([p. 338](#)). If finalized, CMS notes that it will monitor the policy for any program integrity issues, administrative burden, or other issues ([p. 339](#)).

For those documenting E/M visit levels using time, ***CMS proposes:***

- ***To require the practitioner to document the medical necessity of the visit; and***
- ***To show the totally amount of time spent by the billing practitioner face-to-face with the patient*** ([p. 339](#))
- ***CMS seeks input on what the total time should be to qualify for the single Level 2-5 payment rate,*** noting that typical time under the proposed payment

¹⁸ CMS reminds stakeholders that the E/M visit payment provisions outlined elsewhere in the rule apply regardless of the chosen documentation framework ([p. 336](#)).

¹⁹ CMS stated that it considered an alternate proposal to adopt “a single G-code to describe office/outpatient E/M visit levels 2 through 5” with its proposal to establish a single payment rate but declined to do so due to the potential “unnecessary disruption to current billing systems and practices.” ([p. 336](#)).

rate for Levels 2-5 is 31 minutes for an established patient and 38 minutes for a new patient²⁰ (p. 339).

- ***CMS cites an alternative time threshold (relying on the AMA's CPT codebook) whereby the unit of time is attained once the midpoint has passed (i.e. CMS would require documentation that at least 16 minutes had passed for an established patient and at least 20 minutes for a new patient) (p. 340).***
- ***CMS cites an additional approach which would be to require documentation that the "typical" time for the level reported was spent face-to-face with the patient (i.e. 10 minutes for a Level 2 established visit; 25 minutes for a Level 4 established patient) (p. 340).***
- ***CMS also solicits other comment on ways in which the time associated with (or required for) the billing on any add-on codes intersects with time spent for the base E/M visit (when the practitioner is documenting using only time) as CMS proposes that when a practitioner chooses to document using time and also reports prolonged E/M Services, CMS would require documentation that the typical time required for the base or companion code is exceeded by the amount to report the prolonged services (p. 341).***

■ **Additional Information:**

- CMS reports that it has heard from many stakeholders that practitioners rely on the Marshfield Clinic point system to supplement the E/M documentation guidelines. ***CMS requests information on whether Medicare should "use or adopt any aspects of other E/M documentation systems that may be in use among practitioners (including the Marshfield criteria) (p. 342).***
- ***CMS requests input on whether the 1995 and 1997 guidelines are adequate on their own or whether they need to be supplemented (p. 342).***
- ***CMS seeks comment on the ability of practitioners to avail them of the documentation options CMS presents given clinical workflows, EHR templates, and other aspects of clinician work (p. 342)***
- ***CMS seeks input on whether the proposals would actually reduce administrative burden and increase time available for patient care (p. 343).***²¹
- **Removing Redundancy in E/M Visit Documentation (p. 343):** CMS has received feedback that practitioners are required to document information already present in the medical record, a particular concern for history and exam. CMS notes that the 1995 and 1997 documentation guidelines attempt to provide flexibility for parts of the history for established patients and state that the review of systems (ROS) and/or pertinent past, family, and/or social history (PFSH) obtained in an earlier encounter "does not need to be re-recorded if there is evidence that the physician reviewed and updated the previous information" (p. 343). In addition, CMS notes that the ROS and/or PSFH may be "recorded by ancillary staff or on a form completed by the patient" (p. 344).

CMS attempts to further simplify documentation of history and exam for established patients by proposing that "practitioners would only be required to focus their documentation on what has changed since the last visit or on pertinent items that have not changed rather than re-

²⁰ CMS states that these are weighted averages of the intra-service times across current E/M visit utilization also noting that the code times are "typical" and not strictly required to qualify for a certain level (p. 339).

²¹ CMS appears to be grappling with whether this will actually reduce what clinicians document. While much of current information will not be required to submit a claim, physicians might still continue to document under similar practices for different reasons (p. 343).

documenting a defined list of required elements such as review of a specified number of systems and family/social history” (p. 344).²²

CMS is also seeking comment on whether it could implement a similar provision for MDM or for new patients (for instance when prior data is available through an interoperable EHR or other source) (p. 344).

CMS proposes that for new and established patients, practitioners would no longer be required to re-enter information in the medical record regarding the chief complaint and history already entered by ancillary staff or the beneficiary (p. 345). CMS states, however, that it expects that practitioners would continue to “periodically review and assess static or baseline historical information at clinically appropriate intervals.”

- ***Podiatry Visits: CMS proposes “to create separate coding for podiatry visits that are currently reported as E/M office/outpatient visits” where podiatrists would report new G-codes “that more specifically identify and value their services” (p. 345).***

CMS proposes to use “substantially the same” documentation standards as proposed for other office/outpatient E/M visits. With respect to time, if the practitioner chooses to use time to document a podiatry office/outpatient E/M visit, CMS proposes to apply the same documentation standard as for other outpatient/office visits. ***CMS requests input on what the total time would be for payment for the proposed new podiatry G-codes (p. 346).*** (Typical time for proposed codes: 22 minutes for an established patient and 28 minutes for a new patient); ***CMS again puts forward that it could apply the AMA CPT codebook provision for timed services that states that the unit of time is attained when the mid-point is passed (i.e., 12 minutes for established and at least 15 minutes for new). CMS requests input on these approaches and whether CMS should adopt further requirements for podiatric practitioners to document their visits using time (p. 346).***

- ***“Minimizing Documentation Requirements by Simplifying Payment Amounts” (p. 346).*** CMS states that it believes the 10 CPT codes and payment rates for new and established office-based and outpatient E/M visits “no longer appropriately reflect the complete range of services and resource costs associated with furnishing E/M services to all patients across the different physician specialties” (p. 347). Citing the “outdated CPT code set,” CMS proposes to simplify the office-based and outpatient E/M payment rates and documentation rates and to create new add-on codes to capture differential resources for certain types of E/M visits.
 - ***CMS proposes to pay a single payment rate for Levels 2 through 5 E/M visits²³ (p. 347) by developing a single set of RVUs for new patient Levels 2 through 5 and established patients Levels 2 through 5 (p. 348).*** CMS believes that this change will eliminate the need to audit visit levels providing “immediate relief from the burden of documentation.” (p. 349).

²² CMS notes, however that since MDM can only be accurately formed with accurate and timeline information and that the CPT descriptors for all E/M codes continue to include the history and exam elements that it expects clinicians will still conduct “clinically relevant and medically necessary elements of history and physical exam, and conform to the general principles of medical record documentation in the 1995 and 1997 guidelines.” (p. 344).

²³ “[I]t is clear to us that the burden associated with documenting the selection of the level of E/M service arise from not only the documentation guidelines, but also from the coding structure itself. Like the documentation guidelines, the distinctions between visit levels reflect a reasonable assessment of variations in care, effort, and resource costs as identified and articulated several decades ago.” (p. 347).

- **CMS proposes to develop resource inputs based on the current inputs for the individual E/M codes “generally weighted by the frequency at which they are currently billed” using the most recent 5 years of Medicare data (CY 2012-CY 2017) (p. 349).**

CY 2018 Estimates Under New Inputs and Payment Level Consolidation					
New Patient					
	Proposed wRVU	Proposed Physician Time (mins)	Direct PE Inputs	CY 2018 Non-Facility (NF) Payment Rate	CY 2018 NF Payment under proposed methodology
CPT 99201				\$45.00	\$44.00
CPT 99202	1.90	37.79	\$24.98	\$76.00	\$135.00
CPT 99203	1.90	37.79	\$24.98	\$110.00	\$135.00
CPT 99204	1.90	37.79	\$24.98	\$167.00	\$135.00
CPT 99205	1.90	37.79	\$24.98	\$211.00	\$135.00
Established Patient					
CPT 99211				\$22.00	\$24.00
CPT 99212	1.22	31.31	\$20.70	\$45.00	\$93.00
CPT 99213	1.22	31.31	\$20.70	\$74.00	\$93.00
CPT 99214	1.22	31.31	\$20.70	\$109.00	\$93.00
CPT 99215	1.22	31.31	\$20.70	\$148.00	\$93.00

- **“Recognizing the Resource Costs for Different Types of E/M Visits” (p. 351).** CMS puts forward a series of proposals designed to “better reflect the important distinctions between the kinds of visits furnished to Medicare beneficiaries, and would no longer require complex and burdensome billing and documentation rules to effectuate payment.”
 - **Accounting for E/M Resource Overlap Between Stand-alone Visits and Global Periods.** ***CMS proposes an E/M multiple procedure payment adjustment “to account for duplicative resource costs when E/M visits and procedures with global periods are furnished together.” (p. 352)*** CMS reviews that standalone E/M visit codes are not billable on the same day as global procedure codes unless the billing professional specifically indicates that the visit is separately identifiable from the procedure (p. 352). When this happens, the E/M visit is paid based on rates that assume that the E/M service is furnished independently from the procedure. However, CMS is concerned that separately identifiable visits occurring on the same day as a 0-day global procedure have significant overlapping resource costs. To address this concern, ***CMS proposes 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 visit (identified by modifier ~25) (p. 354).***²⁴ ***CMS proposes to allocate the reduced RVUs to the values of the add-on codes proposed for E/M visits for primary care and inherent visit complexity.***
 - **HCPCS G Code Add-ons to Recognize Additional Relative Resources for Certain Kinds of Visits:** ***CMS proposes a HCPCS G-code add-ons “to recognize additional relative resources for primary care visits and inherent visit complexity that require additional work beyond that which is accounted for in the single payment rates for new and established patient levels 2 through level 5 visits” (p. 352)***
 - **Primary Care Visits.** CMS expresses concern that “medical treatment is described imperfectly by relatively generic visit codes” (p. 355). CMS states that it is also

²⁴ CMS estimates this policy will result in a reduction of approximately 6.7 million RVUs (p. 354).

concerned about the distinct resource costs for services provided by primary care including, according to AAFP, time spent coordinating patient care, collaborating with other physicians, and communicating with patients. CMS continues that even though it attempted to address this through the introduction of the chronic care management (CCM) codes and transitional care management (TCM) codes, it believes those efforts do not capture the full range of primary care services nor the resource costs involved in a face-to-face primary care E/M visit ([p. 355](#)). CMS states that there are other policies to address certain other aspects of primary care work and that this proposal is intended to only address resources involved in delivering a face-to-face primary care visit.²⁵ ***CMS proposes a HCPCS G-code add-on that can be billed with the E/M code set to adjust payment to account for additional costs beyond the typical resources accounted for in the single payment rate for Levels 2 through 5*** ([p. 356](#)).

- 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)*):
 - Proposed wRVU: 0.07
 - Proposed Physician Time: 1.75 minutes
 - Proposed PE RVU: 0.07
 - Proposed MP RVU: 0.01
 - CMS states that the code can be reported for other forms of face-to-face care management, counseling, or treatment of acute or chronic conditions “not accounted for by other coding” ([p. 356](#))
 - ***CMS states that it anticipates GPC1X “would be billed with every primary care-focused E/M visit for an established patient”*** ([p. 357](#)).
 - CMS notes that it believes the code will be mostly used by primary care specialties (e.g. family practice or pediatrics), but believe there will be some instances where a specialist functions as the primary care practitioner (e.g. an OB/GYN or cardiologist). ***CMS intends for the code to be used by type of visit regardless of Medicare enrollment specialty but seeks comment on how best to identify whether a primary care visit was furnished “particularly in cases where a specialist is providing those services”*** ([p. 357-358](#)).
 - ***CMS proposes to allow for GPC1X to be billed along with the proposed new code for prolonged E/M services*** ([p. 358](#)).
 - ***CMS seeks input on any unintended consequences of the proposal.***
 - ***CMS seeks comment on other concerns related to primary care for consideration in future rulemaking.***
- **Specialty Visits.** CMS understands that there are some specialists who rely on a high number of Level 4 and Level 5 E/M visits to reflect the services they provide in the absence of more specific procedural codes. ***CMS proposes the creation of a HCPCS G-code to be reported with an E/M for additional resource costs for specialty visits.***
- GCG0X (*Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or*

²⁵ CMS states that “primary care visits are generally reported using level 4 E/M codes” ([p. 356](#)).

*interventional pain management-centered care*²⁶ (Add-on code, list separately in addition to an evaluation and management visit))²⁷

- **CMS proposes a crosswalk to CPT 90785 (Interactive complexity)**²⁸:
 - wRVU: 0.25
 - PE RVU: 0.07
 - MP RVU: 0.01
 - Physician Time: 8.25 minutes
- Proposed HCPCS G-Code to Describe Podiatric E/M Visits: **CMS proposes HCPCS G-codes for podiatric E/M visits** (p. 352). CMS reiterated previous statements that the “vast majority” of podiatric E/M visits are billed at Level 1 or Level 2 (p. 360), and therefore, CMS does not believe podiatric visits are accurately represented by the consolidated E/M structure (p. 361). **CMS proposes 2 G-codes for podiatric visits**²⁹:
 - GPD0X (*Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, new patient*)
 - Proposed wRVU: 1.35
 - Proposed Physician Time: 28.11 minutes
 - Proposed Direct PE Inputs: \$22.53
 - GPD1X (*Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, established patient*)
 - Proposed wRVU: 0.85
 - Proposed Physician Time: 21.60 minutes
 - Proposed Direct PE Inputs: \$17.07

CMS states that the values for the G-codes were based on the average rate for the Level 2 and Level 3 E/M code sets weighted for volume by podiatrists (p. 361).

- Proposed Adjustment to the PE/HR Calculation: **CMS proposes a technical modification to the PE methodology “to stabilize the allocation of indirect PE for visit services”** (p. 352). CMS reiterated its general methodology to allocate indirect costs³⁰ for codes based on direct costs associated with a code *and* the greater of either clinical labor costs or work RVUs (p. 362). CMS then calculates PE/HR based on the mix of specialties that bill for a service. Given CMS’ proposal to consolidate the payment rates for Levels 2 through 5 E/M visits and redirect payments to add-on codes for primary care and complex services, CMS believes there could be a large, unintended effect on specialties given the way that indirect PE is allocated based on mix of

²⁶ CMS states that while some of the specialties listed are surgical, CMS believes that “these surgical specialties are providing increased non-procedural care of high complexity in the Medicare population.” (p. 358); in addition, CMS states “these are specialties for which the resource costs of the visits they typically perform are not fully captured in the proposed single payment rates for the levels 2 through 5 office/outpatient visit codes” (p. 359).

²⁷ Note that in CMS’ impact chart estimating all of the proposed changes related to E/M codes (Table 22) that CMS “assumed that specialties including endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management centered-care utilized the G-code for visit complexity inherent to evaluation and management with *every* office/outpatient E/M visit.” (emphasis added) (p. 369).

²⁸ This is an add-on code for use when psychotherapy or psychiatric service requires more resources due to the complexity of the patient (p. 359); CMS proposes practitioners in psychiatry would not use the new proposed add-on codes because of access to CPT 90785 (p. 360).

²⁹ CMS states that the proposal is based on the coding structure and descriptor for CPT 92004 (*Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program; comprehensive, new patient 1 or more visits*) and CPT 92012 (*Ophthalmological services, medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient*) (p. 361).

³⁰ “Indirect costs include administrative labor, office expense, and all other Pes that are not directly attributable to a particular service for a particular patient.” (p. 362).

specialties furnishing a service. In addition, CMS is uncertain of how specialty utilization will change (including with respect to the new add on codes). Therefore, ***CMS proposes the creation of a single PE/HR value for E/M visits and the proposed, related G-codes of approximately \$136.00 based on the average of the PE/HR across all specialties that bill E/M codes (weighted by the volume of those specialties allowed E/M services (p. 363).*** CMS states that if they finalize the proposal, it will revisit the PE/HR after several years of claims data becomes available.

- Proposed HCPCS G-Code for Prolonged Services: ***CMS proposes a HCPCS G-code add-on for prolonged face-to-face services (p. 352).*** CMS lays out the prolonged services codes already in existence:
 - CPT 99354 (*Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)*)
 - CPT 99355 (*Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)*)

CMS states that stakeholders have stated that the “first hour” threshold makes CPT 99354 difficult to utilize. In order to address this issue and create a code that will align with the new E/M proposals, ***CMS proposes to add GPR01 ((Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service))*** with a proposed wRVU of 1.17 (p. 364).

Proposal Impacts. CMS conducted an analysis to determine the impact of the E/M proposals on each specialty.

- [Table 21: Unadjusted Estimated Specialty Impacts of Proposed Single RVU Amounts for Office/Outpatient E/M 2 Through 5 Levels](#)
- [Table 22: Specialty Specific Impacts Including Payment Accuracy Adjustments](#) (i.e. proposed impact of adopting the E/M proposed single payment rate (Levels 2 through 5), the application of the MPPR to E/M visits, the add-on G-codes, **and** the technical PE/HR adjustments, but does not include use of newly proposed prolonged service code)
 - CMS estimates that those experiencing a decrease are mostly those that bill a large portion of E/M visits on the same day as procedures (thus impacted by the MPPR proposal) (p.369).
 - CMS estimates that some specialties (e.g. allergy/immunology and cardiology) experience a reduction because of the single E/M payment rate (although the adjustments mitigate the losses somewhat) (p. 369).
 - CMS estimates that specialties experiencing an increase (e.g. psychiatry, nurse practitioner, and endocrinology) are doing so because of the single E/M payment rate *and* the add-on codes for inherent visit complexity (p. 370).

Alternatives Considered.

- CMS considered establishing a single payment rate for new and established patients for combined E/M visit Levels 2 through 4 (retaining Level 5 as a separate level) (p. 370). CMS provides impact estimates on the alternative of just collapsing Levels 2 through 4 in [Table 23](#).

- CMS considered a proposal to use the MACRA-mandated patient relationship codes (available for reporting on January 1, 2018) as an alternative to the proposed G-codes as a mechanism to adjust payment for E/M visits “to the extent that these codes are indicative of differentiated resources provided in E/M visits.” **CMS seeks comment on this alternative and on whether the modifiers would accurately reflect differences in resources for E/M visits across specialties (p. 373).**
- **CMS seeks input on the best number of E/M visit levels and how to achieve the balance between the number of visit levels and simpler, updated documentation rules (p. 370).**

Emergency Department and Other E/M Visit Settings.

- **Inpatient Psychiatric Facility Visits:** CMS cited the APA’s concern that changes to the E/M CPT code set for inpatient psychiatric evaluation (CPT 99221-99223) could add to the burden of documentation by requiring two different sets of data or areas of focus (or two different formats) given that the current code set is based on inpatient psychiatric facility Conditions of Participation (CoPs) (p. 374).
- **Emergency Department Visits:** CMS cited issues unique to emergency departments that it believes require further consideration before compressing the ED visit code set (99281-99285). CMS also cited the current RUC review of the code set and concerns about the codes being undervalued. In addition, CMS considered that proposals to the ED visit code set could require parallel changes to facility billing of the codes. Therefore, **CMS does not propose changes to the emergency department E/M code set (p. 375).**
- CMS reiterates that it does not propose changes to the E/M code sets for any settings of care beyond the office-based and outpatient settings. **CMS seeks comment on whether it should make changes to other settings in future years (p. 375).**

Teaching Physician Documentation Requirements for Evaluation and Management Services (p. 376)

Medicare billing rules require that, to make payments in the teaching setting, medical record documentation must show the teaching physician’s participation in the “review and direction of services” performed by residents.

- For procedural services, the participation of the teaching physician can be demonstrated by the notes in the medical records made by a physician, resident, or nurse (p. 376).
- For E/M visits, the teaching physician is required to “personally document their participation in the medical record.” (p. 377).

CMS proposes to eliminate the requirement for notation that may have been previously included in the medical records by residents or other members of the medical team. CMS also proposes that the medical record must document that the teaching physician was present at the time the service is furnished (p. 377).³¹

The revised paragraph in the regulations will specify that 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. The changes include:

- **Deleting** regulatory language that states that the teaching physician must document the extent of their participation in the review and direction of the services furnished to each beneficiary; and
- **Adding** new language to provide that the medical record must document the extent of the teaching physician’s participation in the review and direction of services furnished to each beneficiary (and that

³¹ CMS clarifies that the proposals do not apply to the following services: certain E/M services provided in the hospital outpatient setting and certain other ambulatory settings where CMS is allowed to make payments for resident services without the presence of a teaching physician (as defined in §415.174); services concerning renal dialysis (as governed under §415.176); and resident service coverage rules for psychiatric services as defined in §415.184.

the extent of participation may be demonstrated in notes in the medical record made by a physician, resident, or nurse) ([p. 377](#)).

Solicitation of Public Comments on the Low Expenditure Threshold Component of the Applicable Laboratory Definition under the Medicare Clinical Laboratory Fee Schedule (CLFS) ([p. 378](#))

The Protecting Access to Medicare Act of 2014 (PAMA) required significant changes to how Medicare pays for clinical diagnostic laboratory tests (CDLTs) under the CLFS beginning January 1, 2018. To implement key provisions of the statute, CMS required certain “applicable laboratories” meeting a Medicare low volume threshold to report “applicable data” (i.e., certain private payer data) to the agency for CDLTs that are not advanced diagnostic laboratory tests (ADLTs). Recently, however, stakeholders alerted the agency that its low expenditure threshold, which was set at \$12,500 and excludes most physician office laboratories and many small independent laboratories from reporting, results in incomplete data, and thus, inaccurate CLFS pricing.

To that end, **CMS seeks public comments on reducing the low expenditure threshold by 50 percent, from \$12,500 to \$6,250, in CLFS revenues during a data collection period.** Because such an approach would increase the level of applicable information reported by physician office laboratories and small independent laboratories, **CMS seeks public comments regarding the potential administrative burden. CMS is also soliciting public comments on an approach that would increase the low expenditure threshold by 50 percent, from \$12,500 to \$18,750, in CLFS revenues received in a data collection period.** Since fewer physician office laboratories and small independent laboratories would meet the definition of applicable laboratory, CMS would expect such an approach to result in a decreased level of applicable information reported.

GPCI Comment Solicitation ([p. 381](#))

CMS discussed its statutory requirement to review and, if necessary, adjust the Geographic Practice Cost Index (GPCI) at least every 3 years. CMS is preparing for its mandated CY 2020 update (as the last update was in CY 2017). CMS cited stakeholder concern with the data sources used by CMS for the GPCI calculations. **CMS seeks comments on potential sources of data for commercial rent for use in the next GPCI update** ([p. 381](#)).

Therapy Services ([p. 382](#))

Repeal of the Therapy Caps and Limitation to Ensure Appropriate Therapy ([p. 382](#))

Section 50202 of the BBA of 2018 repealed the application of the Medicare outpatient therapy caps and the therapy cap exceptions process while retaining and adding limitations to ensure therapy services are furnished when appropriate, effective January 1, 2018. Section 50202 also requires that after expenses incurred for the beneficiary’s outpatient therapy services for the year have exceeded one or both of the previous therapy cap amounts, all therapy suppliers and providers must continue to use an appropriate modifier such as the KX modifier on claims for subsequent services in order for Medicare to pay for the services.³² CMS implemented this provision by continuing to use the KX modifier. Just as with the incurred expenses for the prior therapy cap amounts, there is one amount for physical therapy (PT) and speech language pathology (SLP) services combined and a separate amount for occupational therapy (OT) services. These KX modifier threshold amounts are indexed annually by the Medicare Economic Index (MEI). After the beneficiary’s incurred expenditures for outpatient therapy services exceed the KX modifier threshold amount for the year, claims for outpatient therapy services without the KX modifier are denied.

³² By applying the KX modifier to the claim, the therapist or therapy provider is confirming that the services are medically necessary as justified by appropriate documentation in the medical record. ([p. 382](#))

Section 50202 also retains the targeted medical review (MR) process, but at a lower threshold amount of \$3,000. For CY 2018 (and each successive calendar year 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 targeted MR process means that not all claims exceeding the MR threshold amount are subject to review as they once were.

The provider liability procedures which first became effective January 1, 2013, remain in effect, 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.

Proposed Payment for Outpatient PT and OT Services Furnished by Therapy Assistants (p. 383)

Section 53107 of the BBA addresses payment for outpatient therapy services for which payment is made under section 1848 or section 1834(k) of the Act that are furnished on or after January 1, 2022, in whole or in part by a therapy assistant (as defined by the Secretary). Specifically, section 53107 provides for payment of those services at 85 percent of the otherwise applicable Part B payment amount for the service. This reduced payment amount for such outpatient therapy services is applicable when payment is made directly under the PFS, for example when payment is made to therapists in private practice (TPPs); and when payment is made based on the PFS, for example, when payment is made for certain outpatient therapy services, including payment to providers that submit institutional claims for therapy services such as outpatient hospitals, rehabilitation agencies, skilled nursing facilities, home health agencies and comprehensive outpatient rehabilitation facilities (CORFs). The reduced payment rate is not applicable to outpatient therapy services furnished by critical access hospitals.

To implement this payment reduction, section 53107 requires CMS to establish a new modifier, in a form and manner specified by the Secretary, by January 1, 2019 to indicate, in the case of an outpatient therapy service furnished in whole or in part by a therapy assistant, that the service was furnished by a therapy assistant. Although CMS generally considers all genres of outpatient therapy services together (PT/OT/SLP), ***CMS does not believe there are “therapy assistants” in the case of SLP services, so CMS proposes to apply the new modifier only to services furnished in whole or in part by a physical therapist assistant (PTA) or an occupational therapist assistant (OTA).*** Section 53107 requires that each request for payment or 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. As such, the modifier will be required to be reported on claims for outpatient PT and OT services with dates of service on and after January 1, 2020, when the service is furnished in whole or in part by a therapy assistant, regardless of whether the reduced payment described above is applicable. However, the required payment reductions do not apply for these services until January 1, 2022 under the BBA of 2018.

To implement this provision, ***CMS is proposing to establish two new modifiers to separately identify PT and OT services that are furnished in whole or in part by PTAs and OTAs, respectively.*** CMS is proposing to establish two modifiers because the incurred expenses for PT and OT services are tracked and accrued separately in order to apply the two different KX modifier threshold amounts as specified by section 1833(g)(2) of the Act; and the use of the two proposed modifiers will facilitate appropriate tracking and accrual of services furnished in whole or in part by PTAs and OTAs. ***CMS additionally proposes that these two therapy modifiers would be added to the existing three therapy modifiers – GP, GO, and GN – that are currently used to identify all therapy services delivered under a PT, OT or SLP plan of care, respectively.***

For purposes of implementing section 53107, ***CMS is proposing to define “therapy assistant” as an individual who meets the personnel qualifications set forth at §484.4 of its regulations for a physical therapist assistant and an occupational therapy assistant (PTA and OTA, respectively).*** ***CMS is 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 whenever the service is furnished in whole or in part by a PTA or OTA.

Effective for dates of service on and after January 1, 2020, the new therapy modifiers that identify services furnished in whole or in part by a PTA or OTA would be required to be used on all therapy claims instead of the existing modifiers GP and GO, respectively. As a result, CMS is proposing that, beginning in CY 2020, five therapy modifiers 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 existing 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 NPPs.

The creation of therapy modifiers specific to PT or OT services delivered under a plan of care furnished in whole or in part by a PTA or OTA would necessitate that CMS make changes to the descriptors of the existing GP and GO modifiers to clarify which qualified professionals, for example, therapist, physician, or NPP, can furnish the PT and OT services identified by these modifiers, and to differentiate them from the therapy modifiers specific to the services of PTAs and OTAs. CMS also proposes to revise the GN modifier descriptor to conform to the changes to the GP and GO modifiers by clarifying the qualified professionals that furnish SLP therapy services.

CMS is proposing to define the new therapy modifiers for services furnished in whole or in part by therapy assistants and to revise the existing therapy modifier descriptors 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 – that is, physician, nurse practitioner, certified clinical nurse specialist, or physician assistant – 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 – that is, physician, nurse practitioner, certified clinical nurse specialist, or physician assistant – 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 – that is, physician, nurse practitioner, certified clinical nurse specialist, or physician assistant – under an outpatient speech-language pathology plan of care.**

As previously finalized and as required as a condition of payment under current regulations, the person furnishing outpatient therapy services incident to the physician, PA, NP or CNS service must meet the therapist personnel qualification and standards at §484.4, except for licensure. As such, CMS notes that only a therapist, not a therapy assistant, can furnish outpatient therapy services incident to the services of a physician or a non-physician practitioner (NPP), so **the new PT- and OT- Assistant therapy modifiers cannot be used on the line of service when the rendering practitioner identified on the claim is a physician or an NPP.** For therapy services billed by physicians or NPPs, whether furnished personally or incident to their professional services, the GP or GO modifier is required for those PT or OT services furnished under an outpatient therapy plan.

CMS proposes that all services that are furnished “in whole or in part” by a PTA or OTA are subject to the use of the new therapy modifiers. A new therapy modifier would be required to be used whenever a PTA or OTA furnishes all or part of any covered outpatient therapy service.

However, CMS does not believe the provisions of section 53107 were intended to apply when a PTA or OTA performs portions of the service such as administrative tasks that are not related to their qualifications as a PTA or OTA. Rather, CMS believes the provisions of section 53107 were meant to apply when a PTA or OTA is involved in providing some or all of the therapeutic portions of an outpatient therapy service. ***CMS is proposing to define “in part,” for purposes of the proposed new modifiers, 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.*** Therefore, a service furnished “in part” by a therapy assistant would not include a service for which the PTA or OTA furnished only non-therapeutic services that others without the PTA’s or OTA’s training can do, such as scheduling the next appointment, greeting and gowning the patient, preparing or cleaning the room.

CMS reminds therapists and therapy providers that CMS does not recognize PTAs and OTAs to wholly furnish PT and OT evaluations and re-evaluations, that is, CPT codes 97161 through 97164 for PT and CPT codes 97165 through 97168 for OT. CMS provides additional detail on its rationale starting on [p. 388](#). While CMS expects that the therapist will continue to furnish the majority of an evaluative procedure service, the changes in the BBA of 2018 require that the adjusted payment amount (85 percent of the otherwise applicable Part B payment amount) be applied when a therapy assistant furnishes a therapy service “in part,” including part of an evaluative service.

Additionally, CMS clarifies that the requirements for evaluations, including those for documentation, are separate and distinct from those for plans of care (plans). The plan is a statutory requirement for outpatient PT, OT, and SLP services and may only be established by a therapists, physicians, NPs, CNSs, and PAs. This means that if the evaluative procedure is furnished in part by an assistant, the new therapy modifiers that distinguish services furnished by PTAs or OTAs must be applied to the claim; however, the plan, which is not separately reported or paid, must be established by the supervising therapist who furnished part of the evaluation services. All regulatory and subregulatory plan requirements continue to apply.

In summary, ***CMS is proposing to establish two new therapy modifiers to identify the services furnished in whole or in part by PTAs and OTAs. Claims from all providers of PT and OT services furnished on and after January 1, 2020 will be required to include these new PT- and OT-Assistant therapy modifiers for services furnished in whole or in part by a PTA or OTA. CMS proposes that these modifiers will be required, when applicable, in place of the GP and GO modifiers currently used to identify PT and OT services furnished under an outpatient plan of care.*** To test its systems ahead of the required implementation date of January 1, 2020, CMS anticipates allowing voluntary reporting of the new modifiers at some point during CY 2019, which CMS will announce to its contractors and therapy providers through a Change Request, as part of its usual change management process.

CMS seeks comments on these proposals.

Proposed Functional Reporting Modifications ([p. 390](#))

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 RFI on CMS Flexibilities and Efficiencies that was issued in the CY 2018 PFS proposed rule, CMS received comments requesting burden reduction related to the reporting of 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.

The MCTRJCA required CMS to implement a claims-based data collection strategy in order to collect data on patient function over the course of PT, OT, and SLP services in order to better understand patient condition and

outcomes. The functional reporting system CMS implemented collects data using non-payable HCPCS G-codes (HCPCS codes G8978 through G8999 and G9158 through G9186) and modifiers (in the range CH through CN) to describe a patient's functional limitation and severity at: (a) the time of the initial service, (b) at periodic intervals in sync with existing progress reporting intervals, (c) at discharge, and (d) when reporting certain evaluative and re-evaluative procedures (often times billed at time of initial service). Claims without the required functional reporting information are returned to therapy services providers, rather than denied, so that they can add the required information and resubmit claims. Therapy services providers must also document functional reporting information in the patient's medical record each time it is reported. The MCTRJCA also specified that data from the functional reporting system were to be used to aid CMS in recommending changes to, and reforming Medicare payment for outpatient therapy services that were then subject to the therapy caps under section 1833(g) of the Act.

CMS conducted an analysis that focused on the functional reporting data that have been submitted through the claims-based system, both by therapy discipline and by episodes of care by discipline using a similar episode definition (for example, clean 60 calendar day period) that was used in its prior utilization reports for CY 2008 through CY 2010 that can be found on the Therapy Services webpage in the [Studies and Reports page](#). However, CMS did not find the results compelling enough to use as a basis to recommend or undertake administrative reforms of the current payment mechanism for therapy services. Furthermore, going forward, the functional reporting data CMS would collect may be even less useful for purposes of recommending or reforming payment for therapy services because, as described earlier, section 50202 of the BBA of 2018 repealed the application of the Medicare outpatient therapy caps and associated exceptions process, while imposing protections to ensure therapy services are furnished when appropriate.

The general consensus of the commenters was that the functional reporting requirements for outpatient therapy services are overly complex and burdensome. Additional details on comments are provided on [p. 392](#).

As part of the requirements of section 3005(g) of MCTRJCA, CMS established its functional reporting claims-based data collection strategy effective January 1, 2013 and will have been collecting these functional reporting data for the last 5 years at the close of CY 2018. CMS reviewed and analyzed the reported data internally but did not find them particularly useful in considering how to reform payment for therapy services as an alternative to the therapy caps. In the meantime, section 50202 of BBA of 2018, as discussed previously, included reforms to therapy payment. Additionally, because section 3005(g) of MCTRJCA was not codified into the Act, and did not specify how long the data collection strategy should last, CMS does not believe it was intended to last indefinitely.

After consideration of stakeholder comments on the RFI along with a review of all of the requirements under section 3005(g) of MCTRJCA, and in light of the recent statutory amendments in the BBA of 2018, CMS has concluded that continuing to collect more years of these functional reporting data, whether through the same or a reduced format, will not yield additional information that would be useful to inform future analyses, and that allowing the current functional reporting requirements to remain in place could result in unnecessary burden for providers of therapy services without providing further benefit to the Medicare program in the form of additional data.

As a result, ***CMS is proposing to discontinue the functional reporting requirements for services furnished on or after January 1, 2019. Specifically, CMS is proposing to amend its regulations by removing the following:***

- ***conditions of payment that require claims for OT, PT, SLP, and Comprehensive Outpatient Rehabilitation Facility (CORF) PT, OT, and SLP services, respectively, to contain prescribed information on patient functional limitations; and,***
- ***the functional reporting-related phrase that requires the plan's goals to be consistent with functional information on the claim.***

See p. 394 for specific regulatory sections proposed for change.

In addition, CMS would:

- ***remove the functional reporting subregulatory requirements implemented primarily through Change Request 8005 last issued on December 21, 2012, via Transmittal 2622;***
- ***eliminate the functional reporting standard systems edits CMS has applied to claims; and***
- ***remove the functional reporting requirement provisions in its Internet Only Manual (IOM) provisions including the Medicare Claims Processing Manual, Chapter 5; and, the functional reporting requirements in Chapters 12 and 15 of the Medicare Benefits Policy Manual.***

If finalized, these proposals would end the requirements for the reporting and documentation of functional limitation G-codes (HCPCS codes G8978 through G8999 and G9158 through G9186) and severity modifiers (in the range CH through CN) for outpatient therapy claims with dates of service on and after January 1, 2019. Accordingly, CMS would delete the applicable non-payable HCPCS G-codes.

CMS is seeking comment on these proposals.

Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-based Payments (p. 396)

As allowed under statute, separately payable drugs and biologicals furnished by providers and suppliers include an add-on set at 6 percent of the volume-weighted average sales price (ASP) or wholesale acquisition cost (WAC) for the drug or biological (the “6 percent add-on”). While not specifically described in statute, this add-on is widely believed to include services associated with drug acquisition that are not separately paid for, such as handling, and storage, as well as additional mark-ups in drug distribution channels. The Medicare Payment Advisory Commission (MedPAC) and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) have studied the add-on payment and raised broad concerns.

As a result, ***CMS proposes that effective January 1, 2019, WAC based payments for Part B drugs utilize a 3 percent add-on in place of the 6 percent add-on, consistent with MedPAC’s recommendation. CMS proposes to make conforming changes to the regulation text to better align with the statutory text.*** In addition, ***CMS proposes to change the policy articulated in the Claims Processing Manual at Chapter 17 section 20.1.3 to permit MACs to use an add-on percentage of up to 3 percent for WAC-based payments for new drugs.***

Clinical Laboratory Fee Schedule (p. 402)

As discussed above, PAMA required significant changes to how Medicare pays for CDLTs under the CLFS. In general, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018 is based on the applicable information collected during the data collection period and reported to CMS during the data reporting period and is equal to the weighted median of the private payor rates for the test. PAMA provided a phase-in for the CDLT payment reductions; for the first 3 years after implementation (CY 2018 through CY 2020), the reduction cannot be more than 10 percent per year, and for the next 3 years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year.

As noted above, stakeholders raised concerns about incomplete data, and thus, inaccurate CLFS pricing. In addition to concerns above about the lack of data from physician office laboratories and small independent laboratories, stakeholders also raised concerns that most hospital-based laboratories were not applicable

laboratories and did not report data, thus the CY 2018 CLFS payment rates do not reflect their information and are inaccurate.

Proposed Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory (p. 405)

In order for a laboratory to meet the majority of Medicare revenues threshold, the statute requires that, “with respect to its revenues under this title, a majority of such revenues are from” the CLFS and the PFS in a data collection period. In the CLFS final rule, CMS stated that “revenues under this title” are payments received from the Medicare program, which includes fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage (MA) payments under Medicare Part C, and prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period.

However, CMS recognizes that its current interpretation of total Medicare revenues may have the effect of excluding laboratories that furnish Medicare services to a significant number of beneficiaries enrolled in MA plans under Medicare Part C from meeting the majority of Medicare revenues threshold criterion, and therefore, from qualifying as applicable laboratories. After closer examination, CMS believes the statute permits an interpretation that MA plan payments to laboratories not be included in the total Medicare revenues component of the majority of Medicare revenues threshold calculation. Rather, MA plan payments to laboratories can be considered to only be private payor payments under the CLFS. Therefore, for purposes of the applicable laboratory definition only, ***CMS proposes that MA plan payments under Part C would not be considered Medicare revenues, and would revise paragraph (3) of the definition of applicable laboratory at §414.502 accordingly.***

Such a change would have the effect of eliminating the laboratory revenue generated from a laboratory’s Part C-enrolled patient population as a factor in determining whether a majority of the laboratory’s Medicare revenues are comprised of services paid under the CLFS or PFS. This change would permit a laboratory with a significant Medicare Part C revenue component to be more likely to meet the majority of Medicare revenues threshold and qualify as an applicable laboratory. More specifically, MA payments are currently included as total Medicare revenues (the denominator). In order to meet the majority of Medicare revenues threshold, the statute requires a laboratory to receive the majority of its Medicare revenues from the CLFS and or PFS. If MA plan payments were excluded from the total Medicare revenues calculation, the denominator amount would decrease. If the denominator amount decreases, the likelihood increases that a laboratory would qualify as an applicable laboratory.

CMS believes this proposal responds directly to stakeholders’ concerns regarding the number of laboratories for which applicable information must be reported because a broader representation of the laboratory industry may qualify as applicable laboratories, which means CMS would receive more applicable information to use in setting CLFS payment rates. ***CMS welcomes comments on its proposal to modify the definition of applicable laboratory to exclude MA plan payments under Part C as Medicare revenues.***

Solicitation of Public Comments on Other Approaches to Defining Applicable Laboratory (p. 410)

CMS defines applicable laboratory at the NPI level, which means the laboratory’s own billing NPI is used to identify a laboratory’s revenues for purposes of determining whether it meets the majority of Medicare revenues threshold and the low expenditure threshold components of the applicable laboratory definition. Virtually all hospital laboratories, including hospital outreach laboratories, would not be considered an applicable laboratory under this definition because, across the entire TIN-level entity, their revenues under the IPPS and OPFS alone would likely far exceed the revenues they received under the CLFS and PFS.

As noted above, stakeholders raised concerns that excluding hospital outreach laboratories would result in incomplete and inappropriate applicable information, which would skew CLFS payment rates. While CMS was compelled by arguments that hospital outreach laboratory data should be included, it believed Congressional intent was to effectively exclude hospital laboratories as applicable laboratories. Regardless, in prior rulemaking, CMS finalized that an applicable laboratory is the NPI-level entity, which would allow a hospital outreach laboratory assigned a unique NPI – separate from the hospital of which it is a part – would be able to meet the definition of applicable laboratory and its applicable information can be used for CLFS rate-setting.

Stakeholder Continuing Comments and Stakeholder-Suggested Alternative Approaches

CMS believes that its proposed change to the total Medicare revenues component of the applicable laboratory definition and the current policy that requires an entity to bill Medicare Part B under its own NPI, may increase the number of hospital outreach laboratories qualifying as applicable laboratories.

In addition, CMS believes its current policy supports the collection of sufficient applicable information on which to base payments under the CLFS, including those established for CY 2018. However, CMS is considering refinements that would lead to including even more applicable information for the next data reporting period. To that end, the comments and alternative approaches suggested by stakeholders.

Using Form CMS-1450 Bill Type 14x to Determine Majority of Medicare Revenues and Low Expenditure Thresholds

In an effort to increase the number of hospital outreach laboratories, CMS solicits public comments about the utility of using the 14x bill type to determine whether hospital outreach laboratories meet the majority of Medicare revenues threshold (and the low expenditure threshold). CMS has concerns that this approach presents challenges, as use of the 14x bill type does not identify an entity the way an NPI does. Also, some private payors, such as MA plans, may not require hospital laboratories to use the 14x bill type for their outreach laboratory services, which means hospitals may need to develop their own mechanism for identifying and reporting only the applicable information associated with its hospital outreach laboratory services. CMS is interested in public comments about the utility of using the 14x bill type in the way it has described and on the level of administrative burden created if CMS defined applicable laboratory using the Form CMS-1450 14x bill type. CMS is also interested in public comments as to whether revising the definition of applicable laboratory to use the Form CMS-1450 14x bill type would allow laboratories sufficient time to make the necessary systems changes to identify applicable information before the start of the next data collection period.

CMS notes that its current approach provides flexibility for hospital outreach laboratories to not obtain a unique billing NPI, which may be significant particularly where a hospital outreach laboratory performs relatively few outreach services under Medicare Part B. If laboratories were permitted to use the Form CMS-1450 14x bill type, revenues attributed to the hospital outreach laboratory would have to be calculated in every instance where those services exceeded the low expenditure threshold, even for those that perform relatively few outreach services under Medicare Part B. CMS is interested in comments concerning this aspect of using the 14x bill type definition.

Last, 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 CMS-1450 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. **CMS is interested in public comments regarding whether this definition would indeed be inconsistent with the statute, as well as comments that can identify circumstances under this definition whereby a hospital outreach laboratory would not meet the majority of Medicare revenues threshold.**

Using CLIA Certificate to Define Applicable Laboratories

Some industry stakeholders have requested that CMS use the CLIA certificate rather than the NPI to identify a laboratory that would be considered an applicable laboratory. CMS believes a CLIA certificate-based definition of applicable laboratory would be overly inclusive by including all hospital laboratories, as opposed to just hospital outreach laboratories. In addition, the CLIA certificate is used to certify that a laboratory meets applicable health and safety regulations in order to furnish laboratory services; it is not associated with Medicare billing, thus cannot be used to identify revenues for specific services. For these and other reasons, CMS did not adopt this approach previously. However, given stakeholder suggestions, CMS solicits public comments on this approach.

Specifically, CMS is interested in public comments regarding the mechanisms a hospital would need to develop to identify revenues if it used the CLIA certificate for purposes of determining applicable laboratory status, as well as comments about the administrative burden associated with developing such mechanisms.

In addition, CMS notes this approach could have the effect of decreasing as opposed to increasing the number of applicable laboratories, particularly in cases where a single CLIA certificate is assigned to the hospital's entire laboratory business, given the hospital laboratory would be unlikely to meet the majority of Medicare revenues threshold because its laboratory revenues under the IPPS and OPPIPS alone would likely far exceed the revenues it receives under the CLFS and PFS. CMS requests public comments on this potential drawback of defining applicable laboratory at the CLIA certificate level.

Solicitation of Public Comments on the Low Expenditure Threshold in the Definition of Applicable Laboratory (p. 420)

Decreasing the Low Expenditure Threshold

As noted above, CMS seeks public comments on revising the low expenditure threshold to increase the level of participation among physician office laboratories and small independent laboratories. CMS is particularly interested in comments from the physician community and small independent laboratories as to the administrative burden associated with such a revision to the low expenditure threshold. Specifically, CMS requests comments on the following issues: (1) whether physician offices and small independent laboratories currently have adequate staff levels to meet the data collection and data reporting requirements; (2) whether data systems are currently in place to identify, collect, and report each unique private payor rate from each private payor for each CLFS test code and the volume of tests associated with each unique private payor rate; (3) if physician offices and small independent laboratories are generally not prepared to conduct the data collection and data reporting requirements, what is the anticipated timeframe needed for physician office and small independent laboratories to be able to meet the data collection and data reporting requirements; and (4) any other administrative concerns that decreasing the low expenditure threshold may impose on offices and small independent laboratories.

Increasing the Low Expenditure Threshold

Mindful of stakeholder feedback from smaller laboratories that prefer to not be applicable laboratories because of the burden of collecting and reporting applicable information, CMS solicits feedback increasing the low expenditure threshold in the definition of applicable laboratory by 50 percent, from \$12,500 to \$18,750, in CLFS revenues during a data collection period. CMS is particularly interested in comments from the physician community and small independent laboratories on the administrative burden and relief of increasing the low expenditure threshold. Feedback on the topics discussed in this section will help inform potential refinements to the low expenditure threshold. Depending on the comments received, it is possible CMS would consider approaches described in this section.

Proposed Changes to the Regulations Associated with the Ambulance Fee Schedule ([p. 425](#))

CMS reviews its policy for payment for ambulance transportation services beginning on [p. 425](#). In general, Medicare pays for ambulance transportation services “when other means of transportation are contraindicated by the beneficiary’s medical condition and all other coverage requirements are met.”

There have been several statutory provisions related to payment for Medicare ambulance transportation services:

- **Medicare Improvements for Patients and Providers Act of 2009 (MIPPA):** MIPPA established ground ambulance increases ([p. 427](#)):
 - For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area (MSA), the fee schedule amounts shall be increased by 3 percent
 - For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of an MSA, the fee schedule shall be increased by 2 percent.

The original provisions lasted from 2008 to 2010, but they have been extended by Congress several times with the latest extension applying through December 31, 2022. ***CMS proposes to alter the regulations to implement this extension through December 31, 2022*** ([p. 427](#)).

- **Medicare Prescription Drug, Improvement and Modernization of 2003 (MMA):** The MMA provided that for ground ambulance services for which transportation originates in a rural area (as qualified in the statute), the Secretary shall provide a percent increase in the base rate of the fee schedule for these transports to be based on the estimate of the average cost per trip (but not mileage) in the lowest quartile of all rural county populations compared to the average cost per trip (but not mileage) in the highest quartile of rural county populations ([p. 428](#)). CMS previously determined that this percent increase was 22.6%. CMS has referred to this as the “Super Rural Bonus.”

The original provisions applied to services furnished on or after July 1, 2004 and before January 1, 2010, but they have been extended by Congress several times with the latest extension applying through December 31, 2022. Therefore, ***CMS plans to continue to apply the 22.6 percent Super Rural Bonus through December 31, 2022*** ([p. 428](#)).

- **American Taxpayer Relief Act of 2012 (ATRA):** The ATRA included a provision that reduced payments for ambulance services for non-emergency basic life support (BLS) services involving the transport of an individual with end-stage renal disease (ESRD) for renal dialysis services furnished “other than on an emergency basis” by a provider of services or a renal dialysis facility. The payment reduction was 10 percent and applied to services provided on or after October 1, 2013. The Balanced Budget Act of 2018 temporarily modified the reduction from 10 percent to 23 percent for services for services on or after October 1, 2018. Therefore, ***CMS is modifying the regulations to state that the 10 percent reduction continues through September 30, 2018 at which point a 23 percent reduction will be applied required by the BBA*** ([p. 429](#)).

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (p. 431)

Payment for Care Management Services (p. 431)

CMS reviewed its CY 2018 policies for its RHC/FQHC payment methodologies for Chronic Care Management (CCM) services as well as its RHC/FQHC requirements for Behavioral Health Integration (BHI) and psychiatric Collaborative Care Management (CoCM). **CMS proposes to continue the payment methodology (as well as add an addition service to the rules for BHI) (p. 432).**

Communication Technology-Based Services and Remote Evaluation (p. 432)

CMS refers to the proposals it is making in the [Communication Technology-Based Services section](#) of the rule . When considering these services in the context of RHCs and FQHCs, CMS notes that the RHC and FQHC models are distinct from the Medicare Physician Fee Schedule: RHC and FQHC payment is for a comprehensive set of services and supplies associated with the RHC or FQHC visit and a direct comparison between the RHC/FQHC payments (per diem) and the same service in a physician's office (service-based) is not possible (p. 434). CMS states that when "communication-based technology services are furnished in association with an RHC or FQHC billable visit, the costs of these services are included in the RHC AIR or the FQHC PPS and are not separately billable." (p. 435). However, if there is no RHC or FQHC "billable visit" the costs are not part of the payment. Therefore, **CMS proposes that RHCs and FQHCs receive additional payment for the costs of communication technology-based services or remote evaluation services that are not already captured in the RHC AIR or the FQHC PPS payment when the requirements for those services are met (p. 435).**

- **CMS proposes a new Virtual Communications G-code for only for use by RHCs and FQHCs with a payment rate the average of the PFS non-facility payment rate (p. 436).**
- **CMS proposes to waive the RHC and FQHC face-to-face requirements (p. 436).**
- CMS discusses other options that were considered beginning on [p. 436](#).

Appropriate Use Criteria for Advanced Diagnostic Imaging Services (p. 438)

CMS continues to believe the best implementation approach for the Appropriate Use Criteria (AUC) program is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and clinical decision support mechanisms (CDSM) developers. CMS will continue to post information on its [website for this program](#).

Background

Section 218(b) of the Protecting Access to Medicare Act (PAMA) amended Title XVIII of the Act to add section 1834(q) of the Act directing CMS to establish a program to promote the use of AUC for advanced diagnostic imaging services (e.g., CT, PET, nuclear medicine, and MRI). Multiple aspects of this program have been established through prior rulemaking, including:

- Creation of an evidence-based process and transparency requirements for the development of AUC.
- Definition of provider-led entities (PLEs) and establishment of the process by which PLEs may become qualified to develop, modify or endorse AUC. The first list of qualified PLEs was posted on the CMS website at the end of June 2016, at which time their AUC libraries became specified applicable AUC for the program.
- Specification of qualified CDSMs, including the definition of CDSM, requirements CDSMs must meet for qualification, and establishment of a process by which CDSMs may become qualified. The first list of qualified CDSMs was posted on the CMS website in July 2017.
- Definition of applicable payment systems under this program.

- Specification of the first list of priority clinical areas:
 - Coronary artery disease (suspected or diagnosed)
 - Suspected pulmonary embolism
 - Headache (traumatic and non-traumatic)
 - Hip pain
 - Low back pain
 - Shoulder pain (to include suspected rotator cuff injury)
 - Cancer of the lung (primary or metastatic, suspected or diagnosed)
 - Cervical or neck pain.
- Identification of exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services.

In the CY 2018 PFS final rule (82 FR 53190), CMS established the start date of January 1, 2020 for the Medicare AUC program for advanced diagnostic imaging services after multiple previous delays. It is for services ordered on and after this date that ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services and furnishing professionals must report AUC consultation information on the Medicare claim. 2020 will represent an educational and operations testing period during which time claims will not be denied for failure to include proper AUC consultation information. CMS also established a voluntary period from July 2018 through the end of 2019 during which ordering professionals who are ready to participate in the AUC program may consult specified applicable AUC through qualified CDSMs and communicate the results to furnishing professionals, and furnishing professionals who are ready to do so may report AUC consultation information on the claim (see this [CMS guidance document](#) for additional information). To incentivize the early use of qualified CDSMs to consult AUC, CMS established a high-weight improvement activity for ordering professionals who consult specified AUC using a qualified CDSM that would apply under the Merit-Based Incentive Payment System (MIPS) in 2018.

Discussion of Statutory Requirements (p. 440)

This section summarizes in more detail the statutory requirements for the AUC program and implementation progress made to date. Topics include:

- Establishment of AUC ([p. 441](#))
- Mechanism for AUC Consultation ([p. 442](#))
- AUC Consultation and Reporting ([p. 443](#))
- Identification of Outliers for purposes of Applying a Prior Authorization Requirement ([p. 445](#))

Proposals for Continuing Implementation (p. 446)

Expanding Applicable Settings ([p. 446](#))

Section 1834(q)(1)(D) of the Act specifies that the 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 applicable setting to add an independent diagnostic testing facility (IDTF).*** Since IDTF services must be furnished under the appropriate level of physician supervision and all procedures furnished by the IDTF must be ordered in writing by the patient's treating physician or non-physician practitioner, CMS believes the IDTF setting is a provider-led outpatient setting appropriate for this program. CMS also believes this proposal will allow the AUC program to be more consistently applied to outpatient settings.

CMS invites comments on this proposal and on the possible inclusion of any other applicable settings. It reminds commenters that 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 physician fee schedule, the OPPI, and the ASC payment system).

Consultations by Ordering Professionals (p. 448)

Section 1834(q)(1)(E) of the Act defines the term “ordering professional” as a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who orders an applicable imaging service. The AUC consultation requirement applies to these ordering professionals. ***CMS proposes that the consultation with AUC 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. More specifically, CMS proposes to revise the AUC consultation requirement specified at §414.94(j) to specify that the AUC consultation may be performed by auxiliary personnel under the direction of the ordering professional and incident to the ordering professional’s services.***

The statute does not explicitly provide for consultations under the AUC program to be fulfilled by other professionals, individuals or organizations on behalf of the ordering professional; however, CMS continues to seek ways to minimize the burden and understands that many practices currently use clinical staff, working under the direction of the ordering professional, to interact with the CDSM for AUC consultation and subsequent ordering of imaging. It is important to note that the ordering professional is ultimately responsible for the consultation as their NPI is reported by the furnishing professional on the claim for the applicable imaging service. Similarly, it is the ordering professional who could be identified as an outlier ordering professional and become subject to prior authorization based on their ordering pattern in future years.

Reporting AUC Consultation Information (p. 449)

CMS proposes to revise §414.94(k) to clearly reflect the scope of claims for which AUC consultation information must be reported, and to clarify that the requirement to report AUC consultation information is not limited to the furnishing professional. When CMS initially codified the AUC consultation reporting requirement, it specified only that “furnishing professionals” must report AUC consultation information on claims for applicable imaging services. This led some stakeholders to believe that AUC consultation information would be required only on practitioner claims. CMS is revising its regulations to clarify that AUC consultation information must be reported on all claims for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system (i.e., on any claim for an outpatient advanced diagnostic imaging service, including those billed and paid under the PFS, OPPI or ASC payment system). CMS’ interpretation of the statute is that claims from both furnishing professionals and facilities must include AUC consultation information. In other words, CMS would expect this information to be included on the practitioner’s claim for the professional component of the applicable advanced diagnostic imaging service and on the provider’s or supplier’s claim for the facility portion or technical component of the imaging service.

Claims-based Reporting (p. 451)

Since CMS did not finalize a proposal in the CY 2018 PFS final rule, it proposes in this rule to use established coding methods, to include G-codes and modifiers, to report the required AUC information on Medicare claims. Using coding structures that are already in place would allow program to be implemented by January 1, 2020.

In the CY 2018 PFS proposed rule (82 FR 34094), CMS discussed using a combination of G-codes and modifiers to report the AUC consultation information on the Medicare claim. It received numerous public comments objecting to this potential solution. In the 2018 PFS final rule, CMS agreed with many of the commenters that additional approaches to reporting AUC consultation information on Medicare claims should be considered, and it learned from many commenters that reporting a unique consultation identifier (UCI) would be a less burdensome and preferred approach. The UCI would include all the information required under this program,

including an indication of AUC adherence, non-adherence and not applicable responses. Since that rule, CMS has been working with stakeholders to further explore the concept of using a UCI.

Although some commenters were originally in favor of a UCI, CMS reports that some may have changed their position upon further consideration. CMS discusses in this section how it internally explored the feasibility of developing a UCI and concluded that 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 issue that the UCI seems limited to claim-level reporting, all prior to the start of the program. Despite its proposal not to rely on a UCI at this time, CMS will consider future opportunities to use a UCI and looks forward to continued engagement with and feedback from stakeholders on the issue.

Significant Hardship Exception ([p. 453](#))

For CY 2019, CMS proposes to adjust the significant hardship exception requirements under the AUC program to include:

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

This is a change from current regulations, which tied exceptions to the EHR Incentive Program/ACI category of MIPS and which specified that those who received significant hardship exceptions in the following categories would also qualify for significant hardship exceptions under the AUC program:

- Practicing for less than 2 years (as specified in §495.102(d)(4)(ii))
- Extreme and Uncontrollable Circumstances (as specified in §495.102(d)(4)(iii))
- Lack of Control over the Availability of CEHRT (as specified in §495.102(d)(4)(iv)(A))
- Lack of Face-to-Face Patient Interaction (as specified in §495.102(d)(4)(iv)(B))

In regards to the proposed change, CMS estimates that 6,699 eligible clinicians could submit a request due to extreme and uncontrollable circumstances or as a result of a decertification of an EHR, which represents less than one percent of available ordering professionals.

CMS recognizes here that when a significant hardship arises, an application process to qualify for an exception becomes a time-consuming hurdle for health care provider. To minimize burden, ***CMS proposes that ordering professionals would self-attest if they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order and that such attestation be supported with documentation of a 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 and it would be reflected on the furnishing professional's and furnishing facility's claim by appending a HCPCS modifier. The modifier would indicate that the ordering professional has self-attested to experiencing a significant hardship and communicated this to the furnishing professional with the order. Claims for advanced diagnostic imaging services that include a significant hardship exception modifier would not be required to include AUC consultation information.

CMS also invites the public to comment on any additional circumstances that would cause the act of consulting AUC to be particularly difficult or challenging for the ordering professional, and for which it may be appropriate for an ordering professional to be granted a significant hardship exception under the AUC program. CMS reminds readers that circumstances that are not specific to AUC consultation, such as the

ordering professional being in clinical practice for a short period of time or having limited numbers of Medicare patients, would not impede clinicians from consulting AUC through a CDSM as required under this program.

Identification of Outliers (p. 457)

Section 1834(q)(5) of the Act specifies that in future years, CMS would identify outlier ordering professionals who could be subject to prior authorization based on their ordering pattern on a set of priority clinical areas. **In an effort to start a dialogue with stakeholders, CMS invites comments on ideas on a possible methodology for the identification of outlier ordering professionals who would eventually be subject to this prior authorization process when ordering advanced diagnostic imaging services. Specifically, it solicits comments on the data elements and thresholds that CMS should consider when identifying outliers.**

Since its existing prior authorization programs generally do not specifically focus on outliers, CMS intends to perform claims analyses to assist in the development of an outlier methodology for the AUC program. Due to concerns about data integrity and reliability, CMS does not intend to include data from the educational and operations testing period in CY 2020 in the analysis used to develop its outlier methodology. However, following its evaluation of claims data, CMS expects to address outlier identification and prior authorization more fully in CY 2022 or 2023 rulemaking.

Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) (p. 460)

One of the requirements of being a meaningful EHR user is to successfully report the clinical quality measures selected by CMS to CMS or a state, as applicable, in the form and manner specified by CMS or the state, as applicable. As described in statute, in selecting electronic clinical quality measures (eCQMs) for EPs to report under the Promoting Interoperability Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. CMS has taken steps to align various quality reporting and payment programs that include the submission of eCQMs.

eCQM Reporting Requirements for EPs under the Medicaid Promoting Interoperability Program for 2019 (p. 461)

To keep eCQM specifications current and minimize complexity, CMS proposes to align the eCQMs available for Medicaid EPs in 2019 with those available for MIPS eligible clinicians for the CY 2019 performance period. Specifically, CMS proposes that the eCQMs available for Medicaid EPs in 2019 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2019 performance period.

CMS also requests comments on whether in future years of the Medicaid Promoting Interoperability Program beyond 2019, CMS should include all e-specified measures from the core set of quality measures for Medicaid and the Children's Health Insurance Program (CHIP) (the Child Core Set) and the core set of health care quality measures for adults enrolled in Medicaid (Adult Core Set) as additional options for Medicaid EPs. These core measure sets, which are required by statute to be updated annually and are voluntarily reported by states to CMS, comprise measures that specifically focus on populations served by the Medicaid and CHIP programs and are of particular importance to their care.

For 2019, CMS proposes that Medicaid EPs would report on any six eCQMs that are relevant to the EP's scope of practice, regardless of whether they report via attestation or electronically. This policy would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category. ***CMS also proposes to adopt the MIPS requirement that EPs report on at least one***

outcome measure (or, if an applicable outcome measure is not available or relevant, one other high priority measure). CMS requests comments on how high priority measures should be identified for Medicaid EPs. CMS proposes to use all three of the following methods to identify which of the available measures are high priority measures, but invites comment on other possibilities.

1. CMS would use the same set of high priority measures for EPs participating in the Medicaid Promoting Interoperability Program that the MIPS program has identified for eligible clinicians, and proposes to amend §414.1305 to revise the definition of high priority measure for purposes of MIPS to mean an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure, beginning with the 2021 MIPS payment year.
2. For 2019, CMS would also identify as high priority measures the available eQMs that are included in the previous year's Core Sets and that are also included on the MIPS list of eQMs. The eQMs that would be available for EPs to report in 2019, that are both part of the Core Sets and on the MIPS list of eQMs, and that would be considered high priority measures under CMS' proposal are:
 - 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"; and
 - CMS165, "Controlling High Blood Pressure."
3. CMS would also give each state the flexibility to identify which of the available eQMs 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), similar to the flexibility granted states to modify the definition of Meaningful Use at §495.332(f). This would give states the ability to identify as high priority those measures that align with their state health goals or other programs within the state. CMS proposes to amend §495.332(f) to provide for this state flexibility to identify high priority measures.

CMS proposes that any eQMs identified via any of these mechanisms be considered to be high priority measures for EPs participating in the Medicaid Promoting Interoperability Program for 2019, and invites comments on whether all three of these methods should be utilized (as proposed) or whether there are reasons to instead use a subset of these methods, or only one of them.

CMS also proposes that the eQCM reporting period for EPs in the Medicaid Promoting Interoperability Program would be a full CY in 2019 for EPs who have demonstrated meaningful use in a prior year, in order to align with the corresponding performance period in MIPS for the quality performance category. CMS continues to align Medicaid Promoting Interoperability Program requirements with requirements for other CMS quality programs, such as MIPS, to the extent practicable, to reduce the burden of reporting different data for separate programs. The eQCM reporting period for EPs demonstrating meaningful use for the first time, which was established in the final rule entitled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017" (80 FR 62762) (hereafter referred to as "Stage 3 final rule"), would remain any continuous 90- day period (80 FR 62892).

CMS will adjust future years' requirements for reporting eQMs in the Medicaid Promoting Interoperability Program as necessary, through rulemaking, and will continue to align the quality reporting requirements, as logical and feasible, to minimize EP burden. **CMS invites public comment on these proposals.**

Proposed Revisions to the EHR Reporting Period and eCQM Reporting Period in 2021 for EPs Participating in the Medicaid Promoting Interoperability Program ([p. 466](#))

CMS proposes to amend §495.4 to provide that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program would be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021, as required by statute. Similarly, CMS proposes to change the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program to a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021.

CMS proposes to allow states the flexibility to set alternative, earlier final deadlines for EHR or eCQM reporting periods for Medicaid EPs in CY 2021, with prior approval from CMS, through their State Medicaid HIT Plan (SMHP). If a state establishes an alternative, earlier date within CY 2021 by which all EHR or eCQM reporting periods in CY 2021 must end, Medicaid EPs in that state would continue to have a reporting period of a minimum of any continuous 90-day period within CY 2021. The end date for the reporting period would have to occur before the day of attestation, which must occur prior to the final deadline for attestations established by their state. ***CMS proposes to amend §495.332(f) to provide for this state flexibility to identify an alternative date by which all EHR reporting periods or eCQM reporting periods for Medicaid EPs in CY 2021 must end. CMS proposes that any alternative deadline for CY 2021 EHR and eCQM reporting periods set by a state may not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting to that state. CMS invites public comment on this proposal.***

Based on attestation data and information from states' SMHPs regarding the number of years states disburse Medicaid Promoting Interoperability Program payments to hospitals, CMS believes that there will be no hospitals eligible to receive Medicaid Promoting Interoperability Program payments in 2021 due to the requirement that, after 2016, eligible hospitals cannot receive a Medicaid Promoting Interoperability Program payment unless they have received such a payment in the prior fiscal year. At this time, CMS believes that there are no hospitals that will be able to receive incentive payments in 2020 or 2021. ***CMS invites comments and suggestions on whether this belief is accurate, and if not, how the agency could address the issue in a manner that limits the burden on hospitals and states.*** CMS is not proposing any specific policy in this rule, but, if necessary, CMS expects to address the issue in a future proposed rule that is more specifically related to hospital payment.

Proposed Revisions to Stage 3 Meaningful Use Measures for Medicaid EPs ([p. 468](#))

Proposed Change to Objective 6 (Coordination of Care through Patient Engagement)

CMS understands that the two measures under Objective 6 (i.e., View, Download, or Transmit and Secure Electronic Messaging) are the largest barrier to successfully demonstrating meaningful use, especially in rural areas and at safety net clinics. The primary issue is that the view, download, transmit measure requires a positive action by patients, which cannot be controlled by an EP. Medicaid populations that are at the greatest risk have lower levels of internet access, internet literacy and health literacy than the general population. While the Secure Electronic Messaging measure does not require patient action, only that the EP send a secure message, CMS has received feedback that this functionality is not highly utilized by patients, thus it is not productive for EPs to send messages to patients who are unlikely to see them or take action. ***As a result, CMS proposes to amend §495.24(d)(6)(i) such that the thresholds for 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) would remain 5 percent for 2019 and subsequent years. CMS invites comments on this proposal.***

Proposed Change to the Syndromic Surveillance Reporting Measure

Based on feedback from states and public health agencies, CMS proposes to amend §495.24(d)(8)(i)(B)(2), EP **Objective 8 (Public health and clinical data registry reporting), Measure 2 (Syndromic surveillance reporting measure)**, to amend the language restricting the use of syndromic surveillance reporting for meaningful use only to EPs practicing in an urgent care setting. CMS proposes to include any EP defined by the state or local public health agency as a provider who can submit syndromic surveillance data. CMS invites comments on this proposal.

Medicare Shared Savings Program Quality Measures ([p. 471](#))

This section provides background on the Medicare Shared Savings Program (MSSP) and the evolution of quality performance standards used to assess the quality of care furnished by Accountable Care Organizations (ACOs).

Eligible clinicians who are participating in a MSSP ACO that is considered an Advanced APM and subject to MIPS (i.e., they do not become Qualifying APM Participants or QPs) will be scored under the [alternative payment model \(APM\) scoring standard](#) under MIPS (81 FR 77260). Beginning with the 2017 reporting period, measures collected through the CMS Web Interface will be used to determine the MIPS quality performance category score for MIPS eligible clinicians participating in a MSSP ACO; starting with the 2018 performance period, the CAHPS for ACOs survey measures will also be added to this assessment.

In this section of the rule, CMS proposes to eliminate 10 measures and to add one measure to the MSSP quality measure set. CMS also proposes to score two CAHPS Summary Survey Measures that are already collected for information purposes. This would result in 24 measures for which ACOs would be held accountable in 2019.

Proposals for Changes to the CAHPS Measure Set ([p. 476](#))

To enhance the Patient/Caregiver Experience domain and align with MIPS (82 FR 54163), CMS proposes to begin scoring the two Summary Survey Measures (SSMs) that are currently collected with the administration of the CAHPS for ACOs survey and shared with the ACOs for informational purposes only. ***Under this proposal, CMS would add the following CAHPS for ACOs SSMs to the quality measure set for the MSSP. These measures would be scored and included in the ACO quality determination starting in 2019:***

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

Consistent with established regulations, these additional SSMs would be pay-for-reporting for all ACOs for two years (performance years 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](#), beginning in performance year 2021.

Proposed Changes to the CMS Web Interface and Claims-Based Quality Measure Sets ([p. 478](#))

In an effort to streamline quality measures, reduce regulatory burden, and enable ACOs to better utilize their resources toward improving patient care, CMS proposes to reduce the total number of measures in the MSSP quality measure set.

Claims-Based Measures ([p. 480](#))

CMS proposes to retire the following claims-based quality measures, which have a high degree of overlap with other measures that would remain in the measure set:

- **ACO-35-Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM): The vast majority of these SNF readmissions are also captured in the numerator of ACO-8 Risk-Standardized All Condition Readmission.**
- **ACO-36-All-Cause Unplanned Admissions for Patients with Diabetes: Most unplanned admissions for patients with diabetes are captured in the numerator of ACO-38 Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions.**
- **ACO-37-All-Cause Unplanned Admission for Patients with Heart Failure: Most unplanned admissions for patients with heart failure are captured in the numerator of ACO-38 Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions.**

Because these measures are claims-based measures and therefore do not impose any reporting burden on ACOs, CMS intends to continue to provide performance information to ACOs on these measures through a new quarterly claims-based quality outcomes report that ACOs will begin receiving in 2018.

Despite proposing to remove ACO-35, CMS recognizes the value of measuring the quality of care furnished to Medicare beneficiaries in SNFs. Thus, **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 through future rulemaking.** This measure differs from ACO-35 since it looks only at unplanned, potentially preventable readmissions for Medicare Fee-For-Service 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 than does ACO-35 because the two measures' readmission windows differ. Specifically, the readmission window for the SNFQRP measure is 30 days following discharge from a SNF, while the readmission window for ACO-8 is 30 days following discharge from a hospital.

CMS also proposes to retire claims-based measure ACO-44: Use of Imaging Studies for Low Back Pain, as this measure is restricted to individuals 18-50 years of age, which results in low denominator rates and is not a valuable reflection of the beneficiaries cared for by MSSP ACOs. This decision would align ACO quality measurement with the MIPS requirements since this measure was removed from the MIPS program in the CY 2018 QPP final rule (82 FR 54159). However, in recognition of the value in providing feedback to providers on potential overuse of diagnostic procedures, CMS intends to continue to provide ACOs feedback on performance on this measure as part of the new quarterly claims-based quality report.

Web Interface Measures (p. 482)

In the 2017 PFS final rule (81 FR 80499), CMS adopted a policy that any future changes to the CMS Web Interface measures would be proposed and finalized through rulemaking for the QPP, and that such changes would be applicable to ACO quality reporting under the MSSP (rather than proposing these changes separately). As such, CMS is not making any specific proposals related to changes in CMS Web Interface measures reported under the MSSP. Instead, it refers readers to [Tables A, C, and D](#) of **Appendix 1: Proposed MIPS Quality Measures** of this proposed rule for a complete discussion of the proposed changes to the CMS Web Interface measures.

If these proposed changes are finalized, ACOs would no longer be responsible for reporting the following measures for purposes of the MSSP starting with reporting for 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 Adult**
- **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**

CMS also proposes to add the following measure to the CMS Web Interface for purposes of the 2019 QPP:

- **ACO-47 (NQF #0101) Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls**

[Table 25](#) shows the proposed MSSP quality measure set for performance year 2019 and subsequent performance years.

[Table 26](#) shows the maximum possible points that may be earned by an ACO in each domain and overall in performance year 2019, and in subsequent performance years if the proposed changes are finalized.

Physician Self-Referral Law ([p. 488](#))

CMS is revisiting the regulations related to the physician self-referral (or “Stark”) law, which prohibits physicians from making referrals for certain “Designated Health Services” (DHS) to entities in which he or she (or an immediate family member) has a financial relationship, unless an exception applies. The rules also prohibit the entity itself from filing claims with Medicare for those referred services.

Writing Requirement. The Bipartisan Budget Act of 2018 (BBA 2018) enacted provisions related to the writing and signature requirements of the Stark regulations. CMS believes that the provisions were to codify existing CMS policy. Nonetheless, ***CMS had previously created regulations related to satisfaction of the writing requirement with regard to permitting a lease arrangement or personal service arrangement to continue indefinitely beyond the stated expiration of the written documentation describing the arrangement under certain circumstances*** ([p. 488](#)). Because the BBA 2018 provisions are nearly identical, CMS believes no additional changes to the regulation are necessary ([p. 489](#)).

Compensation Arrangement Exceptions. Many exceptions for compensation arrangements require the arrangements to be set out in writing and signed by the parties. BBA 2018 addressed writing and signatures in the statutory compensation arrangement exceptions as well ([p. 489](#)). ***CMS proposes a new special rule on compensation arrangements*** ([p. 489](#)).

- CMS has had longstanding policy that the writing requirement in various compensation arrangement exceptions can be satisfied by a collection of documents “including contemporaneous documents evidencing the course of conduct between the parties” ([p. 490](#)). While CMS had stated this policy, it was not in the regulations. Now codified by BBA 2018, ***CMS proposes to amend the regulations to state that for a compensation arrangement to be in writing, the “writing requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties”*** ([p. 490](#)).
- CMS has an existing special rule where there is temporary noncompliance with the Stark signature requirements that an entity that has a compensation arrangement with a physician that satisfies all of the other applicable requirements *except* the signature requirement may submit a claim and receive payment for a DHS referred by a physician provided that:
 - The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant (without regard to whether any referrals occur or compensation is paid during such 90-day period); and
 - The compensation arrangement otherwise complies with all criteria of the applicable exception ([p. 491](#)).

Use of the special rule is limited to once every 3 years with respect to the same referring physician. However, while the BBA 2018 provisions use similar language about the special rule, the BBA 2018 provisions are not limited to specific exceptions *and* entities are not limited in their use to once every 3 years. Therefore, ***CMS proposes to amend its regulations to conform with the statute including deleting the reference to applying only to specific exceptions, to the occurrence of referrals or the payment of compensation during the 90-day period when the signature requirement is not met, and deleting the limitation on time. CMS also proposes an alternative to delete the current regulatory language addressing this and adding the new provisions in a separate section*** ([p. 492](#)).

CMS also added the effective date of the BBA 2018 provisions was February 9, 2018. ***CMS therefore states that parties who would have otherwise been barred from using the special rule for temporary noncompliance with signature requirements because of the “3 year limitation” may begin to use it as stated in BBA 2018*** ([p. 492](#)).

CY 2019 Updates to the Quality Payment Program ([p. 493](#))

Executive Summary ([p. 493](#))

This proposed rule would make payment and policy changes to the Quality Payment Program (QPP), which was created under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015). CMS believes the third year of the Quality Payment Program (QPP) should build upon the foundation that has been established in the first two years, providing a trajectory for clinicians moving to a performance-based payment system.

For the 2019 performance year/2021 MIPS payment year, CMS estimates that between 160,000 and 215,000 clinicians will become Qualifying APM Participants (QP), and thus be exempt from MIPS and qualify for a five percent lump sum incentive payment based on their aggregate payment amounts for covered professional services for the prior year. CMS estimates that the total lump sum APM incentive payments will be approximately \$600-800 million for the 2021 QPP payment year.

For MIPS,³³ CMS estimates that approximately 650,000 clinicians would be MIPS eligible clinicians in the 2019 MIPS performance period. This number will depend on a number of factors, including the number of eligible clinicians excluded from MIPS based on their status as QPs or Partial QPs, the number that report as groups, and the number that elect to opt-in to MIPS. CMS estimates that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments (\$372 million) and positive MIPS payment adjustments (\$372 million) to MIPS eligible clinicians, to ensure budget neutrality. Positive MIPS payment adjustments will also include up to an additional \$500 million for exceptional performance to MIPS eligible clinicians whose final score meets or exceeds the proposed additional performance threshold of 80 points. CMS anticipates that it will be able to update these estimates with the data from the first year of MIPS in the CY 2019 QPP final rule.

Moving into the third year of the QPP, CMS has taken all stakeholder input into consideration, including recommendations made by the Medicare Payment Advisory Commission (MedPAC). CMS will continue to implement the QPP as required, smoothing the transition where possible and offering targeted educational resources for program participants. Some examples of how CMS is addressing MedPAC’s concerns, include:

³³ Although CMS has posted a [blog](#) that provides preliminary participation information for the first year of MIPS, due to time constraints, it is unable to incorporate and analyze the performance and participation data from the first year of MIPS for the estimates in this proposed rule. Therefore, it bases its estimates for the 2019 MIPS performance period/2021 MIPS payment year on historical 2016 PQRS and Medicare and Medicaid EHR Incentive Program data.

- Focusing on burden reduction
- Reshaping its focus on interoperability
- Ongoing removal of topped-out process measures with a focus on the development and use of more outcome measures

For year three, CMS is committed to reducing clinician burden, implementing the [Meaningful Measures Initiative](#), promoting interoperability, continuing our support of small and rural practices, empowering patients through the Patients Over Paperwork initiative, and promoting price transparency. As part of this effort, CMS continues to offer tailored flexibilities to help clinicians to participate in the program, including:

- Retaining the small practice bonus under MIPS by moving it to the quality performance category.
- Continuing to offer free and customized resources available within local communities, including direct, one-on-one support from the Small, Underserved, and Rural Support Initiative along with other no-cost technical assistance.
- Allow small practices to continue using claims-based data submission for the quality performance category, despite CMS proposing to remove this option for larger practices.
- To continue to allow small practices to choose to participate in MIPS as a virtual group.

MIPS Program Details ([p. 504](#))

MIPS Eligible Clinicians ([p. 504](#))

Under MACRA, CMS has the discretion, beginning with the 2021 MIPS payment year, to specify additional eligible clinicians (as defined in section 1848(k)(3)(B) of the Act) as MIPS eligible clinicians. Such clinicians may include:

- Physical therapists
- Occupational therapists, or qualified speech-language pathologists;
- Qualified audiologists (as defined in section 1861(ll)(3)(B) of the Act);
- Certified nurse-midwives (as defined in section 1861(gg)(2) of the Act);
- Clinical social workers (as defined in section 1861(hh)(1) of the Act);
- Clinical psychologists (as defined by the Secretary for purposes of section 1861(ii) of the Act); and
- Registered dietitians or nutrition professionals

Feedback gathered from these stakeholders generally supported the specification of such clinicians as MIPS eligible clinicians beginning with the 2021 MIPS payment year. However, a CMS analysis found that although improvement activities would generally be applicable and available for each of these clinician types, not all of the clinician types would have sufficient MIPS quality measures applicable and available.

CMS requests comments on its proposal to amend §414.1305 to modify the definition of a MIPS eligible clinician to include, beginning with the 2021 MIPS payment year:

- **Physical therapists;**
- **Occupational therapists;**
- **Clinical social workers (as defined in section 1861(hh)(1) of the Act);**
- **Clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and**
- **A group that includes such clinicians.**

Alternatively, CMS proposes that if the quality measures proposed for removal are not finalized, then it would include these additional clinician types in the definition of a MIPS eligible clinician beginning in 2019, provided that it determines that each applicable eligible clinician type would have at least six MIPS quality measures available to them.

In addition, CMS requests comments on:

- **Specifying qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals as MIPS eligible clinicians beginning with the 2021 MIPS payment year; and**
- **Delaying the specification of one or more additional eligible clinician types as MIPS eligible clinicians until a future MIPS payment year.**

CMS intends to continue to ramp up the requirements of the program to ensure a gradual and incremental transition to the performance threshold until QPP year six. If it finalizes its decision to add additional eligible clinicians to the program starting with the 2021 MIPS payment year, these clinicians would have four years in the program to ramp up, but if they begin in a future year, they would be afforded less time to ramp up.

Note that elsewhere in this rule, CMS [proposes to automatically assign a zero percent weighting](#) for the Promoting Interoperability performance category for these new types of MIPS eligible clinicians.

MIPS Determination Period (p. 507)

Currently, MIPS uses various determination periods to identify certain MIPS eligible clinicians for consideration for certain applicable policies, which has been confusing. For example, the low-volume threshold, non-patient facing, small practice, hospital-based, and ambulatory surgical center (ASC)-based determinations are on the same timeline with slight differences in the claims runout policies, whereas the facility-based determination has a slightly different determination period. The virtual group eligibility determination requires a separate election process.

CMS recognizes that the current use of various MIPS determination periods is complex and causes confusion and strives to provide eligibility determinations as close to the beginning of the performance period as feasible. ***As such, CMS proposes to, beginning with the 2021 MIPS payment year, consolidate several of these policies into a single MIPS determination period that would be used 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. This MIPS determination period would be a 24-month assessment period including a two-segment analysis of claims data consisting of:***

- ***An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period (e.g., October 1, 2017 - September 30, 2018 for the 2019 performance year); and***
- ***A second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs (e.g., October 1, 2018 – September 30, 2019 for the 2019 performance year).***

The first segment would include a 30-day claims run out. The second segment would not include a claims run out, but would include quarterly snapshots for informational use only, if technically feasible. CMS believes these snapshots would be helpful for new TIN/NPIs and TINs created between the first segment and the second segment, allowing them to see their preliminary eligibility status sooner. Without the quarterly snapshots, these clinicians would not have any indication of their eligibility status until just before the submission period.

An individual eligible clinician or group that is identified as not exceeding the low-volume threshold, or a MIPS eligible clinician that is identified as non-patient facing, a small practice, hospital-based, or ASC-based during the first segment would continue to be identified as such for the applicable MIPS payment year regardless of the second segment.

Note that CMS does not believe it would be feasible for many MIPS clinicians to participate as individuals if they join an existing practice (TIN) or a newly formed practice during the final three months of the performance period calendar year. CMS [proposes a reweighting policy for these clinicians](#) later in the rule.

CMS also clarifies situations where eligible clinicians, whose TIN or TIN/NPIs are identified as eligible during the first segment and do not exist in the second segment, are no longer utilizing those same TIN or TIN/NPI combinations. Since the TIN that was assessed for the first segment of the determination period no longer exists, there are no charges or services available to assess in the second segment for that TIN. As such, those TIN or TIN/NPIs would not exceed the low-volume threshold in the second segment and they would no longer be eligible for MIPS. If the new TIN assessed during the second segment was not eligible, the clinician is not required to submit any data based on TIN eligibility determinations despite the clinician exceeding the low-volume threshold criteria initially.

On the other hand, if a TIN or TIN/NPI did not exist in the first segment but does exist in the second segment, these clinicians could be eligible for MIPS. The eligible clinician may not find their TIN or TIN/NPI in the Quality Payment Program lookup tool, but may still be eligible if they exceed the low-volume threshold in the second segment.

Finally, CMS is not proposing to include the facility-based, virtual group, or the rural and HPSA eligibility determination periods in this policy, as the first two require a different process or timeline that does not align with the other determination periods, and the third one does not utilize a determination period. CMS invites public comments on the possibility of incorporating these determinations into the MIPS determination period in the future.

Low-Volume Threshold ([p. 514](#))

Section 1848(q)(1)(C)(iv) of the Act provides that, for performance periods beginning on or after January 1, 2018, the low-volume threshold selected by the Secretary may include one or more or a combination of the following (as determined by the Secretary):

- 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 eligible clinician for the performance period involved;
- The minimum number of covered professional services furnished to part B-enrolled individuals by such clinician for such performance period; and
- The minimum amount of allowed charges for covered professional services billed by such clinician for such performance period.

Eligible clinicians or groups who do not exceed the low-volume threshold for the performance period with respect to a year are excluded from MIPS.

For the 2020 MIPS payment year and future years, the low-volume threshold has already been defined as an individual eligible clinician or group that has Medicare Part B allowed charges less than or equal to \$90,000 or provides care for 200 or fewer Part B-enrolled Medicare beneficiaries.

To comply with the Bipartisan Budget Act of 2018, which amended section 51003(a)(1)(A)(ii) of the Act, CMS proposes to amend §414.1305 to modify the definition of low-volume threshold for the 2018 MIPS performance year so that it utilizes:

- *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 clinician or group during the low-volume threshold determination period.***

These changes clarify that the low-volume exclusion for MIPS will now only be based on “covered professional services,” and not Medicare Part B medications and services billed separately from the Physician Fee Schedule.

CMS also proposes to:

- ***Modify §414.1310 to specify that MIPS applies to payments for covered professional services (rather than “items” as well, such as Part B drugs) furnished by MIPS eligible clinicians on or after January 1, 2019.***
- ***Revise §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 and does not elect to report on applicable measures and activities under MIPS.***
- ***Revise §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 who are not MIPS eligible clinicians, including those who voluntarily report on applicable measures and activities under MIPS.***

For the 2019 performance year and future years, CMS also proposes that:

- ***The low-volume threshold applies to an individual eligible clinician or group that, during the MIPS determination period, has:***
 - ***Allowed charges for covered professional services less than or equal to \$90,000; or***
 - ***Furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals; or***
 - ***Furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individual (NEW for 2019);***
- ***If an eligible clinician or group meets or exceeds at least one, but not all, of the low-volume threshold determinations described above, then such eligible individual or group may choose to opt-in to MIPS;***
- ***A clinician who is eligible to opt-in would be required to make an affirmative election to opt-in to participate in MIPS, elect to be a voluntary reporter, or by not submitting any data the clinician is choosing to not report; and***
- ***If an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to report on applicable measures and activities under MIPS, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year.***

CMS also invites comments on other low-volume threshold criteria and supporting justification for the recommended criteria.

In general, these policies related to the low-volume threshold criteria and opt-in respond to concerns voiced by clinicians who would like to participate in the program, CMS believes these proposals will ensure that a significant number of eligible clinicians have the ability to opt-in if they wish to participate in MIPS. CMS estimates that no additional clinicians would be excluded if it added the third criterion to the low-volume threshold 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. If CMS alternatively set the third criterion at 100 services, then it estimates that 50,260 clinicians would opt-in.

In the regulatory impact analysis section of this rule, CMS also makes the following estimates regarding clinician eligibility based on its proposal:

- 608,000: eligible because they exceed all three criteria of the low-volume threshold and are not otherwise excluded;
- 42,000 (out of a total MIPS eligible clinician population of approximately 650,000): eligible because they exceed at least one, but not all, of the low-volume threshold criteria and elect to opt-in;
- 483,000: potentially eligible if they either did group reporting or elected to opt-in;
- 88,000: excluded because they do not exceed any of the low-volume threshold criteria;
- 302,000: excluded due to noneligible specialty, newly enrolled, or QP status

[Table 28](#) includes possible low-volume threshold determination opt-in scenarios.

To assist the public with commenting on these proposals, CMS developed a [website](#) that provides design examples of the different approaches to MIPS participation in CY 2019.

Opt-In for Individual Clinicians and Groups (p. 520). For individual eligible clinicians and groups interested in opting-in or voluntarily reporting to MIPS, they would make an election via the [QPP portal](#) by logging into their account and selecting either the option to opt-in (positive, neutral, or negative MIPS adjustment) or to remain excluded and voluntarily report (no MIPS adjustment). Once the clinician has elected to participate in MIPS, the decision to opt-in to MIPS would be irrevocable and could not be changed for the applicable performance period. Clinicians and groups that make an election to opt-in would be able to participate in MIPS at the individual, group, or virtual group level for that performance period. Clinicians who do not decide to opt-in to MIPS would remain excluded and may choose to voluntarily report, but would not receive a MIPS payment adjustment factor.

As an alternative, CMS considered allowing the submission of data to signal that the clinician is choosing to participate in MIPS. However, some clinicians who utilize the quality data code (QDC) claims submission type may have their systems coded to automatically append QDCs on claims for eligible patients. CMS was concerned that these clinicians could submit a QDC code and inadvertently opt-in when that was not their intention.

Virtual Groups (p. 522): A virtual group election would constitute a low-volume threshold opt-in for any prospective member of the virtual group (solo practitioner or group with 10 or fewer eligible clinicians) that exceeds at least one, but not all, of the low-volume threshold criteria. As a result of the virtual group election, any such solo practitioner or group would be treated as a MIPS eligible clinician for the applicable MIPS payment year. These clinicians would not need to independently make a separate election to opt-in to participate in the MIPS.

APM Entities in MIPS APMs (p. 524). APM Entities in MIPS APMs, which meet one or two, but not all, of the low-volume threshold elements and are interested in participating in MIPS under the APM scoring standard, would be required to make a definitive choice at the APM Entity level to opt-in to participate in MIPS. These APM Entities would need to make an election via a similar process that individual eligible clinicians and groups will use to make an election to opt-in. Once the APM Entity has elected to participate in MIPS, the decision to opt-in to MIPS is irrevocable, and eligible clinicians in APM Entities in MIPS APMs that opt-in would be subject to the MIPS payment adjustment factor. APM Entities in MIPS APMs that do not decide to opt-in to MIPS cannot voluntarily report.

For applicable eligible clinicians participating in a MIPS APM, whose APM Entity meets one or two, but not all, of the low-volume threshold elements and does **not** decide to opt-in to MIPS, if their TIN or virtual group **does** elect to opt-in, it does not mean that the eligible clinician is opting-in on his/her own behalf, or on behalf of the APM Entity, but that the eligible clinician is still excluded from MIPS participation as part of the APM Entity even

though such eligible clinician is part of a TIN or virtual group. This is necessary because low-volume threshold determinations are currently conducted at the APM Entity level for all applicable eligible clinicians in MIPS APMs, and therefore, the low-volume threshold opt-in option should similarly be executed at the APM Entity level rather than at the individual eligible clinician, TIN, or virtual group level.

Partial QPs (p. 526)

Later in the rule, CMS ***proposes to clarify*** that beginning with the 2021 MIPS payment year, when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, he or she will be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician elects to not report to MIPS, he or she will not be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician does not make any affirmative election to report to MIPS, he or she will not be subject to MIPS reporting requirements and payment adjustments. As a result, beginning with the 2021 MIPS payment year, for eligible clinicians who are determined to be Partial QPs individually, CMS will not use the eligible clinician's actual MIPS reporting activity to determine whether to exclude the Partial QP from MIPS in the absence of an explicit election.

CMS restates here that affirmatively agreeing to participate in MIPS as part of a virtual group does not constitute an explicit election to report under MIPS as it pertains to making an explicit election to either report to MIPS or be excluded from MIPS for individual eligible clinicians or APM Entities that have Partial QP status. CMS clarifies that QP status and Partial QP status, achieved at the APM Entity level or eligible clinician level, is applied to an individual and all of his or her TIN/NPI combinations, whereas virtual group participation is determined at the TIN level. Therefore, CMS does not believe it is appropriate that the actions of the TIN in joining the virtual group should deprive the eligible clinician who is a Partial QP, whether that status was achieved at APM Entity level or eligible clinician level, of the opportunity to elect whether or not to opt-in to MIPS.

Group Reporting (p. 531)

CMS clarifies here that it considers a group to be an entire single TIN that chooses to participate in MIPS at the group level. However, individual eligible clinicians (TIN/NPIs) within that group may receive a MIPS payment adjustment based on the APM scoring standard if they are on the participant list of a MIPS APM.

An overarching theme heard by CMS is that it allow a portion of a group to report as a separate sub-group on measures and activities that are more applicable to the sub-group and to be assessed and scored based on the performance of the sub-group. Because there are several operational challenges with implementing a sub-group option, and because of potential gaming opportunities, CMS is not proposing any such policy in this rule. However, it will consider facilitating the use of a sub-group identifier in the QPP in year four through future rulemaking, as necessary.

CMS requests comments on:

- ***Whether and how a sub-group should be treated as a separate group from the primary group (e.g., if there is one sub-group within a group, how would CMS assess eligibility, performance, scoring, and application of the MIPS payment adjustment at the sub-group level);***
- ***Whether all of the sub-group's MIPS performance data should be aggregated with that of the primary group or should be treated as a distinct entity for determining the sub-group's final score, MIPS payment adjustments, and public reporting, and eligibility be determined at the whole group level;***
- ***Possible low burden solutions for identification of sub-groups (e.g., whether CMS should require registration similar to the CMS Web Interface or a similar mechanism to the low-volume threshold opt-in proposed in this rule); and***

- *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*
- *Other approaches for sub-group reporting that CMS should consider.*

Virtual Groups (p. 533)

CMS proposes to continue to apply the previously established policies regarding the virtual group election process for the 2022 MIPS payment year and future years, with the exception of the proposed policy modification discussed below:

- *Virtual Group Election Process:* CMS would provide for an election to occur in a manner specified by CMS, such as the QPP Web-based Portal, rather than exclusively via email as previously finalized.
- *Virtual Group Eligibility Determinations.*
 - *Beginning with 2019, the virtual group eligibility determination period aligns with the first segment of data analysis under the MIPS eligibility determination period (e.g. Oct. 1, 2017 to Sept. 30, 2018, including 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 each calendar year prior to the applicable performance period. TIN size inquiries would be made through designated technical assistance representatives until the 2020 performance year, when it would shift to the QPP Service Center. Technical assistance resources already available to stakeholders would continue to be available. Any TIN size information provided is only informational; official eligibility would be determined in accordance with the MIPS determination period.*

MIPS Performance Period (p. 538)

CMS proposes to maintain current performance periods for 2019 and for future years as specified below:

- *Quality:* full calendar year (and for 2020 and future years)
- *Cost:* full calendar year (and for 2020 and future years)
- *Improvement Activities:* a minimum of a continuous 90-day period within the calendar year (and for 2020 and future years)
- *Promoting Interoperability:* a minimum of a continuous 90-day period within the calendar year (and for 2020)

Despite comments that were not supportive of a full calendar year performance period, CMS believes that using the full calendar year for the quality and cost categories will be less confusing for clinicians; will include more patient encounters, which will produce larger sample sizes to provide more accurate and actionable information; and is consistent with how many of the measures were designed to be performed and reported.

MIPS Performance Category Measures and Activities (p. 541)

Performance Category Measures and Reporting (p. 541)

Collection Types, Submission Types and Submitter Types (p. 541)

New Terminology

- CMS proposes to revise and define new terminology to more precisely reflect the experience users have when submitting data to the QPP:
 - *Collection type:* 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

*measure; and administrative claims measures. The term **MIPS CQMs** would replace what was formerly referred to as registry measures since entities other than registries may submit data on these measures.*

- ***Submitter type:*** *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.*
- ***Submission type:*** *The mechanism by which the submitter type submits data to CMS, including, as applicable: direct (e.g. via API), 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 welcomes feedback on this terminology. To assist commenters, CMS has developed a [Website](#) that includes schematic drawings to illustrate a subset of the different submission types available for MIPS participation.

CMS also proposes to revise the applicable regulatory text to reflect these changes in terminology.

Claims Submission ([p. 544](#))

- ***CMS proposes to limit the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and to allow clinicians in small practices to report claims as a group.*** CMS discusses its ongoing desire to move away from claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out. While it would like to move towards the utilization of electronic reporting by all clinicians and groups, CMS realizes that small practices continue to face additional challenges.

Web Interface ([p. 545](#))

- ***CMS proposes that the CMS Web Interface submission type would no longer be available for groups to use to submit data for the improvement activities and Promoting Interoperability performance categories.*** Groups that elect to utilize the CMS Web Interface can still submit improvement activities or promoting interoperability data via direct, log in and attest or log in and upload submission types.
- ***CMS also proposes to allow third party intermediaries to submit data to the CMS Web Interface in addition to groups.***
- ***CMS seeks comment on expanding the CMS Web Interface submission type to groups consisting of 16 or more eligible clinicians to inform future rulemaking (versus the current requirement of groups with 25 or more eligible clinicians).***

[Table 29](#) includes a summary of proposed data submission types for MIPS eligible clinicians reporting as individuals.

[Table 30](#) includes a summary of proposed data submission types for MIPS eligible clinicians reporting as groups.

Submission Deadlines ([p. 547](#))

- ***CMS proposes a number of other technical revisions to §414.1325 to more clearly and concisely reflect previously established policies.*** One example is allowing flexibility for CMS to alter submission deadlines for the direct, login and upload, the CMS Web Interface, and login and attest submission types since there might be scenarios where the March 31st deadline falls on a weekend or holiday.

Quality Performance Category ([p. 549](#))

Contribution to Final Score ([p. 549](#))

Using authority granted under the Bipartisan Budget Act of 2018, CMS proposes to weight the quality performance category at 45 percent for the 2019 performance year.

Quality Data Submission Criteria ([p. 550](#))

CMS does not propose any changes to the quality data submission criteria or data completeness criteria for the 2019 MIPS performance year. However, as discussed earlier, it [proposes changes](#) to existing and additional submission related terminology.

Beginning with the 2019 performance year, CMS proposes to clarify in the regulations 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 measures apply to the MIPS eligible clinician or group, report on each measure that is applicable.

Although it's not proposing any changes to the data submission criteria for the CMS Web Interface, **CMS seeks comment on expanding the Web Interface option to groups with 16 or more eligible clinicians**. Preliminary analysis has indicated that expanding the CMS Web Interface option to groups of 16 or more eligible clinicians will likely result in many of these new groups not being able to fully satisfy measure case minimums on multiple CMS Web Interface measures, but CMS can possibly mitigate this issue if it requires smaller groups (with 16-24 eligible clinicians) to report on only a subset of the CMS Web Interface measures, such as the preventive care measures.

[Tables 31](#) provides a summary of **data completeness requirements and performance period** by collection type for the 2018 and 2019 performance years.

[Table 32](#) provides a summary of **quality data submission criteria for individual clinicians and groups** for the MIPS 2019 performance year.

Selection of MIPS Quality Measures for Individual MIPS Eligible Clinicians and Groups Under the Annual List of Quality Measures Available for MIPS Assessment ([p. 556](#))

Addition/Removal of Measures

- **For the 2019 MIPS performance period, CMS proposes the following updates:**
 - **Adding 10 new MIPS quality measures that include 4 patient-reported outcome measures, 7 high priority measures, 1 measure that replaces an existing measure, and 2 other measures on important clinical topics in the Meaningful Measures framework;**
 - **Removing 34 quality measures**

Tables summarizing changes to MIPS quality measures are included in Appendix I:

[Table A:](#) Proposed New Quality Measures for Inclusion in MIPS for the 2021 MIPS Payment Year and Future Years

[Table B:](#) Proposed New and Modified MIPS Specialty Measure Sets for the 2021 MIPS Payment Year and Future Years, which includes new proposed measures, previously finalized measures with proposed modifications, the removal of certain previously finalized measures, and further defined subspecialty sets

Table C: Quality Measures Proposed for Removal from MIPS for the 2019 Performance Period and Future Years

Table D: Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years, including the removal of six measures from the CMS Web Interface in MIPS.

Meaningful Measures Initiative (p. 556)

To streamline quality measures, reduce regulatory burden, and promote innovation, CMS has developed this initiative to identify the highest priority areas for quality measurement and improvement. Through subregulatory guidance, CMS will categorize quality measures by the 19 Meaningful Measure areas as identified on the [Meaningful Measures Initiative Website](#) to provide clinicians with guidance as to how each measure fits into the framework.

High Priority Measure Definition (p. 556)

Currently, a high priority measure is defined as an outcome, appropriate use, patient safety, efficiency, patient experience or care coordination quality measure. ***Beginning with the 2019 performance period, CMS proposes to amend the definition of a high priority measure at §414.1305 to mean an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. CMS also proposes to clarify here that outcome measures would include intermediate-outcome and patient-reported outcome measures. CMS requests comment on this proposal, specifically if stakeholders have suggestions on what aspects of opioids should be measured (e.g., should CMS focus solely on opioid overuse?).***

Specialty Sets (p. 557)

CMS maintains its policy that in instances where an individual MIPS eligible clinician or group reports on a specialty or subspecialty set, if the set has less than six measures, that is all the clinician is required to report.

eQMs (p. 558)

In the 2015 EHR Incentive Program final rule, CMS required eligible clinicians, eligible hospitals, and critical access hospitals (CAHs) to use the most recent version of an eQCM for electronic reporting beginning in 2017 (80 FR 62893). ***CMS proposes this policy for the end-to-end electronic reporting bonus under MIPS and encourage MIPS eligible clinicians to work with their EHR vendors to ensure they have the most recent version of the eQCM.*** CMS will not accept an older version of an eQCM for the quality performance category or the end-to-end electronic reporting bonus within this category. The annual updates to the eQCM specifications are available on the [electronic quality improvement \(eCQI\) Resource Center Website](#) for the applicable performance period.

CMS Web Interface Measures (p. 559)

CMS seeks comment on building upon the CMS Web Interface submission type by expanding the core set of measures available for that submission type to include other specialty specific measures (such as surgery).

Public Health Priority Measurement Sets (p. 559)

To provide clinicians with a more cohesive reporting experience, where they may focus on activities and measures that are meaningful to their scope of practice, CMS discuss in the section on Promoting Interoperability (PI) the development of [public health priority measurement sets](#) that would include measures and activities across the quality, PI, and improvement activities performance categories, focused on public health priorities such as fighting the opioid epidemic.

Topped Out Measures (p. 559)

CMS previously finalized a 4-year timeline to identify and potentially remove topped out measures. After a measure has been identified as topped out for 3 consecutive years through the benchmarks, CMS may propose

to remove the measure through notice and comment rulemaking. CMS also previously finalized a 7-point cap to be applied to measures identified as topped out in the published benchmarks for two consecutive years. CMS refers readers to the [2018 MIPS Quality Benchmarks' file](#) to determine which measure benchmarks 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. Note that the final determination of which measure benchmarks are subject to the topped out cap would not be available until the 2019 MIPS Quality Benchmarks' file is released in late 2018.

CMS proposes to change its existing policy so that once a measure has reached an extremely topped out status (e.g., a measure with an average mean performance within the 98th to 100th percentile range), it may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors. CMS is concerned that topped out non-high priority process measures require data collection burden without added value for eligible clinicians and groups participating in MIPS. CMS would consider retaining the measure if there are compelling reasons as to why it should not be removed (e.g., if the removal would impact the number of measures available to a specialist type or if the measure addressed an area of importance to CMS).

CMS also proposes to exclude QCDR measures from the topped out timeline previously finalized since QCDR measures are not approved or removed from MIPS through the rulemaking timeline or cycle. However, topped out QCDR measures might not be approved through the QCDR measure approval process.

Removal of Quality Measures (p. 561)

In the CY 2018 QPP quality measure set, 102 of the 275 quality measures are process measures that are not considered high priority. Because the removal of all non-high priority process measures would impact most specialty sets, nearly 94 percent, CMS believes incrementally removing non-high priority process measures through notice and comment rulemaking is appropriate.

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

- ***Whether the removal of the process measure impacts the number of measures available for a specific specialty.***
- ***Whether the measure addresses a priority area highlighted in the [Measure Development Plan](#).***
- ***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.***

Categorizing Measures by Value (p. 562)

CMS seeks comment on implementing a system where measures are classified as a particular value (gold, silver or bronze) and points are awarded based on the value of the measure. A more detailed discussion on [the assignment of value and scoring based on measure value](#) is included later in this rule.

Cost Performance Category ([p. 564](#))

Contribution to Final Score ([p. 564](#))

Section 51003(a)(1)(C) of the Bipartisan Budget Act of 2018, authorizes that for each of the second, third, fourth, and fifth years for which the MIPS applies to payments, not less than 10 percent and not more than 30 percent of the MIPS final score shall be based on the cost performance category score. Recognizing that cost measures are still relatively early in the process of development and that clinicians do not have the level of familiarity or understanding of cost measures that they do of comparable quality measures, ***CMS proposes at §414.1350(d)(3) that the cost performance category would make up 15 percent of a MIPS eligible clinician's final score for the 2019 MIPS performance year.*** CMS will address the weight of the cost performance category for future years in future rulemaking.

CMS considered maintaining the weight of the cost performance category at 10 percent for the 2019 MIPS performance year, recognizing that clinicians are still learning about the cost performance category and being introduced to new measures. ***CMS invites comment on whether it should consider an alternative weight for the 2019 MIPS performance year.***

To provide for a smooth transition, 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 percent weight for the 2022 performance year. ***CMS invites comments on this approach to the weight of the cost performance category for the 2020 and 2021 MIPS performance years.***

Cost Criteria ([p. 566](#))

Background

CMS will continue to evaluate cost measures that are included in MIPS on a regular basis and anticipates that measures could be added or removed through rulemaking as measure development continues. CMS will conduct annual evaluations to review the continued accuracy of measure specifications, including coding, risk adjustment and other factors. It will also comprehensively reevaluate the measures every three years to ensure that they continue to meet measure priorities and to inform potential refinements. CMS will also analyze measure performance rates and reassess the reliability and validity of the measures. Throughout these efforts, it will summarize and consider all stakeholder feedback received on the measure specifications during the implementation process and may seek input through public comment periods and Technical Expert Panels. Substantive changes to a measure would be proposed for adoption in future years through notice and comment rulemaking; however, some updates may incorporate changes that would not substantively change the intent of the measure (e.g., updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions).

Section 51003(a)(2) of the Bipartisan Budget Act of 2018, also 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 measure topics, 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 shall be posted no later than December 31 of each year beginning with 2018. CMS expects this posting will provide a list of the cost measures established for the cost performance category for the current performance period, as well as a list of any cost measures that may be proposed for a future performance period through rulemaking. CMS will provide hyperlinks to the measure specifications documents and include the percent of Medicare Part A and Part B expenditures that are covered by these cost measures. The posting will also include a list and description of the measures under development at that time. CMS intends to summarize the timeline for measure development, including the stakeholder engagement activities undertaken, which may include a

TEP, clinical subcommittees, field testing, and education and outreach activities, such as national provider calls and listening sessions. Finally, the posting will provide an overview of potential future topics in cost measure development, such as any clinical areas in which measures may be developed in the future.

Episode-Based Measures Proposed for the 2019 and Future Performance Periods (p. 569)

Here, CMS provides background on episode-based cost measures and CMS's work with stakeholders to develop these types of measures. CMS clarifies that episode costs are payment standardized and risk adjusted to ensure a more accurate comparison of cost across clinicians. Payment standardization adjusts the allowed amount for an item or service to facilitate cost comparisons and limit observed differences in costs to those that may result from health care delivery choices (e.g., removal of any Medicare payment differences due to adjustments for geographic differences in wage levels or policy-driven payment adjustments, such as those for teaching hospitals). Risk adjustment accounts for patient characteristics that can influence spending and are outside of clinician control.

CMS also discusses its field testing of eight new episode-based cost measures developed by relevant clinical subcommittees. From October 16, 2017 to November 20, 2017, solo practitioners and clinician groups were able to access field test reports about their cost measure performance on the CMS Enterprise Portal if they were attributed at least 10 episodes for at least one of these eight measures during the measurement period of June 1, 2016 to May 31, 2017. In addition to the field test reports, stakeholders could review a range of materials about the new episode-based cost measures, including a fact sheet, FAQ document, a mock field test report, and draft measure specifications for each of the new episode-based measures. These materials can be downloaded [here](#). These new episode-based measures were then considered by the National Quality Form (NQF)-convened Measures Application Partnership (MAP), and were all conditionally supported by the MAP, with the recommendation of obtaining NQF endorsement.

Following the successful field testing and review through the MAP process, CMS proposes to add the eight episode-based measures listed below as cost measures for the 2019 MIPS performance period and future performance periods. CMS would also retain the Medicare Spending Per Beneficiary (MSPB) measure and the Total Per Capita Cost measure. Detailed specifications for the newly proposed episode-based cost measures are available [here](#). CMS intends to submit these episode-based measures to NQF for endorsement in the future. It also will continue to work on developing additional episode-based measures that it may consider proposing for the cost performance category in future years.

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 Percutaneous Coronary Intervention (PCI)	Acute inpatient medical condition

Reliability (p. 574)

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 that it has proposed beginning with the 2019 MIPS performance period. CMS previously finalized a reliability threshold of 0.4 for measures in the cost performance category and a case minimum of 20 for the episode-based measures specified for the 2017 MIPS performance period (for informational purposes only). CMS examined the reliability of the proposed eight episode-based measures at various case minimums and found that all of 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 episode-based measures and 20 episodes for acute inpatient medical condition episode-based measures. These case minimums also would balance the goal of increased reliability with the goal of adopting cost measures that are applicable to a larger set of clinicians and clinician groups. [Table 34](#) presents the results of this analysis.

CMS seeks comments on an alternative case minimum of 30 for both TIN/NPIs and TINs for the Simple Pneumonia with Hospitalization measure. Note that the percentage of TIN/NPIs with 0.4 or greater reliability for this measure, while still meeting CMS's reliability threshold, is somewhat lower than that of the other proposed measures. At the alternative case minimum, 100 percent of TIN/NPIs would have 0.4 or greater reliability and the mean reliability would increase to 0.49 for TIN/NPIs and 0.70 for TINs. However, the number of TINs and TIN/NPIs that would meet the case minimum for this important measure would decrease by 29 percent for TINs and by 84 percent for TIN/NPIs.

CMS also proposes to codify the previously finalized case minimum of 35 for the MSPB measure (81 FR 77171), 20 for the Total Per Capita Cost measure (81 FR 77170), and 20 for the episode-based measures specified for the 2017 MIPS performance period (81 FR 77175) at §414.1350(c).

Attribution (p. 577)

For acute inpatient medical condition episode groups specified beginning with the 2019 performance period, CMS proposes to attribute episodes to each MIPS eligible clinician who bills inpatient evaluation and management (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 of 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. Note that the attribution approach proposed here differs from the attribution approach previously established for episode-based measures for acute inpatient medical conditions specified for the 2017 performance period in the CY 2017 QPP final rule (81 FR 77174 through 77175). The previous approach attributed episodes to TIN/NPIs who individually exceed the 30 percent E&M threshold, while excluding all episodes where no TIN/NPI exceeds the 30 percent threshold. CMS believes that the previous approach does not capture patients' episodes when a group collaborates to manage a patient, but no individual clinician exceeds the 30 percent threshold. On [p. 579](#), CMS provides an example of how these attribution rules would apply when 3 MIPS eligible clinicians are part of the same TIN.

For procedural episode groups specified beginning with the 2019 MIPS performance period, 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 of the episodes attributed to the individual. The measure score for a group (TIN) is based on all of 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. This method is similar to that used for procedural episode-based

measures in the 2017 MIPS performance period, but more clearly defines that the services must be provided during the episode and how CMS would address instances in which two NPIs in the same TIN provided a trigger service.

Again, detailed specifications for the newly proposed episode-based cost measures are available [here](#).

Improvement Activities Performance Category (p. 581)

Submission Criteria (p. 583)

CMS proposes to revise §414.1360(a)(1) to more accurately reflect the data submission process for the improvement activities performance category. Instead of “via qualified registries; EHR submission mechanisms; QCDR, CMS Web Interface; or attestation,” CMS would revise the first sentence to state that data would be submitted “via direct, login and upload, and login and attest,” as reflected in the updated [terminology proposals](#) discussed earlier.

Improvement Activities Inventory (p. 586)

CMS proposes to adopt one new criterion— “Include a public health emergency as determined by the Secretary”— to the criteria for nominating new improvement activities beginning with the CY 2019 performance period and future years. A list of the public health emergency declarations is available [here](#).

CMS also proposes to remove the criterion “Activities that may be considered for an advancing care information bonus” beginning with the 2019 performance period. CMS does not believe this criterion remains relevant since later in this rule, CMS [proposes a new approach for scoring the Promoting Interoperability \(PI\) category](#) that would remove the availability of a bonus score for attesting to one or more specified improvement activities using CEHRT.

Currently adopted criteria for nominating new improvement activities are listed on [p. 587](#). If these proposals are finalized, the new list of criteria for nominating new improvement activities for the CY 2019 performance period and future years is listed on [p. 590](#). CMS clarifies that these criteria are but one factor in determining which improvement activities to propose. CMS also generally takes into consideration other factors, such as whether the nominated improvement activity uses publicly available products or techniques (i.e., does not contain proprietary products or information limiting an activity) or whether the nominated improvement activity duplicates any currently adopted activity.

Timeframe for the Annual Call for Activities (p. 594)

The previously established timeline has become operationally challenging for CMS. ***Beginning with the 2019 performance period and future years, CMS proposes:***

- ***That improvement activities nominations (new and modified) received in a particular year will be vetted and considered for the next year’s rulemaking cycle for possible implementation in a future year.*** This timeframe parallels the PI performance category Annual Call for EHR Measures timeframe. For example, an improvement activity nomination submitted during the CY 2020 Annual Call for Activities would be vetted, and if accepted by CMS, would be proposed during the CY 2021 rulemaking cycle for possible implementation starting in CY 2022.
- ***To change the submission timeframe for the Call for Activities from February 1st through March 1st to February 1st through June 30th, providing approximately four additional months for stakeholders to submit nominations.***

Proposed New Improvement Activities and Modifications to and Removal of Existing Improvement Activities (p. 596)

CMS proposes to:

- **Add 6 new improvement activities for the CY 2019 performance period and future years, including multiple activities focused on opioid use (see [Appendix 2, Table A](#))**
- **Modify 5 existing improvement activities for the CY 2019 performance period and future years (see [Appendix 2, Table B](#)); and**
- **Remove 1 existing improvement activity for the CY 2019 performance period and future years (IA_PM_9: Participation in Population Health Research, as noted I in [Appendix 2, Table B](#)).**

High-Weighting Due to Activity Intensity/High Versus Medium-Weighting (p. 591)

CMS discusses considerations it has previously used to assign weights to improvement activities included in the Improvement Activities Inventory. CMS has given certain improvement activities high weighting due to the intensity of the activity (81 FR 77194) (e.g., an activity that requires significant investment of time and resources). In contrast, medium-weighted improvement activities are simpler to complete and require less time and resources. CMS recognizes that it did not previously explicitly state separate considerations for medium-weighted activities specifically.

In response to public requests for additional transparency regarding the weighting of improvement activities (82 FR 53657), ***CMS clarifies that an improvement activity is by default medium-weight unless it meets considerations for high-weighting, as discussed above.*** CMS intends to more thoroughly revisit improvement activity weighting policies in next year's rulemaking. ***As it works to refine the Annual Call for Activities process for future years, CMS invites public comment on the need for additional transparency and guidance on the weighting of improvement activities. Also, in light of [the proposed policy to remove bonus points for improvement activities that may be applicable to the PI performance category](#), CMS recognizes the need to continue incentives for CEHRT and seeks comment on potentially applying high-weighting for any improvement activity employing CEHRT. CMS also invites public comment on any other additional considerations for high- or medium-weighting.***

CMS Study on Factors Associated with Reporting Quality Measures (p. 596)

This study is ongoing, participants are recruited on a yearly basis for a minimum period of 3 years, and current participants can opt-in or out when the study year ends (81 FR 77195). Successful participation in the study results in full credit for the improvement activities performance category of 40 points.

CMS is not proposing any changes to the study purpose, aim, eligibility, or credit for this study (which are discussed in more detail in this section). However, ***CMS does propose for the CY 2019 performance period and future years, the following changes:***

- ***Change the title of the study from "CMS Study on Burdens Associated with Reporting Quality Measures" to "CMS Study on Factors Associated with Reporting Quality Measures;"***
- ***Increase the sample size to a minimum of 200 participants;***
- ***Limit the focus group requirement to a subset of the 200 participants; and***
- ***Require that at least one of the minimum of three required measures be a high priority measure.***

Promoting Interoperability (PI) (previously known as the Advancing Care Information Performance Category) (p. 604)

In this rule, CMS proposes several scoring and measurement policies that would bring this performance category to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information.

Renaming the Advancing Care Information Performance Category (p. 604)

CMS is renaming the advancing care information performance category to the Promoting Interoperability (PI) performance category to help it highlight the enhanced goals of this performance category. CMS proposes revisions to the regulation text under 42 CFR part 414, subpart O, to reflect the new name.

Certification Requirements beginning in 2019 (p. 604)

As previously finalized, beginning with the 2019 performance period, MIPS eligible clinicians must use EHR technology certified to the 2015 Edition certification criteria. Although CMS recognizes there is a burden associated with development and deployment of new technology, it continues to believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019 since it has improved interoperability features and up-to-date standards to collect and exchange relevant patient health information. The 2014 Edition certification criterion includes standards that are significantly out of date, which can impose limits on interoperability and the access, exchange, and use of health information.

Moving exclusively to the 2015 Edition would also eliminate the inconsistencies that are inherent with maintaining and implementing two separate certification programs. It would also reduce the burden for health IT developers, as well as Office of the National Coordinator for Health Information Technology (ONC)-Authorized Testing Laboratories and ONC-Authorized Certification Bodies because they would no longer have to support two, increasingly distant sets of requirements.

Improvements of the 2015 Edition include:

- Application Programming Interface (API) functionality, which supports health care providers and patient electronic access to health information. These functions allow for patient data to move between systems, assist patients with making key decisions about their health care, and contribute to quality improvement and greater interoperability between systems.
- Certification criterion specifying a core set of data known as the Common Clinical Data Set (CCDS) that health care providers have noted are critical to interoperable exchange and can be exchanged across a wide variety of other settings and use cases.
- A requirement that products must be able to export data from one patient, a set of patients, or a subset of patients, which is responsive to health care provider feedback that their data is unable to carry over from a previous EHR. The 2014 Edition did not include a requirement that the vendor allow the MIPS eligible clinician to export the data themselves. In the 2015 Edition, the health care provider has the autonomy to export data themselves without intervention by their vendor, resulting in increased interoperability and data exchange in the 2015 Edition.

In the last calendar year, the number of new and unique 2014 Edition products have been declining, showing that the market acknowledges the shift towards newer and more effective technologies. CMS also notes that a large proportion of the sector is ready to use only the 2015 Edition of CEHRT. As of the beginning of the first quarter of CY 2018, ONC confirmed that at least 66 percent of MIPS eligible clinicians have 2015 Edition CEHRT available based on previous Medicare and Medicaid EHR Incentive Programs attestation data. Based on these data, and as compared to the transition from 2011 Edition to 2014 Edition, it appears that the transition from the 2014 Edition to the 2015 Edition is on schedule for the performance period in CY 2019.

Scoring Methodology (p. 608)

Scoring Methodology for 2017 and 2018 Performance Periods (p. 608)

In accordance with Section 1848(q)(5)(E)(i)(IV) of the Act, the PI performance category will continue to comprise 25 percent of a MIPS eligible clinician's final score for the 2021 MIPS payment year.

A general summary overview of the scoring methodology for the 2018 performance period is provided in the [Table 35](#).

CMS heard from many stakeholders that the current scoring methodology is complicated and difficult to understand. CMS received hundreds of questions requesting clarification of various aspects of the scoring methodology. Many indicated that they dislike the base score because it is a required set of measures and provides no flexibility because the scoring is all-or-nothing. Others noted that the current requirements detract from their ability to provide care to their patients. Others voiced concern that the PI requirements do not align with the requirements of the Medicare PI Program for eligible hospitals and creates a burden for the medical staff who are tasked with overseeing the participation of both clinicians and hospitals in these programs.

Proposed Scoring Methodology Beginning with the MIPS Performance Period in 2019 (p. 612)

Based on the concerns expressed above and to provide increased flexibility, CMS proposes a new scoring system that would move away from the current base, performance and bonus score methodology. ***CMS proposes that beginning with the 2019 performance period, the new scoring methodology would:***

- ***Include a combination of new measures, as well as the existing PI performance category measures, broken into a smaller set of four objectives and scored based on performance. The smaller set of objectives would include e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange.***
- ***MIPS eligible clinicians would be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level.***
- ***Each measure would be scored based on the MIPS eligible clinician's performance for that measure, based on the submission of a numerator and denominator, except for the measures associated with the Public Health and Clinical Data Exchange objective, which require "yes or no" submissions.***
- ***Each measure would contribute to the MIPS eligible clinician's total PI performance category score. The scores for each of the individual measures would be added together to calculate the PI performance category score of up to 100 possible points for each MIPS eligible clinician.***
- ***The MIPS eligible clinician would need to report on all of the required measures across all objectives in order to earn any score at all for the PI category. 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 performance category score of zero.***
- ***The Security Risk Analysis measure ([p. 618](#)) would remain part of the requirements for the PI category, but would no longer be scored as a measure and would not contribute to the MIPS eligible clinician's PI score. To earn any score in the PI category, CMS proposes that a MIPS eligible clinician would have to report that they completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the performance period occurs.***

TABLE 36: Proposed Scoring Methodology for the MIPS Performance Period in 2019

Objectives	Measures	Maximum Points
e-Prescribing	e-Prescribing ³⁴	10 points
	<i>Bonus (optional):</i> Query of Prescription Drug Monitoring Program [NEW for 2019]	5 points bonus
	<i>Bonus (optional):</i> Verify Opioid Treatment Agreement [NEW for 2019]	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 [NEW for 2019] ³⁵	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange ³⁶	Choose two of the following: Immunization Registry Reporting Electronic Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Syndromic Surveillance Reporting	10 points

TABLE 38 includes an example of how this proposed scoring methodology would be applied during the 2019 performance period. When calculating the performance rates, measure and objective scores, and PI performance category score, CMS would generally round to the nearest whole number.

³⁴ For MIPS clinicians who are eligible for and claim an exclusion for the e-Prescribing measure, the 10 points available for that measure would be redistributed equally among the two measures under the Health Information Exchange objective.

³⁵ Clinicians who cannot implement this measure could claim an exclusion. The 20 points would be redistributed to the Support Electronic Referral Loops by Sending Health Information measure.

³⁶ The MIPS eligible clinician 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. Reporting more than two measures for this objective would not earn the MIPS eligible clinician any additional points. 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 if they do not submit a “yes” or claim an exclusion for at least two measures. If a MIPS eligible clinician claims two exclusions, the 10 points for this objective would be redistributed to the Provide Patients Electronic Access to their Health Information measure.

TABLE 37: Proposed Scoring Methodology Beginning with MIPS Performance Period in 2020

Objectives	Measures	Maximum Points
e-Prescribing ³⁷	e-Prescribing	5 points
	Query of Prescription Drug Monitoring Program ³⁸	5 points
	Verify Opioid Treatment Agreement ⁷	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 ³⁹	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	35 points
Public Health and Clinical Data Exchange ⁴⁰	Choose two of the following: Immunization Registry Reporting Electronic Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Syndromic Surveillance Reporting	10 points

CMS seeks comments on the feasibility of the proposed new scoring methodology in 2019 and whether MIPS eligible clinicians would be able to implement the new measures and reporting requirements under this scoring methodology. CMS also seeks comment on whether these measures are weighted appropriately, or whether a different weighting distribution, such as equal distribution across all measures would be better suited to this program and this proposed scoring methodology.

CMS also considered an alternative approach in which 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 alternative, instead of six required measures, the MIPS eligible clinician total PI performance category score would be based on only four measures, one measure from each objective. Each objective would be weighted similarly to how the objectives are weighted in its 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, such as allowing MIPS eligible clinicians to select which measures to report on within an objective and how those objectives should be weighted, as well as whether additional scoring approaches or methodologies should be considered.**

If CMS does not finalize a new scoring methodology, it proposes to maintain for the performance period in 2019 the current PI performance category scoring methodology with the same objectives,

³⁷ MIPS eligible clinicians who claim the exclusion under the existing e-Prescribing measure would automatically receive an exclusion for all three of the measures under the e-Prescribing objective; they would not have to also claim exclusions for the other two opioid measures. If a MIPS eligible clinician is excluded from reporting all three of the measures associated with the e-Prescribing objective, the 15 points 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.

³⁸ CMS proposes to require clinicians to report the two opioid measures beginning with the MIPS performance period in 2020. Since not all MIPS eligible clinicians would be able to e-prescribe controlled substances due to varying State requirements, CMS would offer an exclusion for clinicians unable to report these measures in accordance with applicable law. The 5 points assigned to these measures would be redistributed to the e-Prescribing measure.

³⁹ See 2019 measure proposal.

⁴⁰ See 2019 measure proposal.

measures and requirements as established for 2018, except that CMS would discontinue the 2018 Promoting Interoperability Transition Objectives and Measures (82 FR 53677) because they are associated with 2014 Edition CEHRT. In addition, CMS would include the two new opioid measures, if finalized.

Promoting Interoperability/Advancing Care Information Objectives and Measures Specifications for the 2018 Performance Period (p. 624)

This section summarizes the Advancing Care Information (now PI) performance category objectives and measures for the 2018 performance period.

Promoting Interoperability Performance Category Measure Proposals for MIPS Eligible Clinicians (p. 631)

In this section, CMS discusses in more detail its proposed changes to the PI measures.

- ***CMS proposes to remove six measures from the PI objectives and measures beginning with the 2019 performance period.***
 - ***Two of the measures being proposed for removal – Request/Accept Summary of Care (p. 653) and Clinical Information Reconciliation (p. 655) – would be replaced by the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, which combines the functionalities and goals of the two measures it is replacing.*** CMS does not believe that the Request/Accept Summary of Care is feasible for machine calculation and often creates a burdensome workflow to document the manual action to request or obtain an electronic record (e.g., clicking a check box to document each phone call). It also feels the Clinical Information Reconciliation measure is redundant and not fully health IT based since the exchange of health care information is not required to complete the measure action.
 - ***Four of the measures, which comprise the entirety of the Coordination of Care Through Patient Engagement objective – Patient-Specific Education; Secure Messaging; View, Download, or Transmit; and Patient-Generated Health Data– would be removed because they are burdensome to MIPS eligible clinicians in ways that were unintended and may detract from clinicians' progress on current program priorities (p. 633, p. 661).***
- ***CMS proposes to add three new measures to the PI objectives and measures beginning with the 2019 performance period.***
 - ***For the e-Prescribing objective, CMS proposes two new measures:***
 - 1) Query of PDMP***
 - 2) Verify Opioid Treatment Agreement***

Currently, MIPS eligible clinicians have the option to include or exclude controlled substances in the e-Prescribing measure denominator as long as they are treated uniformly across patients and all available schedules and in accordance with applicable law (81 FR 77227). However, because the intent of these two new measures is to improve prescribing practices for controlled substances, MIPS eligible clinicians would have to include Schedule II opioid prescriptions in the numerator and denominator or claim the applicable exclusion. CMS also clarifies that the intent of the proposed measures is not to dissuade the prescribing or use of opioids for patients with medical diagnoses or conditions that benefit from their use, such as patients diagnosed with cancer or those receiving hospice. ***CMS seeks comment on the impact that implementing these measures could have on patients who receive opioids due to medical diagnoses such as cancer or receiving hospice care, as well as treatment of patients under a program involving substance abuse education, treatment, or prevention. CMS also seeks comment on the federal and state statutory and regulatory requirements that may impact implementation of these measures.***

Although CMS has proposed these two new measures focuses on e-prescribing of controlled substances, it requests comment on whether stakeholders would be interested in a measure focused only on the number of Schedule II opioids prescribed and the successful use of e-prescribing of controlled substances for permissible prescriptions electronically prescribed.

Measure Title	Description	Numerator	Denominator	Exclusion (beginning in 2020)
Query of PDMP (p. 639)	For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.	The number of Schedule II opioid prescriptions in the denominator for which data from CEHRT is used to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law. A numerator of at least one is required to fulfill this measure.	Number of Schedule II opioids electronically prescribed using CEHRT by the MIPS eligible clinician during the performance period.	Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period.

The query of the PDMP for prescription drug history must be conducted prior to the electronic transmission of the Schedule II opioid prescription. However, clinicians would have flexibility to query the PDMP using CEHRT in any manner allowed under their State law. CMS proposes to include in this measure all permissible prescriptions and dispensing of Schedule II opioids regardless of the amount prescribed during an encounter in order for MIPS eligible clinicians to identify multiple health care provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities. **CMS requests comment on these policy proposals, including whether additional queries should be performed and under which circumstances, as well as whether the query should have additional constraints concerning when it should be performed.**

CMS also requests comment on the proposed exclusion criteria and whether there are circumstances which may justify other exclusions for the Query of PDMP measure and what those circumstances might be including medical diagnoses such as cancer or patients under care of hospice.

CMS notes that there are no existing certification criteria for the query of a PDMP, but that the NCPDP SCRIPT 2017071 standard for e-prescribing is now available and can help to support PDMP and EHR integration. **CMS seeks public comment on whether ONC should consider adopting standards and certification criteria to support the query of a PDMP, and if such criteria were to be adopted, on what timeline should CMS require their use to meet this measure.**

Additionally, CMS seeks comment on the challenges associated with querying the PDMP with and without CEHRT integration and whether this proposed measure should require certain standards, methods or functionalities to minimize burden. CMS also seeks input on perceived and real technological barriers to effective implementation of e-prescribing for controlled

substances, including but not limited to input on two-factor authentication and on the effective and appropriate uses of technology, including the use of telehealth modalities to support established patient and health care provider relationships subsequent to in-person visit(s) and for prescribing purposes.

If CMS does not finalize the proposed scoring methodology, it proposes that MIPS eligible clinicians must report at least one prescription in the numerator to report on this new measure and earn points towards the bonus score.

Measure Title	Description	Numerator	Denominator	Exclusion (beginning in 2020)
Verify Opioid Treatment Agreement (p. 643)	For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the MIPS eligible clinician seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient's electronic health record using CEHRT.	The number of unique patients in the denominator for whom the MIPS eligible clinician seeks to identify a signed opioid treatment agreement and, if identified, incorporates the agreement in CEHRT. A numerator of at least one is required to fulfill this measure.	Number of unique patients for whom a Schedule II opioid was electronically prescribed by the MIPS eligible clinician using CEHRT during the performance period and the total duration of Schedule II opioid prescriptions is at least 30 cumulative days as identified in the patient's medication history request and response transactions during a 6-month look-back period.	Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids in accordance with applicable law during the performance period.

The intent of this measure is for MIPS eligible clinicians to identify whether there is an existing opioid treatment agreement when they electronically prescribe a Schedule II opioid using CEHRT if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days. CMS believes seeking to identify an opioid treatment agreement will further efforts to coordinate care between health care providers and foster a more informed review of patient therapy.

CMS proposes that the 6-month look-back period would begin on the date on which the MIPS eligible clinician electronically transmits their Schedule II opioid prescription using CEHRT. CMS proposes a 6-month look-back period to identify more egregious cases of potential overutilization of opioids and to cover timeframes for use outside the performance period.

CMS recognizes that there is debate among practitioners about the value and appropriateness of opioid treatment agreements. There are also challenges related to prescribing practices and multiple State laws, which may present barriers to the uniform implementation of this proposed measure. **As such, CMS requests comment on the challenges this proposed measure may create for MIPS eligible clinicians, how those challenges might be mitigated, and whether this measure should be included as part of the PI performance category.**

There also may be burdens specific to identifying the existence of a treatment agreement, which could require additional time and changes to existing workflows, determining what constitutes a treatment agreement due to a lack of a definition, standard or electronic format and manual calculation of the measure. In addition, limitations in the completeness of care team information may limit the ability of a MIPS eligible clinician to identify all potential sources for querying and obtaining information on a treatment agreement for a specific patient. **CMS cites pilots currently in development that are focused on increasing connectivity and data exchange among health care providers to better integrate behavioral health information and seeks comment on other similar pathways to facilitate the identification and exchange of treatment agreements and opioid abuse treatment planning.**

CMS does not propose to define an opioid treatment agreement as a standardized electronic document; nor does it propose to define the data elements, content structure, or clinical purpose for a specific document to be considered a “treatment agreement.” However, **it seeks comment on:**

- **What characteristics should be part of an opioid treatment agreement including data, content and clinical purpose into CEHRT, including which functionalities could be utilized to accomplish this.**
- **Methods or processes for incorporation of the treatment agreement into CEHRT, including which functionalities could be utilized to accomplish this task. CMS also seeks comment on whether there are specific data elements that are currently standardized that should be incorporated via reconciliation and if the “patient health data capture” functionality could be used to incorporate a treatment plan that is not a structured document with structured data elements.**
- **The proposed exclusion criteria and whether there are additional circumstances that should be added to the exclusion criteria and what those circumstances might be including medical diagnoses such as cancer or patients under care of hospice.**
- **Whether these types of agreements could create a burden on clinicians and patients, particularly clinicians who serve patients with cancer or those practicing in hospice, as well as the patients they serve.**

In the event that CMS do not finalize the proposed scoring methodology, it proposes that MIPS eligible clinicians must report at least one unique patient in the numerator to report on this new measure and earn points towards the bonus score. CMS believes a threshold of at least one unique patient is appropriate to account for the varying support for the use of opioid treatment agreements and acknowledging that not all patients who receive at least 30 cumulative days of Schedule II opioids would have a treatment agreement in place.

- ***For the Health Information Exchange objective, CMS also proposes the following new measure:***

3) Support Electronic Referral Loops by Receiving and Incorporating Health Information

Measure Title	Description	Numerator	Denominator	Exclusion (beginning in 2020)
Support Electronic Referral Loops by Receiving and Incorporating Health Information (p. 656)	For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, medication allergy, and current problem list.	The number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period.

This measure would include actions from the Request/Accept Summary of Care and Clinical Information Reconciliation measures. By combining these two measures, CMS can better focus on the exchange of the health care information, reduce administrative burden, and streamline and simplify reporting.

The MIPS eligible clinician would no longer be required to manually count each individual non-health-IT related action taken to engage with other providers of care and care team members to identify and obtain the electronic summary of care record. Instead, the proposed measure would focus on the result of these actions when an electronic summary of care record is successfully identified, received, and reconciled with the patient record.

CMS proposes to apply its existing policy for cases in which the MIPS eligible clinician determines no update or modification is necessary within the patient record based on the electronic clinical information received, and the MIPS eligible clinician may count the reconciliation in the numerator without completing a redundant or duplicate update to the record. CMS welcomes comment on methods by which this specific action could potentially be electronically measured by the MIPS eligible clinician's health IT system – such as incrementing on electronic signature or approval by an authorized health care provider – to mitigate the risk of burden associated with manual tracking of the action, such as having to click check boxes.

It also seeks comment on:

- **The proposed exclusion criteria and whether there are additional circumstances that should be added to the exclusion criteria and what those circumstances might be.**
 - **Methods and approaches to quantify the reduction in burden for MIPS eligible clinicians implementing streamlined workflows for this proposed health IT based measure.**
 - **The impact these proposed modifications may have for health IT developers in updating, testing, and implementing new measure calculations related to these proposed changes and whether ONC should require developers to recertify their EHR technology as a result of the changes proposed, or whether they should be able to make the changes and engage in testing without recertification.**
 - **The appropriate timeline for such requirements, factoring in the proposed continuous 90-day performance period.**
- **CMS also proposes to modify some of the existing PI objectives and measures beginning with the performance period in 2019.**
 - **Rename the *Send a Summary of Care* measure to *Support Electronic Referral Loops by Sending Health Information* (p. 650)** to better reflect the emphasis on completing the referral loop and improving care coordination. CMS clarifies that in the event that a MIPS eligible clinician is the recipient of a transition of care or referral, and subsequent to providing care the MIPS eligible clinician transitions or refers the patient back to the referring provider of care, this transition of care should be included in the denominator of the measure for the MIPS eligible clinician. In response to concerns about burden, CMS also clarifies that under the ONC Health IT Certification Program 2015 Edition, CEHRT must have the capability to exchange all of the information in the Common Clinical Data Set (CCDS) as part of a summary care record structured according to the Consolidated Clinical Document Architecture (CCDA) standard. To provide flexibility, CMS proposes that MIPS eligible clinicians may use any document template within the CCDA standard that is most appropriate to their clinical workflows for purposes of the measures under the Health Information Exchange objective.
 - **Rename the *Patient Electronic Access* objective to *Provider to Patient Exchange*, which would include one measure, the existing *Provide Patient Access* measure, which CMS proposes to rename *Provide Patients Electronic Access to Their Health Information* (p. 661)**
 - **Rename the *Public Health and Clinical Data Registry Reporting* objective to *Public Health and Clinical Data Exchange* and require reporting on at least two measures of the MIPS eligible clinician's choice (p. 663).** CMS also proposes exclusion criteria for each of these measures. Since in 2018, these measures are not required for the base score, CMS did not establish exclusion criteria for them. Its proposals are based on the exclusions previously finalized in rulemaking under the EHR Incentive Programs (80 FR 62862 through 62871) and are outlined below:

Measure	Exclusions
Immunization Registry Reporting	Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Immunization Registry Reporting measure if the MIPS eligible clinician: 1. Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period.

	<p>2. Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period.</p> <p>3. Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.</p>
Syndromic Surveillance Reporting	<p>Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Syndromic Surveillance Reporting measure if the MIPS eligible clinician:</p> <ol style="list-style-type: none"> 1. Is not in a category of health care providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system. 2. Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the performance period. 3. Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from MIPS eligible clinicians as of 6 months prior to the start of the performance period.
Electronic Case Reporting	<p>Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Electronic Case Reporting measure if the MIPS eligible clinician:</p> <ol style="list-style-type: none"> 1. Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period. 2. Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period. 3. Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period.
Public Health Registry Reporting	<p>Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Public Health Reporting measure if the MIPS eligible clinician;</p> <ol style="list-style-type: none"> 1. Does not diagnose or directly treat any disease or condition associated with a public health registry in the MIPS eligible clinician's jurisdiction during the performance period. 2. Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period. 3. Operates in a jurisdiction where no public health registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the performance period.
Clinical Data Registry Reporting	<p>Any MIPS eligible clinician meeting one or more of the following criteria may be excluded from the Clinical Data Registry Reporting measure if the MIPS eligible clinician;</p> <ol style="list-style-type: none"> 1. Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the performance period.

	<p>2. Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period.</p> <p>3. Operates in a jurisdiction where no clinical data registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the performance period.</p>
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CMS seeks comment on the proposed exclusions and whether there are circumstances that would require additional exclusion criteria for the measures.

CMS continues to believe that public health reporting is valuable in terms of health information exchange between MIPS eligible clinicians and public health and clinical data registries. Nevertheless, **CMS intends to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than 2022, and is seeking public comment on whether MIPS eligible clinicians will continue to share such data with public health entities once the Public Health and Clinical Data Exchange objective is removed, as well as other policy levers outside of the PI performance category that could be adopted for continued reporting to public health and clinical data registries, if necessary.** While CMS believes these registries provide the necessary monitoring of public health nationally and contribute to the overall health of the nation, its aim is to reduce burden and identify other appropriate venues in which reporting to public health and clinical data registries could be reported. **CMS seeks comment on the role that each of the public health and clinical data registries should have in the future of the PI performance category and whether the submission of this data should still be required. CMS also seeks comment on whether the PI performance category is the best means for promoting sharing of clinical data with public health entities.**

- **CMS also seeks comment on a potential concept for future rulemaking to add two additional measure options related to health information exchange with providers other than MIPS eligible clinicians (i.e., providers in a wider range of settings) (p. 669).**

Measure Title	Description	Numerator	Denominator
Support Electronic Referral Loops by Sending Health Information Across the Care Continuum (p. 670)	For at least one transition of care or referral to a provider of care other than a MIPS eligible clinician, the MIPS eligible clinician creates a summary of care record using CEHRT; and electronically exchanges the summary of care record.	The number of transitions of care and referrals in the denominator where a summary of care record was created and exchanged electronically using CEHRT.	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transitioning or referring health care provider to a <u>provider of care other than a MIPS eligible clinician</u>
Support Electronic Referral Loops By Receiving and Incorporating Health Information Across the Care Continuum (p. 671)	For at least one electronic summary of care record received by a MIPS eligible clinician from a transition of care or referral from a provider of care other than a MIPS eligible clinician, the MIPS eligible clinician conducts clinical information reconciliation	The number of electronic summary of care records received for which clinical information reconciliation was completed using CEHRT for the following three clinical information sets: (1) Medication--Review of the patient's medication, including the name, dosage,	The number of electronic summary of care records received for a patient encounter during the performance period for which a MIPS eligible clinician was the recipient of a transition of care or referral from a <u>provider of</u>

	for medications, medication allergies, and problem list.	frequency, and route of each medication; (2) Medication allergy-- Review of the patient's known medication allergies; and (3) Current Problem List-- Review of the patient's current and active diagnoses.	<u>care other than a MIPS eligible clinician.</u>
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CMS seeks comment on:

- **Whether these two measures should be combined into a single measure, including both the sending and receiving of electronic patient health information.**
- **Whether the denominators should be combined to a single measure, including both transitions of care to and from a MIPS eligible clinician.**
- **Whether the numerators should be combined to a single measure including both the sending and receiving of electronic patient health information.**
- **Whether the potential new measures should be considered for inclusion in a future program year or whether stakeholders believe there is sufficient readiness and interest in the measures to implement them as early as CY 2019.**
- **Whether the potential new measures should be limited to transitions of care to and/or from referrals involving long-term and post-acute care, skilled nursing care, and behavioral health care.**
- **Whether additional settings of care should be considered for inclusion in the denominators and whether a MIPS eligible clinician should be allowed to limit the denominators to a specific type of care setting based on their organizational needs, clinical improvement goals, or participation in an alternative payment model.**
- **CMS is also interested in comments regarding the feasibility of these measures in instances where a MIPS eligible clinician receives information from a non-MIPS eligible clinician that is not using CEHRT.**

[Table 39](#) provides a summary of the PI measure proposals.

[Table 40](#) includes the 2015 Edition certification criteria required to meet the objectives and measures.

Improvement Activities Bonus Score under the Promoting Interoperability Performance Category and Future Reporting Considerations (p. 672)

CMS is not proposing to continue the bonus for completing certain improvement activities using CEHRT for the performance period in 2019, and subsequent performance periods. CMS seeks comments on this decision and on other ways to promote the use of CEHRT. While CMS continues to believe that the use of CEHRT in completing improvement activities is extremely valuable and vital, it does not believe that awarding a bonus in the PI performance category would directly support the goals of placing greater emphasis on interoperability and patient access to health information. Instead, it is considering alternative ways to reduce burden, as discussed below.

Creating a More Cohesive Reporting Experience to Reduce Burden (p. 674)

CMS is considering alternative mechanisms to reduce MIPS reporting burdens and make the program more meaningful to clinicians, including:

- Linking Performance Categories. CMS has been looking into linking three of the performance categories—quality, improvement activities and PI—to reduce burden and create a more cohesive and closely linked MIPS program. One possibility is to establish several sets of new multi-category measures that would cut across the different performance categories and allow MIPS eligible clinicians to report once for credit in all three performance categories. **CMS seeks comment on this reporting model, as well as measure and activity suggestions to enhance the link between the three performance categories.** Currently, CMS is only seeking comment on this concept since it is still evaluating the appropriate measure combinations and feasibility of a multi-category model.
- Public Health Priority Sets. CMS also intends to consider proposing in future rulemaking MIPS public health priority sets across the four performance categories (quality, improvement activities, PI, and cost). The public health priority sets would be built across performance categories and decrease the burden of having to report for separate performance categories as relevant measures and activities are bundled. They could also identify where there are measurement gaps, and what areas measure development should focus on, such as the lack of sufficient measures for certain specialists. CMS intends to develop the first few public health priority sets around: opioids; blood pressure; diabetes; and general health (healthy habits). **CMS seeks comments on:**
 - **Additional public health priority areas that should be considered, and whether these public health priority sets should be more specialty focused versus condition specific.**
 - **How CMS could implement public health priority sets in ways that further minimize burden for providers (e.g., by offering sets which emphasize use of common health IT functionalities).**
 - **How CMS could encourage or incentivize health care providers to consider using these public health priority sets.**

Additional Considerations (p. 675)

- Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists (p. 676). **CMS proposes to continue its policy for the 2019 performance period to assign a weight of zero to the PI performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs.** CMS will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the PI measures, but if they choose to report, they will be scored on the category like all other MIPS eligible clinicians.
- Physical Therapists, Occupational Therapists, Clinical Social Workers, and Clinical Psychologists (p. 677). Earlier in the rule, CMS **proposes to add these clinician types to the definition of a MIPS eligible clinician**, beginning with the performance period in 2019. **For these clinicians, CMS is proposing 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.** These clinicians may choose to submit PI measures; however, if they choose to report, they would be scored on the PI category like all other MIPS eligible clinicians.

APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs (p. 679)

Overview (p. 679)

In the CY 2017 QPP rule, CMS finalized the APM scoring standard, which is designed to reduce reporting burden for participants in certain APMs by reducing the need for duplicative data submission to MIPS and their respective APMs, and to avoid potentially conflicting incentives between those APMs and the MIPS. CMS previously established that:

- The MIPS performance period applies for the APM scoring standard.
- 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.
- The MIPS final score under the APM scoring standard is comprised of the four MIPS performance categories, which are weighted as follows for 2018:
 - Quality: 50 percent
 - Cost: 0 percent
 - Improvement activities: 30 percent
 - Advancing Care Information: 20 percent

CMS proposes to amend the regulations 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.

MIPS APM Criteria (p. 680)

In the CY 2017 QPP final rule, CMS established that for an APM to be considered a MIPS APM, it 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 clinician 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 year, nor an APM in the final year of operation for which the APM scoring standard is impracticable.

Due to concerns about ambiguity in the third criterion, CMS clarifies that it intended the word “measures” to modify only “quality” and not “cost/utilization.” ***To make this criterion clearer, CMS proposes to change the order in which the requirements in the third criterion are listed to state that the APM bases payment incentives on performance on quality measures and cost/utilization.*** This proposed change would make it clear that a MIPS APM could take into account performance in terms of cost/utilization using model design features other than the direct use of cost/utilization measures. ***It also proposes to modify the regulation 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 also clarifies that it will consider each distinct track of an APM and whether it meets the above criteria in order 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, however, further consider whether the individual APM Entities or MIPS eligible clinicians participating within a given track each satisfy all of the above MIPS APM criteria. The term “track” refers 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.

CMS also discusses situations where an APM begins after the first day of the MIPS performance period for the year (currently January 1), but requires 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 require duplicative reporting of quality measures for both the APM and MIPS, and to create potentially conflicting incentives between the quality scoring requirements and payment incentive structures under the APM and MIPS. Thus, for 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.

Based on the MIPS APM criteria, for the 2019 MIPS performance year, CMS expects that ten APMs likely will satisfy the requirements to be MIPS APMs:

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

Calculating MIPS APM Performance Category Scores (p. 682)

For the quality performance category, MIPS eligible clinicians in APM Entities will continue to be scored only on the quality measures that are required under the terms of their respective APMs.

- **Web Interface Reporters (p. 682).** CMS previously finalized that it would use quality measure data that participating APM Entities submit using the Web Interface and CAHPS surveys as required under the terms of the APM, and to use MIPS benchmarks for these measures when APM benchmarks are not available, in order to score quality for MIPS eligible clinicians at the APM Entity level under the APM scoring standard. In the event a MSSP ACO does not report quality measures as required by the MSSP, an exception will be triggered and 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 category according to MIPS group submission/reporting requirements in order to avoid a score of zero for the category.

To account for the challenges a solo practitioner might face in this situation trying to comply with group reporting requirements, CMS proposes to modify this exception such that beginning in 2019, it would allow a solo practitioner to report on any available MIPS measures, including individual measures, in the event that their ACO fails to complete reporting for all Web Interface measures. CMS also clarifies here that any “partial” reporting through the CMS Web Interface by the ACO that does not satisfy the requirements of the MSSP will be considered a failure to report. ***However, it proposes that, beginning with the 2019 performance period, the complete reporting requirement for Web Interface reporters be modified to specify that if an APM Entity (i.e., an ACO) fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACOs survey, CMS will score the CAHPS for ACOs survey and apply it towards the APM Entity’s quality performance category score. In this scenario the MSSP TIN-level reporting exception would not be triggered and all MIPS eligible clinicians within the ACO would receive the APM Entity score.***

For the 2019 MIPS performance year, CMS anticipates that there will be four Web Interface Reporter APMs:

- 1) MSSP
 - 2) Track 1+ Model
 - 3) Next Generation ACO Model
 - 4) Vermont ACO Medicare Initiative
- **Other MIPS APMs (p. 684).** For each “Other MIPS APM,” the MIPS quality performance category score is calculated for the APM Entity using the data submitted by the APM Entity based on their respective measure sets and reporting requirements as specified by CMS through notice and comment rulemaking. CMS previously finalized that for MIPS APMs, other than the Shared Savings Program, it will attribute one PI performance category score to each MIPS eligible clinician in an APM Entity group based on either individual or group-level data submitted for the MIPS eligible clinician and using the highest available score. CMS will then use these scores to create an APM Entity group score equal to the average of the highest scores available for each MIPS eligible clinician in the APM Entity group.

For the MSSP, ACO participant TINs are required to report on the PI category, and CMS will weight and aggregate the ACO participant TIN scores to determine an APM Entity group score.⁴¹ However, CMS has found that limiting reporting to the ACO participant TIN creates unnecessary confusion and restricts PI reporting options for MIPS eligible clinicians who participate in the MSSP. ***Therefore, beginning in the 2019 MIPS performance period, CMS proposes to no longer apply this unique requirement and to instead permit MIPS eligible clinicians who participate in the MSSP to report on the PI performance category at either the individual or group level like all other MIPS eligible clinicians under the APM scoring standard.***

In the 2019 MIPS performance year, CMS anticipates that there will be up to six Other MIPS APMs:

- 1) The Oncology Care Model
- 2) Comprehensive ESRD Care Model
- 3) Comprehensive Primary Care Plus Model
- 4) The Bundled Payments for Care Improvement Advanced
- 5) Maryland Primary Care Program
- 6) Independence at Home Demonstration (in the event of an extension)

The measure sets for each of these “Other APMs” are listed started on [p. 686](#).

[TABLE 41](#): MIPS APM Measure List-- Comprehensive ESRD Care

[TABLE 42](#): MIPS APM Measure List-- Comprehensive Primary Care Plus (CPC+) Model

[TABLE 43](#): MIPS APM Measure List-- Oncology Care Model

[TABLE 44](#): MIPS APM Measure List--Bundled Payments for Care Improvement

[TABLE 45](#): MIPS APM Measure List—Maryland Total Cost of Care Model (Maryland Primary Care Program) Advanced

[TABLE 46](#): MIPS APM Measure List-- Independence at Home Demonstration

MIPS APM Performance Feedback (p. 685)

Regarding access to performance feedback, CMS clarifies here that whereas 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 MSSP, which only includes full-TIN ACOs, will be able to access their performance feedback at the ACO participant TIN level.

⁴¹ This policy was meant to align requirements between the MIPS PI measures and the MSSP ACO-11 measure, which is used to assess MSSP ACOs based on the MIPS PI measures.

MIPS Final Score Methodology (p. 710)

Converting Measures and Activities into Performance Category Scores (p. 710)

In the CY 2017 QPP final rule, CMS finalized a unified scoring system to determine a final score across the 4 performance categories. For the 2019 MIPS performance period, CMS proposes to build on the scoring methodology CMS previously finalized, focusing on encouraging MIPS eligible clinicians to meet data completeness requirements. CMS also highlights that Section 51003 of the BBA of 2018 provides flexibility to continue the gradual ramp up of the QPP and enables CMS to extend some of the transition year policies to the 2019 performance period, as further detailed below.

Unless otherwise noted, ***for purposes of this MIPS Final Score Methodology section, the term “MIPS eligible clinician” will refer to MIPS eligible clinicians who collect and submit data and are scored at either the individual or group level, including virtual groups; it will not refer to MIPS eligible clinicians who are scored by facility-based measurement, as discussed further below.*** CMS also notes that the APM scoring standard applies to MIPS eligible clinicians in APM Entities in MIPS APMs, and those policies take precedence where applicable.

Scoring the Quality Performance Category for the Following Collection Types: Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, CMS Web Interface Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures (p. 711)

Although CMS does not propose changing the basic scoring system that CMS finalized in the CY 2018 QPP final rule for the 2019 MIPS performance period, ***CMS is proposing several modifications to scoring the quality performance category, including removing high-priority measure bonus points for CMS Web Interface measures and extending the bonus point caps, and adding a small practice bonus to the quality performance category score.*** The following section describes these previously finalized policies and CMS’ new proposals.

CMS is also proposing regulatory text updates in an effort to more clearly and concisely capture previously established policies, which are not intended to be substantive in nature, but rather to bring more clarity to the regulatory text. (§414.1380(b)(1))

Scoring Terminology (p. 712)

In the CY 2017 and CY 2018 QPP final rules, CMS used the term “submission mechanisms” in reference to the various ways in which a MIPS eligible clinician or group can submit data to CMS. It has come to CMS’ attention that the way CMS has described the various ways in which MIPS eligible clinicians, groups and third-party intermediaries can submit data to its systems does not accurately reflect the experience users have when submitting data. CMS refers readers to the section on MIPS data collection types, submission types, and submitter types of this proposed rule for further discussion on its proposed changes to the scoring terminology related to measure specification and data collection and submission. Additionally, throughout the scoring discussion, CMS notes that these changes result in updates to the regulatory text citations where specific policies are addressed.

Quality Measure Benchmarks (p. 713)

CMS refers readers to the CY 2017 and CY 2018 QPP final rules for its previously established benchmarking policies. In the CY 2018 QPP final rule, CMS solicited comments on how CMS could improve its method of benchmarking quality measures. Several commenters raised concerns and provided suggestions for changes to the methodology.

When CMS developed the quality measure benchmarks, CMS sought to develop a system that enables MIPS eligible clinicians, beneficiaries, and other stakeholders to understand what is required for a strong performance in MIPS while being consistent with statutory requirements. The feedback CMS has received is helping to inform its approach to the benchmarking methodology, especially as CMS looks for possible ways of aligning with Physician Compare benchmarks. As described in more detail below, **CMS is seeking comment on potential future approaches to scoring the quality performance category to continue to promote value and improved outcomes**. CMS anticipates changes in scoring would be paired with potential modifications to measure selection and criteria.

Revised Terminology for MIPS Benchmarks (p. 714)

CMS previously established separate benchmarks for the following submission mechanisms: EHR; QCDR/registry, claims; CMS Web Interface; CMS-approved survey vendor; and administrative claims. CMS is not proposing to change its basic approach to its benchmarking methodology; however, ***CMS is proposing to amend regulation text consistent with the proposed data submission terminology changes discussed in its discussion of Quality Performance category requirements***. Specifically, beginning with the 2019 MIPS performance period, ***CMS proposes to establish separate benchmarks for the following collection types: eCQMs; QCDR measures; MIPS CQMs; Medicare Part B claims measures; CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures. CMS would apply benchmarks based on collection type rather than submission mechanism. CMS would also establish separate benchmarks for QCDR measures and MIPS CQMs since these measures do not have comparable specifications***. In addition, CMS notes that its proposed benchmarking policy allows for the addition of future collection types as the universe of measures continues to evolve and as new technology is introduced. Specifically, ***CMS proposes to amend regulation text to remove the mention of each individual benchmark and instead state that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period. (§414.1380(b)(1)(ii))***

Assigning Points Based on Achievement (p. 715)

Floor for Scored Quality Measures (p. 715)

For the first two MIPS program years, CMS finalized a global 3-point floor for each scored quality measure, as well as for the hospital readmission measure (if applicable). In this way, MIPS eligible clinicians would receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements. For measures with a benchmark based on the performance period (rather than on the baseline period), CMS stated that CMS would continue to assign between 3 and 10 measure achievement points for performance periods after the first transition year. For measures with benchmarks based on the baseline period, CMS stated that the 3-point floor was for the transition year and that CMS would revisit the 3-point floor in future years.

For the 2019 MIPS performance period, ***CMS proposes to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period, and to amend regulation text accordingly (§414.1380(b)(1)(i)).*** CMS will revisit the 3-point floor for such measures again in future rulemaking.

Additional Policies for the CAHPS for MIPS Measure Score (p. 715)

While participating in the CAHPS for MIPS survey is optional for all groups, some groups will be unable to participate in the CAHPS for MIPS survey because they do not meet the minimum beneficiary sampling requirements. CMS' sampling timeframes necessitate notifying groups of their inability to meet the sampling requirements late in the performance period. As a result, CMS is concerned that some groups that expect and plan to meet the quality performance category requirements using the CAHPS for MIPS survey may find out late in the performance period that they are unable to meet the sampling requirements and, therefore, are unable to have their performance assessed on this measure.

CMS wants to encourage the reporting of the CAHPS for MIPS survey and does not want the uncertainty regarding sampling requirements to be a barrier to selecting the CAHPS for MIPS survey. To mitigate this concern, beginning with the 2019 MIPS performance period, ***CMS is proposing to reduce the denominator (that is, the total available measure achievement points) for the quality performance category by 10 points for groups that register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements.*** By reducing the denominator instead of only assigning the group a score of zero measure achievement points (because the group would be unable to submit any CAHPS for MIPS survey data), CMS is effectively removing the impact of the group's inability to submit the CAHPS for MIPS survey. ***CMS does not want groups to register for the CAHPS for MIPS survey if they know in advance that they are unlikely to be able to meet the sampling requirement, so CMS seeks comment on whether CMS should limit this proposed policy to groups for only one MIPS performance period.***

Assigning Measure Achievement Points for Topped Out Measures (p. 717)

As finalized last year, for the 2018 MIPS performance period, six measures will receive a maximum of 7 measure achievement points, provided that the applicable measure benchmarks are identified as topped out again in the benchmarks published for the 2018 MIPS performance period. Beginning with the 2019 MIPS performance period, measure benchmarks (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years will receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out.

CMS refers readers to the 2018 MIPS Quality Benchmarks' file, that is located on the [QPP resource library](#) to determine which measure benchmarks 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. CMS notes that the final determination of which measure benchmarks are subject to the topped out cap will not be available until the 2019 MIPS Quality Benchmarks' file is released in late 2018.

CMS did not propose to apply its previously finalized topped out scoring policy to the CAHPS for MIPS survey. Last year, CMS received limited feedback when CMS sought comment on how the topped out scoring policy should be applied to CAHPS for MIPS survey. In this proposed rule, ***CMS is seeking feedback on potential ways CMS can score CAHPS for MIPS Summary Survey Measures (SSM).*** For example, ***CMS could score all SSMs, which means there would effectively be no topped out scoring for CAHPS for MIPS SSMs, or CMS could cap the SSMs that are topped out and score all other SSMs.*** CMS seeks comment on these approaches and additional approaches to the topped out scoring policy for CAHPS for MIPS SSMs. CMS notes that CMS would like to encourage groups to report the CAHPS for MIPS survey as it incorporates beneficiary feedback.

Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmarks Requirements (p. 718)

CMS previously established scoring policies for a measure that is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement. A summary of the current and proposed policies is provided in [Table 47](#).

CMS invites public comment on ways CMS can improve its case-minimum policy. CMS recognizes that small practices and individual MIPS eligible clinicians may have difficulty meeting its case minimum standard. In determining future improvements to its case minimum policy, its goal is to balance the concerns of MIPS eligible clinicians who are unable to meet the case minimum requirement and for whom CMS cannot capture enough data to reliably measure performance, while not creating incentives for MIPS eligible clinicians to choose measures that do not meet case minimum even though other more relevant measures are available.

CMS proposes to maintain the policies finalized for the CY 2018 MIPS performance period regarding measures that do not meet the case-minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria for the CY 2019 MIPS performance period, and to amend regulation text accordingly. CMS also proposes to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period and to amend regulation text accordingly. Measures submitted by small practices would continue to receive 3 points for all future CY MIPS performance periods, although CMS may revisit this policy through future rulemaking. (§414.1380(b)(1)(i)(B)(1))

Scoring Flexibility for Measures with Clinical Guideline Changes During the Performance Period ([p. 720](#))

Last year, CMS finalized that, beginning with the 2018 MIPS performance period, CMS will assess performance on measures considered significantly impacted by ICD-10 updates based only on the first 9 months of the 12-month performance period (for example, January 1, 2018, through September 30, 2018, for the 2018 MIPS performance period). Performance on measures that are not significantly impacted by changes to ICD-10 codes would continue to be assessed on the full 12-month performance period (January 1 through December 31). Lastly, CMS finalized that CMS will publish the list of measures requiring a 9-month assessment process on the CMS website by October 1st of the performance period if technically feasible, but by no later than the beginning of the data submission period (for example, January 2, 2019, for the 2018 MIPS performance period).

CMS remains concerned about instances where clinical guideline changes or other changes to evidence supporting a measure occur during the performance period that may significantly impact a measure. CMS sought comment in the CY 2018 QPP final rule regarding whether CMS should apply scoring flexibility to measures significantly impacted by clinical guideline changes. Comments are detailed on [p. 721](#).

Given concerns about using measures that rely on outdated guidelines, and to further align with policies adopted within other value-based programs such as the Hospital VBP Program, ***CMS is proposing to suppress a measure without rulemaking, if during the performance period a measure is significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns. CMS would rely on measure stewards for notification in changes to clinical guidelines. CMS will publish on the CMS Web site suppressed measures whenever technically feasible, but by no later than the beginning of the data submission period.***

CMS proposes policies to provide scoring flexibility in the event that CMS needs to suppress a measure during a performance period. Scoring for a suppressed measure would result in a zero achievement points for the measure and a reduction of the total available measure achievement points by 10 points beginning with the 2019 MIPS performance period, and to make corresponding regulation text changes (§414.1380(b)(1)(vii)). CMS believes that this approach effectively removes the impact of the eligible clinician's inability to receive measure achievement points for the measure, if a submitted measure is later suppressed.

Scoring for MIPS Eligible Clinicians that Do Not Meet Quality Performance Category Criteria ([p. 723](#))

Last year, CMS finalized that, beginning with the 2019 MIPS performance period, CMS will validate the availability and applicability of quality measures only with respect to the collection type that a MIPS eligible clinician utilizes for the quality performance category for a performance period, and only if a MIPS eligible clinician collects via claims only, MIPS CQMs only, or a combination of MIPS CQMs and claims collection types. CMS will not apply the validation process to any data collection type that the MIPS eligible clinician does not utilize for the quality performance category for the performance period. CMS sought comment on how to modify the validation process for the 2019 MIPS performance period when clinicians may submit measures collected via multiple collection types. As discussed above, CMS is proposing to revise its terminology regarding data submission. This updated terminology will more accurately reflect CMS' current submissions and validation policies. ***CMS proposes to modify its validation process to provide that it only applies to MIPS CQMs and the***

claims collection type, regardless of the submitter type chosen. For example, this policy would not apply to eCQMs even if they are submitted by a registry.

CMS notes that a MIPS eligible clinician may not have available and applicable quality measures. If CMS is unable to score the quality performance category, then CMS may reweight the clinician's score according to the reweighting policies described in this proposed rule.

Small Practice Bonus (p. 724)

In the CY 2018 QPP final rule, CMS finalized the addition of a small practice bonus of 5 points to the final score for the 2018 MIPS performance period for MIPS eligible clinicians, groups, APM Entities, and virtual groups that meet the definition of a small practice and submit data on at least one performance category in the 2018 MIPS performance period. For 2019 performance, CMS believes a small practice bonus specific to the quality performance category is preferable and appropriate for the 2019 MIPS performance period and future years based on observations using historical data, which indicate that small practices are less likely to submit quality performance data, less likely to report as a group and use the CMS Web interface, and more likely to have lower performance rates in the quality performance category than other practices. CMS also considered whether to continue to apply the small practice bonus through bonus points in all four performance categories, but discusses its rationale for not doing so on [p. 725](#).

Starting with the 2019 MIPS performance period, **CMS proposes to add a small practice bonus of 3 points in the numerator of the quality performance category for MIPS eligible clinicians in small practices if the MIPS eligible clinician submits data to MIPS on at least 1 quality measure.** Because MIPS eligible clinicians in small practices are not measured on the readmission measure and are not able to participate in the CMS Web Interface, they generally have a quality performance category denominator of 60 total possible measure achievement points. Thus, its proposal of 3 measure bonus points generally represents 5 percent of the quality performance category score. For clinicians in many small practices, the quality performance category weight may be up to 85 percent of the final score (for example, if a small practice applies for the Promoting Interoperability significant hardship application and does not meet the sufficient case minimum for cost measures). With a weight of 85 percent, a small practice bonus of 3 points added to the quality performance category will result in 4.25 bonus points added to the final score for clinicians in small practices.²⁹ CMS believes this is appropriate because it is similar to the impact of the small practice bonus CMS finalized for the 2018 MIPS performance period (5 points added to the final score). While CMS recognizes that the impact of the small practice bonus for MIPS eligible clinicians in small practices who do not receive reweighting for the cost and/or Promoting Interoperability performance categories will be less than 4.25 points added to the final score, CMS believes a consistent approach is preferable for simplicity, and CMS does not believe that a larger bonus is appropriate as that could potentially inflate the quality performance category score and the final score and mask poor performance.

Incentives to Report High-Priority Measures (p. 726)

In the CY 2017 QPP final rule, CMS established a cap on high-priority measure bonus points for the first 2 years of MIPS at 10 percent of the denominator (total possible measure achievement points the MIPS eligible clinician could receive in the quality performance category) of the quality performance category. **CMS is proposing to maintain the cap on measure bonus points for reporting high-priority measures for the 2019 MIPS performance period/2021 MIPS payment year, and to amend regulation text accordingly.** (**\$414.1380(b)(1)(v)(A)(1)(ii)**)

CMS established the scoring policies for high-priority measure bonus points in the CY 2017 QPP final rule. CMS noted that, in addition to the required measures, CMS Web Interface reporters may also report the CAHPS for MIPS survey and receive measure bonus points for submitting that measure. **For the 2019 MIPS performance**

period/2021 MIPS payment year, CMS proposes to modify the policies finalized in the CY 2017 QPP final rule to discontinue awarding measure bonus points to CMS Web Interface reporters for reporting high-priority measures. As CMS continues to move forward in implementing the MIPS program, CMS no longer believes that it is appropriate to award CMS Web Interface reporters measure bonus points to be consistent with other policies regarding selection of measures, as detailed on [p. 727](#). CMS notes the CMS Web Interface users may still elect to report the CAHPS for MIPS survey in addition to the CMS Web Interface, and if they do, they would receive the high priority bonus points for reporting the survey.

As part of its move towards fully implementing the high value measures, CMS believes that bonus points for high priority measures for all collection types may no longer be needed, and as a result, CMS intends to consider in future rulemaking whether to modify its scoring policy to no longer offer high priority bonus points after the 2019 MIPS performance period.

Incentives to Use CEHRT to Support Quality Performance Category Submissions ([p. 728](#))

Statute requires the Secretary to encourage MIPS eligible clinicians to report on applicable quality measures through the use of CEHRT. Under current regulations, 1 bonus point is available for each quality measure submitted with end-to-end electronic reporting, under certain criteria. ***CMS is proposing to maintain the cap on measure bonus points for reporting measures using end-to-end electronic reporting for the 2019 MIPS performance period/2021 MIPS payment year.***⁴² ***CMS also proposes to continue to assign bonus points for end-to-end electronic reporting for the 2019 performance period***, as CMS has seen that this policy encourages electronic reporting. ***CMS proposes to amend regulation text accordingly.*** (§414.1380(b)(1)(B)(v)(B))

CMS also is proposing to modify its end-to-end reporting bonus point scoring policy based on the proposed changes to the submission terminology discussed in section III.H.3.h.(1)(b) of this proposed rule. CMS proposes that the end-to-end reporting bonus can only apply to the subset of data submitted by direct, log in and upload, and CMS Web Interface that meet the criteria finalized in the CY 2017 QPP final rule. However, the end-to-end reporting bonus would not be applied to the claims submission type because it does not meet the criteria discussed above. This is not a policy change but rather a clarification of its current process in light of the proposed terminology changes.

CMS believes that in the future bonus points for end-to-end reporting for all submission types will no longer be needed as CMS moves towards fully implementing the program, and as a result CMS intends to consider in future rulemaking modifying its scoring policy to no longer offer end-to-end reporting bonus points after the 2019 MIPS performance period. ***CMS invites comment on other ways that CMS can encourage the use of CEHRT for quality reporting.***

Calculating Total Measure Achievement and Measure Bonus Points ([p. 729](#))

Calculating Total Measure Achievement and Measure Bonus Points for Non-CMS Web Interface Reporters ([p. 729](#))

In the CY 2017 and 2018 QPP final rules, CMS established the policy for calculating total measure achievement and measure bonus points for Non-CMS Web Interface reporters. CMS is not proposing any changes to the policy for scoring submitted measures collected across multiple collection types that was finalized last year.⁴³

⁴² The preamble states: “We are proposing to maintain the cap on measure bonus points for reporting *high-priority measures* [note: not for end-to-end electronic reporting] for the 2021 MIPS payment year... We propose to amend §414.1380(b)(1)(v)(B) accordingly.” However, in the proposed regulation text provided at prior to the Appendix, language regarding the end-to-end bonus is included at §414.1380(b)(1)(B)(v)(B), and that language specifies a cap of 10 percent of the total available measure achievement points for end-to-end electronic reporting, consistent with previous years.

⁴³ Among other policies, CMS finalized that if a MIPS eligible clinician submits the same measure via 2 different submission mechanisms, CMS will score each mechanism by which the measure is submitted for achievement and take the highest measure achievement points of the 2 mechanisms. A MIPS eligible clinician can only be scored on one submission mechanism for a given measure.

Although CMS has established a policy to account for scoring in circumstances when the same measure is collected via multiple collection types, CMS anticipates that this will be a rare circumstance and does not encourage clinicians to submit the same measure collected via multiple collection types. CMS refers readers to [Table 48](#), which provides examples of how to assigning achievement and bonus points who submit measures across multiple collection types, in order to illustrate and provide additional clarity due to the changes in terminology.

[Calculating Total Measure Achievement and Measure Bonus Points for CMS Web Interface Reporters \(p. 732\)](#)
In the CY 2017 and 2018 QPP final rules, CMS finalized the scoring policies for CMS Web Interface reporters. CMS does not propose any new policies in this area.

[Future Approaches to Scoring the Quality Performance Category \(p. 732\)](#)

CMS anticipates making changes to the quality performance category to reduce burden and increase the value of the measures CMS is collecting. CMS discussed that existing measures have differing levels of value and its approaches for implementing a system where points are awarded based on the value of the measure. Should CMS adopt these approaches, CMS anticipates needing to modify its scoring approaches accordingly. In addition, CMS has received stakeholder feedback asking CMS to simplify scoring for the quality performance category.

Therefore, CMS is seeking comment on the following approaches to scoring that CMS may consider in future rulemaking and whether these approaches move the clinicians towards reporting high value measures and more accurate performance measurement.

- One option for simplification is restructuring the quality requirements with a pre-determined denominator, for example, 50 points, but no specific requirements regarding the number of measures that must be submitted. Further, CMS would categorize MIPS and QCDR measures by value, because CMS recognizes that not all measures are created equal. CMS seeks to ensure that the collection and submission of data is valuable to clinicians and worth the cost and burden of collection of information. A system to classify measures as a particular value (for example, gold, silver, or bronze) is discussed earlier in this proposed rule. With such a system, CMS could envision awarding points for achievement as follows: up to 15 to 20 points in the top tier; up to 10 points in the next tier; and up to 5 points in the lowest tier. Similar to the structure of the improvement activities performance category, a clinician that chooses a top-tier measure would not have to submit as many measures to MIPS. CMS would still want to ensure the submission of high value measures and might include requirements that restrict the number of lower tier measures that could be submitted; alternatively, CMS could add a requirement that a certain number of higher tier measures would need to be submitted. With this approach, CMS could still incentivize reporting on high-priority measures by classifying them as “gold” standard measures which would be eligible for up to 15 to 20 achievement points.
- Alternatively, CMS could keep its current approach for the quality performance category requiring 6 measures including one outcome measure, with every measure worth up to 10 measure achievement points in the denominator, but change the minimum number of measure achievement points available to vary by the measure tier. For example, high-tier measures could qualify for high priority bonus and/or have a higher potential floor (for example, 5 measure achievement points instead of the floor of 3 measure achievement points for “gold” standard measures, which would be eligible for up to 10 measure achievement points.); whereas low-tier measures could have a lower floor.

Taking into consideration the potential future quality performance category change, CMS also believes that removing the validation process to determine whether the eligible clinician has measures that are available and applicable would simplify the quality performance category significantly. Several stakeholders expressed their confusion with the validation process. A move to sets of measures in the quality performance category, potentially with some criteria to define the clinicians for whom these measures are applicable, would eliminate the need for a validation process for measures that are available and applicable. Moving to sets of measures

would also enable CMS to develop more robust benchmarks. CMS also believes that in the next few years, CMS could remove the validation process for measures that are available and applicable if CMS sets the denominator at a pre-determined level (as outlined in the example above at 50 points) and let clinicians determine the best method to achieve 50 points.

For the first two MIPS program years, MIPS eligible clinicians and groups who report on QCDR measures that do not have an available benchmark based on the baseline or performance period but meet data completeness are assigned a score of 3 measure achievement points (small practices receive 3 points regardless of whether they meet data completeness). Stakeholders have noted that MIPS eligible clinicians are hesitant to report QCDR measures without established benchmarks due to risk of being limited to a 3-point score for that QCDR measure. In addition, QCDRs have inquired about the possibility of creating QCDR benchmarks. **To encourage reporting of QCDR measures, CMS seeks comment on an approach to develop QCDR measure benchmarks based off historical measure data.** This may require QCDRs to submit historical data in a form and manner that meets benchmarking needs as required by CMS. CMS anticipates that the historical QCDR measure data would need to be submitted at the time of self-nomination of the QCDR measure, during the self-nomination period. However, CMS also discusses some concerns with using historical data on [p. 735](#). In addition to seeking comment on developing QCDR measure benchmarks from historical data, **CMS also seeks comment as to how such concerns may be addressed for future rulemaking.**

CMS also recognizes that improving the electronic capture, calculation, and reporting of quality measures is also an important component of reducing provider burden. **CMS invites comment on how CMS can incorporate incentives for the use of electronic clinical quality measurement into the future approaches described under this section, as well as other ways to encourage more efficient technology-enabled measurement approaches.**

CMS seeks comment on these approaches and other approaches to simplify scoring, provide incentives to submit more impactful measures that assess outcomes rather than processes, and develop data that can show differences in performance and determine clinicians that provide high value care.

Improvement Scoring for the MIPS Quality Performance Category Percent Score ([p. 736](#))

Statute stipulates that, beginning with the second year to which MIPS applies, if data sufficient to measure improvement is available, the improvement of the quality performance category score for eligible clinicians should be measured. To measure improvement CMS requires a direct comparison of data from one QPP year to another. CMS also adopted a policy that MIPS eligible clinicians must fully participate to receive a quality performance category improvement percent score greater than zero. CMS discusses a technical change it implemented to clarify full participation on [p. 737](#).

CMS finalized that it would compare the 2018 performance to an assumed 2017 quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year. ***CMS proposes to continue this policy for the 2019 MIPS performance period and amend regulation text accordingly. CMS proposes to compare the 2019 performance to an assumed 2018 quality performance category achievement percent score of 30 percent.***
(§414.1380(b)(1)(vi)(C)(4))

Calculating the Quality Performance Category Percent Score Including Achievement and Improvement Points ([p. 737](#))

In the CY 2017 and CY 2018 QPP final rules, CMS finalized policies on incorporating the improvement percent score into the quality performance category percent score. No policy changes on these topics are proposed.

Scoring the Cost Performance Category ([p. 738](#))

Scoring Achievement in the Cost Performance Category (p. 738)

In the CY 2017 QPP final rule, CMS established that it will determine cost measure benchmarks based on cost measure performance during the performance period. CMS also established that at least 20 MIPS eligible clinicians or groups must meet the minimum case volume that CMS specifies for a cost measure in order for a benchmark to be determined for the measure, and that if a benchmark is not determined for a cost measure, the measure will not be scored. ***CMS proposes to codify these final policies in regulation text.***

Scoring Improvement in the Cost Performance Category (p. 738)

Section 51003(a)(1)(B) of the BBA of 2018 specified that the cost performance category score shall not take into account the improvement of the MIPS eligible clinician for each of the second, third, fourth, and fifth years for which the MIPS applies to payments. CMS does not believe this change requires CMS to remove its existing methodology for scoring improvement in the cost performance category, but it does prohibit CMS from including an improvement component in the cost performance category percent score for each of the 2018 through 2021 MIPS performance periods. Therefore, ***CMS proposes to revise regulation text to provide that the maximum cost improvement score for the 2018 through 2021 MIPS performance periods (2020, 2021, 2022, and 2023 MIPS payment years) is zero percentage points. (§414.1380(b)(2)(iv)(E))*** Under its existing policy, the maximum cost improvement score for the 2018 MIPS performance period is 1 percentage point, but due to the statutory changes and under its proposal, the maximum cost improvement score for the 2018 MIPS performance period would be zero percentage points. ***CMS is also proposing to modify the performance standards to reflect that the cost performance category percent score will not take into account improvement until the 2022 MIPS performance period (2024 MIPS payment year). (§414.1380(a)(1)(ii))***

Facility-Based Measures Scoring Option for the 2019 MIPS Performance period (2021 MIPS Payment Year) for the Quality and Cost Performance Categories ([p. 740](#))

In the CY 2018 QPP final rule, CMS established a facility-based measurement scoring option for clinicians that meet certain criteria beginning with the 2019 MIPS performance period/2021 MIPS payment year. CMS originally proposed a facility-based measurement scoring option for the 2018 MIPS performance period but did not finalize the policy for 2018 performance due to operational concerns.

Facility-Based Measurement Applicability (p. 740)

In the CY 2018 QPP final rule, CMS limited facility-based reporting to the inpatient hospital in the first year for several reasons. CMS also limited measures applicable for facility-based measurement to those used in the Hospital Value-Based Purchasing (VBP) Program. CMS noted that it was open to the consideration of additional facility types in the future but recognized that adding a facility type would be dependent upon the status of the VBP program applicable to that facility, the applicability of measures, and the ability to appropriately attribute a clinician to a facility. ***CMS does not propose to add additional facility types for facility-based measurement in this proposed rule, but CMS is interested in potentially expanding to other settings in future rulemaking,*** as further addressed below.

Facility-Based Measurement by Individual Clinicians ([p. 741](#))

In the CY 2018 QPP final rule, CMS established individual eligibility criteria for facility-based measurement – specifically, that a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes for inpatient hospital (POS code 21) or emergency room (POS code 23) based on claims for a period prior to the performance period as specified by CMS is eligible as an

individual for facility-based measurement.⁴⁴ Commenters on these policies expressed concern about the omission of the on-campus outpatient hospital POS code (POS code 22) for observation services, which are similar to and often take place in the same physical location as inpatient services.

CMS is proposing to modify its determination of a facility-based individual in four ways:

- ***First, CMS proposes to add on-campus outpatient hospital (as identified by POS code 22) to the settings that determine whether a clinician is facility-based.***
- ***Second, CMS proposes that a clinician must have at least a single service billed with the POS code used for the inpatient hospital or emergency room.***
- ***Third, CMS proposes that, if CMS is unable to identify a facility with a VBP score to attribute a clinician's performance, that clinician is not eligible for facility-based measurement.***
- ***Fourth, CMS proposes to align the time period for determining eligibility for facility-based measurement with changes to the dates used to determine MIPS eligibility and special status detailed earlier in this proposed rule.***

CMS believes that these proposals will further expand the opportunity for facility-based measurement and eliminate issues associated with the provision of observation services while still restricting eligibility to those who work in an inpatient setting.

First, CMS proposes to add the on-campus outpatient hospital (POS code 22) to the list of sites of service used to determine eligibility for facility-based measurement. CMS agrees with commenters that limiting the eligibility to its current definition may prevent some clinicians who are largely hospital-based from being eligible. However, expanding eligibility without taking into account the relationship between the clinician and the facility and facility's performance could result in unfairly attributing to a clinician performance for which the clinician is not responsible or has little to no role in improving. CMS does believe that a significant provision of services in the on-campus outpatient hospital are reflected in the quality captured by the Hospital VBP Program – for example related to treatment of patients in observation status. Therefore, CMS is convinced that a sufficient nexus exists for attributing the hospital's VBP performance to clinicians that provide services in on-campus outpatient hospital settings.

Second, CMS proposes to require that clinicians bill at least a single service with the POS codes for inpatient hospital or the emergency room in order to be eligible for facility-based measurement. CMS believes that a clinician who is to be measured according to the performance of a hospital should at least have a minimal presence in the inpatient or emergency room setting. CMS remains concerned about including clinicians who provide at least 75 percent of their services at on-campus outpatient hospitals (with POS code 22) when such clinicians exclusively provide outpatient services that are unrelated to inpatient hospital service – e.g. a dermatologist who provides office-based services in a hospital-owned clinic but who never admits or treats patient within the inpatient or emergency room setting does not meaningfully contribute to the quality of care for patients measured under the Hospital VBP Program.

CMS considered different ways to best identify those who contribute to the quality of care in the inpatient setting while keeping the facility-based scoring option as simple as possible, as discussed on [p. 744](#). However, CMS believes that using a single service as the threshold provides a simple, bright-line to differentiate those who never provide inpatient services from clinicians that do provide inpatient services, as well as outpatient services. CMS recognizes this requirement of one service with the inpatient or emergency department POS may not demonstrate a significant presence in a particular facility, and ***CMS seeks comment on whether a better***

⁴⁴ CMS had noted, as a part of its proposal summary, that CMS would use the definition of professional services in section 1848(k)(3)(A) of the Act in applying this standard. 1848(k)(3)(A) states that the term "covered professional services" means services for which payment is made under, or is based on, the fee schedule established under this section and which are furnished by an eligible professional.

threshold could be used to identify those who are contributing to the quality of care for patients in the inpatient setting without creating barriers to eligibility for facility-based measurement.

CMS' provides its rationale and reasoning for these first two proposals, including analysis of data and impacts on specialists like emergency physicians, anesthesiologists and family physicians, on [p. 745](#), noting that a relatively small percentage of clinicians in non-emergency specialties would have qualified under the previously finalized eligibility policies.

CMS' third proposal is to add a new criterion: to be eligible for facility-based measurement, CMS must be able to attribute a clinician to a particular facility that has a VBP score. Based on its definition of facility-based measurement, this means a clinician must be associated with a hospital with a Hospital VBP Program Total Performance Score. CMS is concerned that its proposed expansion of eligibility for facility-based measurement could increase the number of clinicians who are eligible for facility-based measurement but whom CMS is unable to attribute to a particular facility that has a VBP score. CMS believes that such a situation would be relatively rare. ***Those clinicians who are identified as facility-based but for whom CMS is unable to attribute to a hospital must participate in MIPS quality reporting through another method, or they will receive a score of zero in the quality performance category. CMS therefore proposes to add the requirement that a clinician must be able to be attributed to a particular facility with a VBP score under the methodology for determining the applicable facility score that would be used in order to meet eligibility for facility-based measurement.*** CMS' new regulatory text addresses both attribution to a facility and the need for that facility to have a VBP score by conditioning eligibility for facility-based scoring for an individual clinician on the clinician being attributed under to a facility with a VBP score. (§414.1380(e)(2)(i)(C))

Fourth, CMS proposes to change the dates of determining eligibility for facility-based measurement. As discussed earlier, CMS proposes to modify the dates of the MIPS determination period that would provide eligibility determination for small practice size, non-patient facing, low-volume threshold, ASC, hospital-based, and facility-based determination periods. To align eligibility determinations for facility-based measurement with these other determination periods, ***CMS proposes to use data from the initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period with a 30-day claims run out in determining eligibility for facility-based measurement.***

Facility-Based Measurement by Group ([p. 747](#))

In the CY 2018 QPP final rule, CMS finalized that a MIPS eligible clinician is eligible for facility-based measurement under MIPS if they are determined to be facility-based as part of a group. CMS established that a facility-based group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements to be facility-based as an individual. ***CMS does not propose any changes to the determination of a facility-based group but acknowledges that its proposal to change how individual clinicians are determined to be eligible for facility-based measurement will necessarily have a practical impact for practice groups.***

Facility Attribution for Facility-Based Measurement ([p. 747](#))

In the CY 2018 QPP final rule, CMS finalized a method to identify the hospital whose scores would be associated with a MIPS eligible clinician or group that elects facility-based measurement scoring. Specifically, a facility-based clinician or group receives a score under the facility-based measurement scoring standard derived from the VBP score for the facility at which the clinician or group provided services to the most Medicare beneficiaries during the year claims are drawn. If an equal number of Medicare beneficiaries are treated at more than one facility, then CMS will use the VBP score for the highest-scoring facility. CMS is revisiting facility-based attribution for groups in this proposed rule.

In considering the issue of facility attribution for a facility-based group, CMS believes that a change to facility-based attribution is appropriate to better align the policy with the determination of a facility-based group. A facility-based group is one in which 75 percent or more of the eligible clinician NPIs billing under the group's TIN are eligible for facility-based measurement as individuals. Additionally, under the current regulation, the VBP score for the highest scoring facility would be used in the case of a tie among the number of facilities at which the group provided services to Medicare beneficiaries. ***CMS proposes to revise the regulation text to differentiate how a facility-based clinician or group receives a score based on whether they participate as a clinician or a group. (§414.1380(e)(5)). Specifically, CMS proposes that a facility-based group receives a score under the facility-based measurement scoring standard derived from the VBP score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined if the clinicians had been scored under facility-based measurement as individuals.*** CMS believes that using the plurality of clinicians reinforces the connection between an individual clinician and facility and is more easily understandable for larger groups. CMS details specific changes to regulation text on [p. 749](#).

No Election of Facility-Based Measurement ([p. 749](#))

In the CY 2018 QPP final rule, CMS did not finalize its proposal for how individual MIPS eligible clinicians or groups who wish to have their quality and cost performance category scores determined based on a facility's performance would elect to do so through an attestation. CMS did finalize that an individual clinician or group would elect to use a facility-based score. The proposal had specified that such clinicians or groups would be required to submit their election during the data submission period through the attestation submission mechanism established for the improvement activities and the Promoting Interoperability performance categories. An alternative approach, which likewise was not finalized, did not require an election process, but instead would have automatically applied a facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement, if such an application were technically feasible.

In the CY 2018 QPP final rule, CMS requested further comment on the propriety of automatically assigning a clinician or group a score under facility-based measurement, but where CMS would notify and give the clinician the opportunity to opt-out of facility-based measurement. CMS subsequently received comments both in favor of and opposed to an opt-out approach. After further considering the advantages and disadvantages of an opt-in or an opt-out process, ***CMS is proposing a modified policy that does not require an election process. Instead, CMS proposes to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and who would benefit by having a higher combined quality and cost performance category score.*** That is, if the MIPS eligible clinician or group is eligible for facility-based measurement, CMS would calculate a combined quality and cost performance category score. ***CMS proposes to use the facility-based score to determine the MIPS quality and cost performance category scores, unless CMS receives another submission of quality data for or on behalf of that clinician or group and the combined quality and cost performance category score for the other submission results in a higher combined quality and cost performance score. If the other submission has a higher combined quality and cost performance score, then CMS would not apply the facility-based performance scores for either the quality or cost performance categories.*** Under its proposal, the combined score for the quality and cost performance categories would determine the scores to be used for both the quality and cost performance categories, for both individual clinicians and for groups. CMS does not propose to adopt a formal opt-out process because, under its proposal, the higher of the quality and cost performance scores available or possible for the clinician or clinician group would be used, which would only benefit the clinician or group. CMS believes that requiring a clinician or group to elect a measurement process (or to opt-out of a measurement process) based on facility performance would add unnecessary burden.

In MIPS, CMS scores clinicians as individuals unless they submit data as a group. CMS believes that same policy should apply to facility-based measurement, even though there are no submission requirements for the quality

performance category for individuals under facility- based measurement. Therefore, ***CMS proposes that there are no submission requirements for individual clinicians in facility-based measurement but a group must submit data in the improvement activities or Promoting Interoperability performance categories as a group in order to be measured as a group under facility-based measurement.*** If a group does not submit improvement activities or Promoting Interoperability measures, then CMS would apply facility-based measurement to the individual clinicians and such clinicians would not be scored as a group. In the case of virtual groups, MIPS eligible clinicians would have formed virtual groups prior to the MIPS performance period; as a result, ***virtual groups eligible for facility-based measurement would always be measured as a virtual group.*** Submission of data on the improvement activities or Promoting Interoperability measures indicates an intent and desire to be scored as a group. Hence, CMS believes that using the choice to submit data as a group to identify a group in the context of facility-based scoring will preserve choices made by clinicians and groups while avoiding the burden of an election process to be scored as a group solely for the purpose of facility-based scoring. ***CMS solicits comment specifically on this proposal and other means to achieve the same ends.***

In the CY 2018 QPP final rule, CMS established that if a clinician or group elects facility-based measurement but also submits MIPS quality data, then the clinician or group would be measured on the method that results in the higher quality score. CMS proposes to adopt this same scoring principle in conjunction with its proposal not to use (or require) an election process. Therefore, ***CMS proposes that the MIPS quality and cost score for clinicians and groups eligible for facility-based measurement will be based on the facility-based measurement scoring methodology unless the clinician or group receives a higher combined score for the MIPS quality and cost performance categories through data submitted to CMS for MIPS (§414.1380(e)(6)(vi)). CMS also proposes conforming regulation text changes to remove references to election of facility-based measurement, as detailed on [p. 752](#).***

As already finalized in regulation text, MIPS eligible clinicians in MIPS APMs are scored under the MIPS APM scoring standard, so those clinicians would not be scored using facility-based measurement (§414.1380(d)).

Facility-Based Measures ([p. 753](#))

Statute provides that the Secretary may use measures used for payment systems other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories. However, the Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. Last year, CMS proposed, but did not finalize, policies to include for the 2018 MIPS performance period all the measures adopted for the FY 2019 Hospital VBP Program on the MIPS list of quality measures and cost measures for purposes of facility-based measurement. CMS noted its intent to propose measures that would be available for facility-based measurement for the 2019 MIPS performance period/2021 MIPS payment year in future rulemaking.

Measures in Facility-Based Scoring ([p. 754](#))

CMS continues to believe it is appropriate to adopt all the measures for the Hospital VBP Program into MIPS for purposes of facility-based scoring. CMS also believes it is appropriate to adopt the performance periods for the measures, which generally are consistent with the dates that CMS use to determine eligibility for facility-based measurement. Therefore, ***beginning with the 2019 MIPS performance period, CMS proposes to adopt for facility-based measurement, the measure set that CMS finalizes for the fiscal year Hospital VBP program for which payment begins during the applicable MIPS performance period (§414.1380(e)(1)(i)). For example, for the 2019 MIPS performance period, which runs on the 2019 calendar year, CMS proposes to adopt the FY 2020 Hospital VBP Program measure set, for which payment begins on October 1, 2019.*** The performance period for these measures varies but performance ends in 2018 for all measures.

CMS also proposes that, starting with the 2019 MIPS performance period (2021 MIPS payment year), the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period (§414.1380(e)(1)(ii)). Therefore, for the 2019 MIPS performance period (2021 MIPS payment year), the Total Performance Score methodology for the FY 2020 Hospital VBP program would apply for facility-based scoring.⁴⁵ CMS notes that this approach of adopting all the measures in the Hospital VBP program can be applied to other VBP programs in the future, should CMS decide to expand facility-based measurement to settings other than hospitals in the future.

In the CY 2018 QPP final rule CMS also established that the available quality and cost measures for facility-based measurement are those adopted under the VBP program of the facility for the year specified. CMS established that it will use the benchmarks adopted under the VBP program of the facility program for the year specified. CMS noted that it would determine the particular VBP program to be used for facility-based measurement in future rulemaking but would routinely use the benchmarks associated with that program. Likewise, CMS established that the performance period for facility-based measurement is the performance period for the measures adopted under the VBP program of the facility program for the year specified. CMS noted that these provisions referred to the general parameters of its method of facility-based measurement and that CMS would address specific programs and years in future rulemaking. ***CMS now proposes regulation for these three provisions to specify that the measures, performance period, and benchmark period for facility-based measurement are the measures, performance period, and benchmark period established for the VBP program used to determine the score.*** As an example, for the 2019 MIPS performance period and 2021 MIPS payment year, the measures used would be those for the FY 2020 Hospital VBP program along with the associated benchmarks and performance periods.⁴⁶

Measures for MIPS 2019 Performance Period/2021 MIPS Payment Year (p. 756)

For informational purposes, CMS is providing a list of measures included in the FY 2020 Hospital VBP Program measures in determining the quality and cost performance category scores for the 2019 MIPS performance period/2021 MIPS payment year. The FY 2020 Hospital VBP Program has adopted 12 measures covering 4 domains. The performance period for measures in the Hospital VBP Program varies depending on the measure, and some measures include multi-year performance periods. CMS includes the FY 2020 Hospital VBP Program measures in [Table 49](#). CMS notes that these measures are determined through separate rulemaking. As noted above, CMS would adopt these measures, benchmarks, and performance periods for the purposes of facility-based measurement.

Scoring Facility-Based Measurement (p. 758)

Scoring Achievement in Facility-Based Measurement (p. 758)

In the CY 2018 QPP final rule, CMS adopted certain scoring policies for clinicians and groups in facility-based measurement. CMS established that the quality and cost performance category percent scores would be established by determining the percentile performance of the facility in the VBP purchasing program for the specified year, then awarding scores associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not scored using facility-based

⁴⁵ The preamble states: “Therefore, for the 2021 MIPS payment year, the Total Performance Score methodology for 2019 [emphasis added] would apply for facility-based scoring.” Based on language included elsewhere throughout this section, and on [Table 49](#), which reflects measures for the FY 2020 Hospital VBP Program, we believe CMS intends to reference the FY 2020 Hospital VBP Program here.

⁴⁶ The preamble states: “As an example, for the 2019 MIPS performance period and 2021 MIPS payment year, the measures used would be those for the FY 2019 [emphasis added] Hospital VBP program along with the associated benchmarks and performance periods.” Again, based on language included elsewhere through this section, and on [Table 49](#), which reflects measures for the FY 2020 Hospital VBP Program, we believe CMS intends to reference the FY 2020 Hospital VBP Program here.

measurement for the MIPS payment year. CMS also finalized that clinicians scored under facility-based measurement would not be scored on other cost measures.

Because CMS proposes to not require or allow an opt-in process for facility-based measurement, ***CMS proposes a change to the determination of the quality and cost performance category scores. CMS proposes that the quality and cost performance category percent scores would be established by determining the percentile performance of the facility in the Hospital VBP Program for the specified year, then awarding a score associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not eligible to be scored under facility-based measurement for the MIPS payment year.*** This proposed change allows for the determination of percentile performance independent of those clinicians who would not have their quality or cost scores determined until CMS made the determination of their status under facility-based measurement.

Scoring Improvement in Facility-Based Measurement (p. 759)

In the CY 2018 QPP final rule, CMS finalized that it would not give a clinician or group participating in facility-based measurement the opportunity to earn improvement points based on prior performance in the MIPS quality and cost performance categories; CMS noted that the Hospital VBP Program already takes improvement into account in determining the score. ***CMS proposes to add this previously finalized policy to regulatory text at §414.1380(e)(6)(iv) and (v).***

However, CMS did not address a policy for a clinician or group who participates in facility-based measurement for one performance period, and then does not participate in facility-based measurement in the subsequent performance period. After further considering the issue, CMS does not believe it is possible to assess improvement in the quality performance category for those who are measured under facility-based measurement in 1 year and then through another method in the following year. CMS' method of assessing and rewarding improvement in the MIPS quality performance category separates points awarded for measure performance from those received for bonus points. CMS' method of determining the quality performance category score using facility-based measurement does not allow for the separation of achievement from bonus points. For this reason, ***CMS proposes to not assess improvement for MIPS-eligible clinicians who are scored in MIPS through facility-based measurement in 1 year but through another method in the following year §414.1380(b)(1)(xi)(A)(4).***

Expansion of Facility-Based Measurement to Use in Other Settings (p. 759)

CMS initiated the process of facility-based measurement focusing on the inpatient hospital setting but noted that CMS wished to consider opportunities to expand the concept into other facilities and programs and future years. ***CMS is particularly interested in the opportunity to expand facility-based measurement into post-acute care (PAC) and the end-stage renal disease (ESRD) settings and seeks comment on how CMS may do so.***

PAC is a significant sector in the spectrum of healthcare services, providing services to over 6.9 million Medicare beneficiaries annually through Long-Term Care Hospitals (LTCHs), Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), Home Health Agencies (HHAs), and Hospice. Recent legislative efforts have focused on improving patient outcomes for PAC through the use of standardized patient assessment data to enable information sharing and cross-setting quality assessment intended to improve outcomes in specified clinical domains. Additionally, In response to previous rulemakings, commenters have requested the opportunity for clinicians who furnish care in PAC settings and bill Medicare Part B to be measured similarly to hospital-based clinicians.

In light of the importance of PAC services, PAC legislative changes, and the interest of the stakeholder community, CMS wishes to explore the opportunity to further align quality and cost measurement from the PAC

QRPs with the clinicians who provide care in those settings. CMS needs to consider alternative ways in which CMS may use measures from the PAC QRPs to measure clinicians in MIPS through facility-based measurement. **Therefore, CMS is seeking comment on how CMS may attribute the quality and cost of care for patients in PAC settings to clinicians.** For the facility-based measurement for MIPS program, clinicians receive a score that is based on the VBP score of a particular hospital at which the clinician or group provides services to patients. **CMS specifically solicits comment on whether a similar approach could work for PAC given the number and variation of PAC settings and clinicians. CMS is particularly interested to learn what level of influence MIPS-eligible clinicians have in determining performance on quality measures for individual settings and programs in the PAC setting.**

In addition, CMS invites comments on which PAC QRP measures may be best utilized to measure clinician performance. Under its current approach for facility-based measurement, all measures in the Hospital VBP Program are used to determine the MIPS score. **CMS also requests comments on methods to identify the appropriate measures for scoring, and what measures would be most influenced by clinicians. Specifically, CMS solicits comment on whether all measures that are reported as part of the PAC QRPs should be included or whether CMS should identify a subset of measures,** and discusses current and proposed PAC QRP measures on [p. 762](#).

Finally, considering the attribution challenges of using measures reported by a facility to measure clinicians, **CMS solicits comment on whether CMS should limit facility-based measurement to specific PAC settings and programs such as the IRF QRP or LTCH QRP, or whether CMS should consider all PAC settings in the facility-based measurement discussion.**

In addition to its consideration of PAC settings, **CMS also solicits comment on opportunities to consider facility-based measurement for patients with ESRD.** The ESRD Quality Incentive Program (QIP) only allows ESRD facilities that meet a certain threshold to avoid a negative payment adjustment and does not allow for a positive payment adjustment. CMS generally believes the scoring methodology associated with the ESRD QIP could be integrated into its current approach but recognizes that the structure is different from the Hospital VBP Program.

Additionally, CMS believes MIPS eligible clinicians' roles in dialysis centers differ from their roles in hospitals, but that these clinicians have a significant impact on the quality of care for patients. **CMS seeks comment on the extent to which the quality measures of dialysis centers reflect clinician performance. Additionally, CMS seeks comments on whether CMS might be able to attribute the performance of a specific facility to an individual clinician** and considers the applicability of the attribution methodology under the Comprehensive ESRD Care model. **CMS also seeks comment on whether another approach, similar to its consideration of the PAC measures, might be more appropriate in this setting.**

Scoring the Improvement Activities Performance Category (p. 764)

Regulatory Text Updates (p. 764)

In this proposed rule, **CMS is proposing updates to both §§414.1380(b)(3) and 414.1355 to more clearly and concisely capture previously established policies.** Policies clarify regulation text around:

- Improvement Activities performance category score and total required points. Additionally, CMS is also clarifying that the improvement activities performance category score cannot exceed 100 percent.
- Weighting of improvement activities
- APM improvement activities performance category score
- Patient-centered medical homes (PCMH) and comparable specialty practices
- Improvement Activities Performance category weighting for final score. CMS is clarifying that unless a different scoring weight is assigned by CMS, performance in this category comprises 15 percent of the

final score for the 2019 MIPS payment year and each year thereafter.

CMS is also proposing one substantive change with respect to PCMH and comparable specialty practices. It has come to CMS' attention that in the preamble of the CY 2017 QPP final rule, the terminology "automatic" was used in reference to PCMH or comparable specialty practice improvement activities scoring credit. While CMS used the term "automatic" then, CMS has since come to believe it is inaccurate because an eligible clinician or group must attest to their status as a PCMH or comparable specialty practice in order to receive full credit for the improvement activities performance category, as specified in the CY 2018 QPP final rule. ***Therefore, in this proposed rule, CMS is codifying regulation text to require that an eligible clinician or group must attest to their status as a PCMH or comparable specialty practice in order to receive this credit. Specifically, MIPS eligible clinicians who wish to claim this status for purposes of receiving full credit in the improvement activities performance category must attest to their status as a PCMH or comparable specialty practice for a continuous 90-day minimum during the performance period.***

CEHRT Bonus ([p. 766](#))

In the CY 2017 and CY 2018 QPP final rules, CMS established that certain activities in the improvement activities performance category will qualify for a bonus under the Promoting Interoperability performance category (not the improvement activities performance category) if they are completed using CEHRT. As described above, CMS reminds readers that it is proposing a new approach for scoring the Promoting Interoperability performance category that is aligned with its MIPS program goals of flexibility and simplicity. CMS does not discuss any policy changes related to this bonus.

CMS invites public comment on these proposals.

Scoring the Promoting Interoperability Performance Category ([p. 766](#))

CMS refers readers to the Promoting Interoperability performance category section of this proposed rule, where CMS discuss its proposals for scoring the Promoting Interoperability performance category.

Calculating the Final Score (p. 767)

In this proposed rule, ***CMS proposes to continue the complex patient bonus for the 2019 MIPS performance period (2021 MIPS payment year), proposes a modification to the final score calculation for the 2019 MIPS performance period, and proposes refinements to reweighting policies.***

Accounting for Risk Factors and Considerations for Social Risk ([p. 767](#))

Statute requires CMS to consider risk factors in its scoring methodology. Additional details regarding statutory requirements are included on [p. 767](#).

In this section, CMS summarizes its efforts related to social risk and the relevant studies conducted under the IMPACT Act. ***CMS also proposes to adjust the final score by continuing a bonus to address patient complexity for the 2019 MIPS performance period (2021 MIPS payment year).*** CMS intends to explore options for adjustment of individual quality measures used in MIPS in future years. CMS also intends to explore additional approaches to account for patient risk factors through adjustments to the performance category scores or the final score. However, CMS believes it is appropriate to maintain the complex patient bonus for the 2019 MIPS performance period. CMS plans to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

Complex Patient Bonus for the 2019 MIPS Performance period (2021 MIPS Payment Year) (p. 769)

In the CY 2018 QPP final rule, CMS finalized a complex patient bonus of up to 5 points to be added to the final score for the 2020 MIPS payment year. CMS intended for this bonus to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while CMS continues to work with stakeholders on methods to account for patient risk factors. CMS' overall goal for the complex patient bonus was two-fold: (1) to protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while CMS review the completed studies and research to address the underlying issues. CMS noted that CMS would assess on an annual basis whether to continue the bonus and how the bonus should be structured.

For the 2019 MIPS performance period/2021 MIPS payment year, ***CMS proposes to continue the complex patient bonus as finalized for the 2018 MIPS performance period/2020 MIPS payment year and to revise regulation text to reflect this policy (§414.1380(c)(3)).*** CMS does not believe it has sufficient information available at this time to develop a long-term solution to account for patient risk factors in MIPS such that CMS would be able to include a different approach in this proposed rule and provides details on additional data and analyses that are expected. CMS also proposes this policy to maintain consistency with the 2020 MIPS payment year and minimize confusion, consistent with stakeholder requests.

Although CMS is not proposing changes to the complex patient bonus for the 2019 MIPS performance period, the dates used in the calculation of the complex patient bonus may change as a result of other proposals CMS is making in this proposed rule. That is, CMS is proposing to change the dates of the eligibility determination period (now referred to as the MIPS determination period) beginning with the 2019 MIPS performance period. Specifically, the second 12-month segment would begin on October 1 of the calendar year preceding the applicable performance period and end on September 30 of the calendar year in which the applicable performance period occurs. ***If this proposed change to the MIPS determination period is finalized, then beginning with the 2019 MIPS performance period (2021 MIPS payment year), the second 12-month segment of the MIPS determination period (beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs) would be used when calculating average HCC risk scores and proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians.***

Final Score Performance Category Weights (p. 772)

General Weights (p. 772)

Statute specifies weights for the performance categories included in the MIPS final score - in general:

- 30 percent for the quality performance category;
- 30 percent for the cost performance category;
- 25 percent for the Promoting Interoperability performance category (formerly the advancing care information performance category); and
- 15 percent for the improvement activities performance category.

CMS is proposing that, for the 2019 MIPS performance period (2021 MIPS payment year), the cost performance category would make up 15 percent and the quality performance category would make up 45 percent of a MIPS eligible clinician's final score. [Table 50](#) summarizes the weights specified for each performance category and is included below.

Finalized and Proposed Weights by MIPS Performance Category and MIPS Performance Period

Performance Category	Transition Year (previously finalized)	2018 MIPS Performance Period (Previously Finalized)	2020 MIPS Performance Period (Proposed)
Quality	60%	50%	45%
Cost	0%	10%	15%
Improvement Activities	15%	15%	15%
Promoting Interoperability	25%	25%	25%

Flexibility for Weighting Performance Categories ([p. 773](#))

Under statute, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category. In the case of a MIPS eligible clinician who fails to report on an applicable measure or activity that is required to be reported by the clinician, the clinician must be treated as achieving the lowest potential score applicable to such measure or activity. In this scenario of failing to report, the MIPS eligible clinician would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Assigning a scoring weight of zero percent and redistributing the weight to the other performance categories differs from the scenario of a MIPS eligible clinician failing to report on an applicable measure or activity that is required to be reported, as detailed further below.

Scenarios Where the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories Would Be Reweighted ([p. 773](#))

CMS has explained its interpretation of what it means for there to be sufficient measures applicable and available for the quality and cost performance categories, and CMS finalized policies for first two MIPS program years under which CMS would assign a scoring weight of zero percent to the quality or cost performance category and redistribute its weight to the other performance categories in the event there are not sufficient measures applicable and available.

- For the quality performance category, having sufficient measures applicable and available means that CMS can calculate a quality performance category percent score for the MIPS eligible clinician because at least one quality measure is applicable and available to the clinician.
- For the cost performance category, having sufficient measures applicable and available means that CMS can reliably calculate a score for the cost measures that adequately captures and reflects the performance of a MIPS eligible clinician.
 - If a MIPS eligible clinician is not attributed enough cases for a measure (in other words, has not met the required case minimum for the measure), or if a measure does not have a benchmark, then the measure will not be scored for that clinician.
 - If CMS does not score any cost measures for a MIPS eligible clinician in accordance with this policy, then the clinician would not receive a cost performance category percent score.

CMS is proposing to codify these policies for the quality and cost performance categories at §414.1380(c)(2)(i)(A)(1) and (2), respectively, and to continue them for the 2019 MIPS performance period (2021 MIPS payment year) and each subsequent MIPS payment year.

For the Promoting Interoperability performance category, CMS has established policies for assigning a scoring weight of zero percent to the Promoting Interoperability performance category and redistributing its weight to the other performance categories in the final score. ***CMS is proposing to codify those policies under §414.1380(c)(2)(i) and (iii).***

For the improvement activities performance category, CMS continues to believe that all MIPS eligible clinicians will have sufficient activities applicable and available, except for limited extreme and uncontrollable circumstances, such as natural disasters, where a clinician is unable to report improvement activities, and circumstances where a MIPS eligible clinician joins a practice in the final 3 months of the performance period as discussed below. Barring these circumstances, CMS believes that all MIPS eligible clinicians will have sufficient improvement activities applicable and available.

Reweighting the Quality, Cost, and Improvement Activities Performance Categories for Extreme and Uncontrollable Circumstances (p. 775)

CMS is proposing to codify its policy that, beginning with the 2018 MIPS performance period/2020 MIPS payment year, CMS will reweight the quality, cost, and improvement activities performance categories based on a request submitted by a MIPS eligible clinician, group, or virtual group that was subject to extreme and uncontrollable circumstances (§414.1380(c)(2)(i)(A)(5)).

CMS sought comment in the CY 2018 QPP final rule on two topics related to its extreme and uncontrollable policies. First, CMS sought comment on ways CMS could modify its improvement scoring policies to account for clinicians who have been affected by extreme and uncontrollable circumstances. In response, CMS received one comment expressing support for an improvement score without providing any additional details. ***At this time, CMS is not proposing modifications to its improvement scoring; therefore, MIPS eligible clinicians who receive a zero percent weighting for the quality or cost performance categories due to extreme and uncontrollable circumstances would not be eligible for improvement scoring because data sufficient to measure improvement would not be available from the performance period in which the quality or cost performance categories are weighted at zero percent.***

CMS also sought comment on alternatives to the finalized policies, such as using a shortened performance period, which may allow CMS to measure performance, rather than reweighting the performance categories to zero percent. While many commenters support CMS' final policies, one commenter requested that CMS reconsider its policy to not include issues third party intermediaries might have submitting information to CMS on behalf of a MIPS eligible clinician. CMS considered updating its policy to include third party intermediaries; however, CMS continues to believe that inclusion of third party intermediaries is not necessary because MIPS eligible clinicians may identify multiple ways to submit data and participate in MIPS. ***CMS seeks comments on the specific circumstances under which the extreme and uncontrollable circumstances policy should be made applicable to third party intermediary issues.***

One commenter recommended that CMS require MIPS eligible clinicians to submit data before an extreme and uncontrollable event and within a reasonable timeframe after the event to incentivize quality improvement while allowing for flexibility. Although CMS considered this alternative approach, CMS continues to believe that MIPS eligible clinicians who demonstrate (through a reweighting application) that an extreme and uncontrollable event impacted their ability to report for a given performance category should have reweighting for that performance category for the performance period. However, CMS may consider modifying its policies in future years which CMS would propose through future rulemaking.

CMS is proposing a few minor modifications to its extreme and uncontrollable circumstances policy. ***First, beginning with the 2019 MIPS performance period/2021 MIPS payment year, CMS is proposing that, if a MIPS eligible clinician submits an application for reweighting based on extreme and uncontrollable circumstances, but also submits data on the measures or activities specified for the quality or improvement activities performance categories, he or she would be scored on the submitted data like all other MIPS eligible clinicians, and the categories would not be reweighted.*** However, CMS provides further clarification of this policy.

- ***CMS discusses cases when quality data are reported via claims, potentially prior to knowledge of an extreme or uncontrollable circumstance.*** Under CMS' proposal, CMS would score the quality performance category because CMS has received data. However, CMS previously finalized that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold. If a clinician experiences an extreme and uncontrollable event that affects all of the performance categories, then under its proposal the clinician would also have to submit data for the improvement activities or the Promoting Interoperability performance categories in order to be scored on two or more performance categories and receive a final score different than the performance threshold.
- ***CMS notes that this proposal does not include administrative claims data that CMS receives through the claims submission process and use to calculate the cost measures and certain quality measures.*** As there are no data submission requirements for the cost performance category and for certain quality measures used to assess performance in the quality performance category, CMS does not believe that it would be appropriate to void a reweighting application based on administrative claims data CMS receives for measures that do not require data submission for purposes of MIPS.

CMS also proposes to apply the policy CMS finalized for virtual groups in the CY 2018 QPP final rule to groups submitting reweighting applications for the quality, cost, or improvement activities performance categories based on extreme and uncontrollable circumstances. For groups, CMS would evaluate whether sufficient measures and activities are applicable and available to MIPS eligible clinicians in the group on a case-by-case basis and determine whether to reweight a performance category based on the information provided for the individual clinicians and practice location(s) affected by extreme and uncontrollable circumstances and the nature of those circumstances. While CMS did not specifically propose to apply this policy to groups in the CY 2018 QPP proposed rule, its intention was to apply the same policy for groups and virtual groups, and thus ***if CMS adopts this proposal, CMS would apply the policy to groups beginning with the 2018 performance period/2020 MIPS payment year.***

Reweighting the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories for MIPS Eligible Clinicians Who Join a Practice in the Final 3 Months of the Performance Period Year (p. 779)
Beginning with the 2019 MIPS performance period, CMS is proposing that a MIPS eligible clinician who joins an existing practice (existing TIN) during the final 3 months of the calendar year in which the MIPS performance period occurs (the performance period year) that is not participating in MIPS as a group would not have sufficient measures applicable and available. CMS is also proposing that a MIPS eligible clinician who joins a practice that is newly formed (new TIN) during the final 3 months of the performance period year would not have sufficient measures applicable and available, regardless of whether the clinicians in the practice report for purposes of MIPS as individuals or as a group. In each of these scenarios, CMS is proposing to reweight all four of the performance categories to zero percent for the MIPS eligible clinician and, because he or she would be scored on fewer than two performance categories, the MIPS eligible clinician would receive a final score equal to the performance threshold and a neutral MIPS payment adjustment. CMS proposes to codify these policies at §414.1380(c)(2)(i)(A)(3).

CMS is proposing this policy because CMS is not currently able to identify these MIPS eligible clinicians (or groups if the group is formed in the final 3 months of the performance period year) at the start of the MIPS submission period based on its timeline for making eligibility determinations, as discussed on [p. 779](#).

If a MIPS eligible clinician joins a practice (existing TIN) in the final 3 months of the performance period year, and the practice is not newly formed and is reporting as a group for the performance period, the MIPS eligible clinician would be able to report as part of that group. In this case, CMS is able to accept data for the group because the TIN would be in its MIPS eligibility determination files. Therefore, CMS believes the measures and activities would be available in this scenario, and reweighting would not be necessary for the MIPS eligible

clinician. 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 its system at the start of the MIPS data submission period; however, if the MIPS eligible clinician qualifies to receive the group final score under its proposal, CMS would apply the group final score to the MIPS eligible clinician's TIN/NPI combination as soon as the information becomes available.

Proposed Automatic Extreme and Uncontrollable Circumstances Policy Beginning with the 2020 MIPS Payment Year (p. 781)

In conjunction with the CY 2018 QPP final rule, CMS issued an interim final rule with comment period (IFC) in which CMS adopted on an interim final basis a policy for automatically reweighting the quality, improvement activities, and advancing care information (now referred to as Promoting Interoperability) performance categories for the transition year of MIPS (the 2017 performance period/2019 MIPS payment year) for MIPS eligible clinicians who are affected by extreme and uncontrollable circumstances affecting entire regions or. ***CMS proposes to codify this policy for the quality and improvement activities performance categories at §414.1380(c)(2)(i)(A)(6) and for the advancing care information (now Promoting Interoperability) performance category at §414.1380(c)(2)(i)(C)(3).***

CMS believes that a similar automatic extreme and uncontrollable circumstances policy would be appropriate for any year of the MIPS program to account for natural disasters and other extreme and uncontrollable circumstances that impact an entire region or locale. ***CMS proposes at §414.1380(c)(2)(i)(A)(7) and (c)(2)(i)(C)(3) to apply the automatic extreme and uncontrollable circumstances policy CMS adopted for the transition year to subsequent years of the MIPS program, beginning with the 2018 MIPS performance period and the 2020 MIPS payment year, with a few additions to address the cost performance category.***

In the IFC, CMS stated that it was not including the cost performance category in the automatic extreme and uncontrollable circumstances policy for the transition year because the cost performance category is weighted at zero percent in the final score for the 2017 MIPS performance period/2019 MIPS payment year. CMS finalized a 10 percent weight for the cost performance category for the 2018 MIPS performance period/2020 MIPS payment year and is proposing a 15 percent weight for the 2019 performance period/2021 MIPS payment year. For the reasons discussed in the CY 2018 QPP final rule, CMS believes a MIPS eligible clinician's performance on measures calculated based on administrative claims data, such as the measures specified for the cost performance category, could be adversely affected by a natural disaster or other extreme and uncontrollable circumstance, and that the cost measures may not be applicable to that MIPS eligible clinician. ***Therefore, CMS is proposing to include the cost performance category in the automatic extreme and uncontrollable circumstances policy beginning with the 2018 MIPS performance period/2020 MIPS payment year. CMS is proposing for the cost performance category, if a MIPS eligible clinician is located in an affected area, CMS would assume the clinician does not have sufficient cost measures applicable to him or her and assign a weight of zero percent to that category in the final score, even if CMS receives administrative claims data that would enable CMS to calculate the cost measures for that clinician.***

In the interim final rule, CMS did not include an automatic extreme and uncontrollable circumstances policy for groups or virtual groups, and CMS continues to believe such a policy is not necessary, as discussed on p. 783.

Redistributing Performance Category Weights (p. 784)

In the CY 2017 and CY 2018 QPP final rules, CMS established policies for redistributing the weights of performance categories for the 2017 and 2018 MIPS performance periods in the event that a scoring weight different from the generally applicable weight is assigned to a category or categories. ***CMS is proposing to codify these policies under §414.1380(c)(2)(ii).***

For the 2019 MIPS performance period, ***CMS proposes to apply similar reweighting policies as finalized for the 2018 MIPS performance period. In general, CMS would redistribute the weight of a performance category or categories to the quality performance category. CMS continues to believe redistributing weight to the quality performance category is appropriate because of the experience MIPS eligible clinicians have had reporting on quality measures under other CMS programs. CMS proposes to continue to redistribute the weight of the quality performance category to the improvement activities and Promoting Interoperability performance categories. However, for the 2019 MIPS performance period, with its proposal to weight cost at 15 percent, CMS proposes to reweight the Promoting Interoperability performance category to 45 percent and the improvement activities performance category to 40 percent when the quality performance category is weighted at zero percent.*** CMS chose to weight Promoting Interoperability higher in order to align with goals of interoperability and for simplicity because CMS generally have avoided assigning partial percentage points to performance category weights. Reweighting scenarios under this proposal are presented in [Table 51](#) and below.

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%
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%

CMS has heard from stakeholders in previous years that its reweighting policies place undue weight on the quality performance category, and, although CMS continues to believe the policies are appropriate, ***CMS seeks comment on alternative redistribution policies in which CMS would also redistribute weight to the improvement activities performance category*** (as shown in [Table 52](#)).

While CMS has not redistributed weight to the cost performance category under its existing policies and proposals for the 2019 MIPS performance period, CMS also believes that cost is a critical component of the QPP and that placing additional emphasis on the cost performance category in future years may be appropriate. ***Therefore, CMS seeks comment on redistributing weight to the cost performance category in future years.***

Final Score Calculation (p. 787)

CMS is proposing to revise the formula at §414.1380(c) for calculating the final score since CMS is not proposing to continue to add the small practice bonus to the final score for the 2019 MIPS performance period and is instead proposing to add a small practice bonus to the quality performance category score starting with the 2019 MIPS performance period. Therefore, ***CMS is proposing to revise the formula to omit the small***

practice bonus from the final score calculation beginning with the 2019 MIPS performance period. CMS requests public comments on this proposal.

In the CY 2018 QPP final rule, CMS requested public comment on approaches to display scores and provide feedback to MIPS eligible clinicians in a way that MIPS eligible clinicians can easily understand how their scores are calculated, including how performance category scores are translated to a final score. CMS details comments it received and thanks the commenters for their suggestions, which CMS will take into consideration in future rulemaking. CMS also discusses challenges with implementing some of the suggestions raised by commenters. However, CMS notes that it continues to value simplicity in its scoring for MIPS and intends to explore approaches to simplify its scoring whenever possible in future years. **CMS seeks comments on approaches to simplify calculation of the final score that take into consideration these limitations described in this section.**

MIPS Payment Adjustments (p. 789)

Final Score Used in Payment Adjustment Calculation (p. 789)

Under current policies, for groups submitting data using the TIN identifier, CMS will apply the group final score to all the TIN/NPI combinations that bill under that TIN during the performance period. CMS is proposing to modify this policy for the application of the group final score, beginning with the 2019 performance period/2021 MIPS payment year. ***CMS is proposing 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). CMS is proposing for groups submitting data using the TIN identifier, CMS would apply the group final score to all of the 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 that informs a group or eligible clinician of who is eligible.

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 its system at the start of the MIPS data submission period; however, if the MIPS eligible clinician qualifies to receive the group final score under its proposal, CMS would apply the group final score to the MIPS eligible clinician's TIN/NPI combination as soon as the information becomes available.

Establishing the Performance Threshold (p. 790)

Under statute, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors. The performance threshold for a year must be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. Statute also includes a special rule for the initial 5 years of MIPS (as amended by the BBA of 2018), which requires the Secretary, prior to the performance period for such years, to establish a performance threshold and an additional performance threshold, each of which must be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. In addition, the BBA of 2018 also includes an additional special rule that requires the Secretary increase the performance threshold for each of the third, fourth, and fifth years of MIPS (the 2019 through 2021 MIPS performance periods) to ensure a gradual and incremental transition to the performance threshold based on the mean or median.

To determine a performance threshold to propose for the third year of MIPS (2019 MIPS performance period), CMS notes that the final scores for MIPS eligible clinicians for 2017 were not yet available to include in the

development of this proposal, so instead CMS reviewed the data relied upon for the CY 2017 QPP final rule regulatory impact analysis. Specifically, CMS used data from claims, MIPS eligibility data, 2015 PQRS data, 2014 PQRS Experience Report, 2014 VM data, National Plan and Provider Enumeration System Data, APM participation lists, and initial analyses for QP determination to model the estimated MIPS eligible clinicians, final scores, and the economic impact of MIPS final score. CMS provides additional detail on its analysis of that data on [p. 792](#). Based on that data, CMS found that the mean final score was between 63.50 and 68.98 points and the median was between 77.83 and 82.5 points based on the different participation assumptions, and has decided to use the mean final score for purposes of estimating the performance threshold for the 2022 MIPS performance period/2024 MIPS payment year.⁴⁷

CMS proposes a performance threshold of 30 points for the 2019 MIPS performance period (2021 MIPS payment year). A performance threshold of 30 points would be a modest increase over the performance threshold for the 2018 MIPS performance period (15 points), and CMS believes it would provide a gradual and incremental transition to the performance threshold CMS would establish for the 2022 MIPS performance period, which CMS currently estimates would be between 63.50 and 68.98 points.⁴⁸

CMS provides its rationale for choosing a performance threshold of 30 starting on [p. 794](#). CMS believes that a performance threshold of 30 points represents a meaningful increase compared to 15 points, while maintaining flexibility for MIPS eligible clinicians in the pathways available to achieve this performance threshold. CMS provides a few examples of how a MIPS eligible clinician that is reporting individually and is not in a small practice and no reweighting could meet the performance threshold of 30 points:

- Example 1: By earning 40 measure achievement points out of 60 total possible measure achievement points in the quality category. This could be achieved through performing at the highest level of performance for 2 measures and earning 5 measure achievement points for each of the 4 other measures submitted for a total of 6 required measures submitted in the quality performance category (assuming an outcome measure is submitted).
- Example 2: By achieving performance at 50 percent for the Promoting Interoperability performance category (12.5 points), receiving a 50 percent performance category score for the cost performance category (7.5 points), and also earning the maximum number of points for the improvement activities performance category (15 points), which collectively would produce a final score of at least 35 points.

CMS invites public comment on the proposal to set the performance threshold for the 2019 MIPS performance period at 30 points. Alternatively, CMS considered whether the performance threshold should be set at a higher or lower number, for example, 25 points or 35 points, and also seeks comment on alternative numerical values for the performance threshold for the 2019 MIPS performance period.

CMS also seeks comment on its approach to estimating the performance threshold for the 2022 MIPS performance period, which CMS based on the estimated mean final score for the 2017 MIPS performance period. CMS is particularly interested in whether CMS should use the median, instead of the mean, and whether in the future CMS should estimate the mean or median based on the final scores for another MIPS payment year. In its model estimates, CMS has seen that the mean scores are lower than the median and would expect a larger proportion of clinicians estimated to have final scores above the mean, rather than the median, because the mean is lower than the median with those who do not submit the required data getting the lowest possible score. That in turn could lower the scaling factor compared to a performance threshold based on the median. **CMS also seeks comment on whether establishing a path forward to a performance threshold for the**

⁴⁷ CMS makes this estimate to ensure a gradual and incremental transition from the performance threshold for the 2019 MIPS performance period to the 2022 MIPS performance period/2024 MIPS payment year.

⁴⁸ CMS notes that these values are only estimates and that CMS will propose the actual performance threshold for the 2022 MIPS performance period in future rulemaking.

2022 MIPS performance period that provides certainty to clinicians and ensures a gradual and incremental increase from the performance threshold for the 2019 MIPS performance period to the estimated performance threshold for the 2022 MIPS performance period would be beneficial. For example, CMS could consider setting a performance threshold of 30 points for the 2019 MIPS performance period, 50 points for the 2020 MIPS performance period, and 70 points for the 2021 MIPS performance period as gradual and incremental increases toward the estimated performance threshold for the 2022 MIPS performance period based on its estimated median final scores discussed above; or CMS could have slightly lower values if CMS were to continue to estimate the performance threshold for the 2022 MIPS performance period based on its estimated mean final scores. CMS believes there may be value to MIPS eligible clinicians in knowing in advance the performance threshold for the 2020 and 2021 MIPS performance periods to encourage and facilitate increased clinician engagement and prepare clinicians for meeting the performance threshold for the 2022 MIPS performance period. Alternatively, CMS also believes that its estimates for the 2022 MIPS performance period performance threshold may change as CMS analyzes actual MIPS data and, therefore, it may be appropriate to propose the performance threshold annually as CMS better understand the mean and median final scores.

Additional Performance Threshold for Exceptional Performance (p. 797)

Statute requires the Secretary to compute, for each year of the MIPS, an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors for exceptional performance. For each such year, the Secretary must apply either of the following methods for computing the additional performance threshold: (1) the threshold shall be the score that is equal to the 25th percentile of the range of possible final scores above the performance threshold; or (2) the threshold shall be the score that is equal to the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold for the prior period. However, for the first five years, the special rule described above that applies for the performance threshold also applies for the additional performance threshold.

A MIPS eligible clinician with a final score at or above the additional performance threshold will receive an additional MIPS payment adjustment factor and may share in the \$500,000,000 of funding available for the year. ***For the 2021 MIPS payment year, CMS is proposing to again decouple the additional performance threshold from the performance threshold.*** Because CMS does not have actual MIPS final scores for a prior performance period, if CMS does not decouple the additional performance threshold from the performance threshold, then CMS would have to set the additional performance threshold at the 25th percentile of possible final scores above the proposed performance threshold of 30 points, or 47.5 points, which CMS does not believe demonstrates exceptional performance. CMS believes these additional incentives should only be available to those clinicians with very high performance on the MIPS measures and activities. Therefore, ***CMS is relying on the special rule and proposes to set the additional performance threshold at 80 points for the 2019 MIPS performance period (2021 MIPS payment year),*** which is higher than the 25th percentile of the range of the possible final scores above the performance threshold. CMS provides its rationale for this proposal on [p. 798](#). For future years, CMS may consider additional increases to the additional performance threshold.

Application of the MIPS Payment Adjustment Factors (p. 799)

Application to the Medicare Paid Amount for Covered Professional Services (p. 799)

In the CY 2018 QPP final rule, CMS finalized the application of the MIPS payment adjustment factor, and if applicable, the additional MIPS payment adjustment factor, to the Medicare paid amount for items and services paid under Part B and furnished by the MIPS eligible clinician during the year. The BBA of 2018 replaced the references to “items and services” with “covered professional services,” which are those services for which payment is made under, or is based on, the Medicare Physician Fee Schedule and which are furnished by an eligible professional. ***As a result of these changes, the MIPS payment adjustment factor, and as applicable, the additional MIPS payment adjustment factor, will be applied to Part B payments for covered professional***

services furnished by a MIPS eligible clinician during a year beginning with the 2019 MIPS payment year and not to Part B payments for other items and services.

CMS details conforming changes to regulatory text on [p. 800](#).

Application for Non-Assigned Claims for Non-Participating Clinicians ([p. 801](#))

In the CY 2018 QPP final rule, CMS did not address the application of the MIPS payment adjustment for non-assigned claims for non-participating clinicians. In the CY 2018 QPP final rule, CMS responded to a comment requesting guidance on how the MIPS payment adjustment and the calculation of the Medicare limiting charge amount would be applied for non-participating clinicians, and CMS stated its intention to address these issues in future rulemaking.

Beginning with the 2019 MIPS payment year, CMS is proposing that the MIPS payment adjustment does not apply for non-assigned claims for non-participating clinicians. This approach is consistent with the policy for application of the value modifier that was finalized in the CY 2015 Physician Fee Schedule final rule. When 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. This is referred to as a non-assigned claim. Application of the MIPS payment adjustment to these non-assigned claims would not affect payment to the MIPS eligible clinician. Rather, it would only affect Medicare payment to the beneficiary. CMS continues to believe that it is important that beneficiary liability not be affected by the MIPS payment adjustment and that the MIPS payment adjustment should be applied to the amount that Medicare pays to MIPS eligible clinicians. On that basis, ***CMS proposes to apply the MIPS payment adjustment to claims that are billed and paid on an assignment-related basis, and not to any non-assigned claims, beginning with the 2019 MIPS payment year. CMS does not expect this proposal, that the MIPS payment adjustment would not apply to non-assigned claims, would be likely to affect a clinician's decision to participate in Medicare or to otherwise accept assignment for a particular claim, but CMS seeks comment on whether stakeholders and others believe clinician behavior would change as a result of this policy.***

Waiver of the Requirement to Apply the MIPS Payment Adjustment Factors to Certain Payments in Models Tested under Section 1115A of the Social Security Act ([p. 802](#))

CMS tests models under CMS Innovation Center authority found at section 1115A of the Act that may include model-specific payments made only to model participants under the terms of the model, some of which may be considered payments for covered professional services furnished by a MIPS eligible clinician, meaning that the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) would normally apply to those payments.

Section 1115A(d)(1) of the Act authorizes the Secretary to waive requirements of Title XVIII of the Act (and certain other requirements) as may be necessary solely for the purposes of testing section 1115A models. CMS believes it is necessary to waive the requirement to apply the MIPS payment adjustment factors to a model-specific payment or payments (to the extent such a payment or payments are subject to the requirement to apply the MIPS payment adjustment factors) for purposes of testing a section 1115A model under which such model-specific payment or payments are:

- made in a specified payment amount (for example, \$160 per-beneficiary, per-month); or
- paid according to a methodology for calculating a model-specific payment that is applied in a consistent manner to all model participants.

In both cases, applying the MIPS payment adjustment factors to these model-specific payments would introduce variation in the amounts of model-specific payments paid across model participants, which could compromise the model test and the evaluation thereof.

CMS proposes to amend its regulations to specify that the MIPS payment adjustment factors would not apply to certain model- specific payments as described above for the duration of a section 1115A model's testing, beginning in the 2019 MIPS payment year. (§414.1405) CMS is proposing to waive the requirement to apply the MIPS payment adjustment factors specifically for these types of payments because the waiver is necessary solely for purposes of testing models that involve such payments. This waiver would not apply to payments made outside of a section 1115A model with respect to both MIPS eligible clinicians that are participating in and MIPS eligible clinicians that are not participating in a section 1115A model. To illustrate how this waiver would apply, CMS provides details on the \$160 per-beneficiary per-month payment provided to practices participating in the Oncology Care Model (OCM), called the Monthly Enhanced Oncology Services (MEOS) payment on [p. 804](#). The duration of this waiver would begin with the 2019 MIPS payment year and continue for the duration of OCM. CMS believes it is necessary to waive the requirement to apply the MIPS payment adjustment factors to the MEOS payments solely for purposes of testing OCM because CMS is specifically testing the impact and appropriateness of \$160 as the per beneficiary per month MEOS payment amount to OCM Practitioners. If the MEOS payments were subject to the MIPS payment adjustment, the MEOS payment amount would not be consistent for all OCM Practitioners across the OCM. CMS is concerned that the resulting differential MEOS payment amounts would increase the complexity of the model evaluation. Differential payment amounts may also potentially distort CMS's intent to incentivize the provision of enhanced oncology care by OCM Practitioners via a standardized per-beneficiary per-month payment for such services.

CMS proposes to provide the public with notice that this proposed new regulation applies to model-specific payments that the Innovation Center elects to test in the future in two ways:

- ***First, CMS will update the QPP website (www.qpp.cms.gov) when new model-specific payments subject to this proposed waiver are announced, and***
- ***Second, CMS will provide a notice in the Federal Register to update the public on any new model-specific payments to which this waiver will apply.***

CY 2018 Exclusion of MIPS Eligible Clinicians Participating in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration (p. 806)

In conjunction with releasing this proposed rule, CMS announced the MAQI Demonstration, authorized under section 402 of the Social Security Amendments of 1968 (as amended). The MAQI Demonstration is designed to test whether excluding MIPS eligible clinicians who participate to a sufficient degree in certain payment arrangements with Medicare Advantage Organizations (MAOs) from the MIPS reporting requirements and payment adjustment will increase or maintain participation in payment arrangements similar to Advanced APMs with MAOs and change the manner in which clinicians deliver care.

If the waivers proposed below are finalized, the MAQI Demonstration will allow certain participating clinicians to be excluded from the MIPS reporting requirements and payment adjustment without meeting the criteria to be QPs or otherwise meeting a MIPS exclusion criterion under the QPP. For purposes of the MAQI Demonstration, CMS would apply requirements for Qualifying Payment Arrangements that are consistent with the criteria for Other Payer Advanced APMs under the QPP. In addition, CMS is proposing that the combined thresholds for Medicare payments or patients through Qualifying Payment Arrangements with MAOs and Advanced APMs that a participating clinician must meet in order to attain waivers of the MIPS reporting requirements and payment adjustment through the MAQI Demonstration matches 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.

Section 402(b) of the Social Security Amendments of 1968 (as amended) authorizes the Secretary to waive requirements of Title XVIII that relate to payment and reimbursement in order to carry out demonstrations under section 402(a). ***CMS proposes to use this waiver authority, subject to conditions outlined in the Demonstration, to waive:***

- ***the requirements to apply the MIPS adjustment factor to covered professional services,***
- ***the payment consequences (positive, negative or neutral adjustments) of the MIPS, and***
- ***the associated MIPS reporting requirements.***

As a practical matter, the waiver would have the effect of acting as another exclusion from MIPS for eligible clinicians who participate in the MAQI Demonstration and meet the performance thresholds set in the demonstration.

Demonstration parameters are described in the table below.

Demonstration Parameter	Specifications
Qualification for waivers	To qualify for waivers, a participating clinician must: <ul style="list-style-type: none"> • Have sufficient participation in the combination of the following during the performance period for the year: <ul style="list-style-type: none"> ○ Qualifying Payment Arrangements with MAOs and ○ Advanced APMs • Not meet criteria to qualify for QP or Partial QP status • Not otherwise meet any MIPS exclusion criteria
Sufficient participation options	Across a combination of Advanced APMs and Qualifying Payment Arrangements with MAOs, a participating clinician must have either of the following tied to participation in such models/arrangements: <ul style="list-style-type: none"> • Sufficient percentage of payments • Sufficient percentage of patients
Sufficient participation thresholds	Sufficient participation thresholds will match the thresholds under the Medicare Option of the QPP.
Demonstration start	2018 Performance Period
Demonstration duration	5 years

The Demonstration will also waive the requirement that the Secretary permit any eligible clinician to report on applicable measures and activities, so that the Demonstration will prohibit reporting under the MIPS by eligible clinicians who participate in the Demonstration and meet the thresholds to receive the waivers from the MIPS reporting requirements and payment adjustment for a given year. This waiver is necessary to prevent the potential gaming opportunity wherein participating clinicians could intentionally report artificially poor performance under the MIPS for years in which they receive waivers from MIPS payment consequences, then receive artificially inflated quality improvement points under MIPS in later years when they do not receive waivers from MIPS payment consequences.

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 population across which positive and negative payment adjustments

are calculated under MIPS may affect the payment adjustments for other MIPS eligible clinicians to whom the waivers do not apply. ***The Demonstration is contingent on the finalization of these waivers through rulemaking due to its effect on MIPS payment adjustments for other clinicians.***

CMS invites comment on this proposal.

Example of Adjustment Factors (p. 809)

CMS provides [Figure A](#) and several tables as illustrative examples of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on its proposed policies for the 2019 MIPS performance period/2021 MIPS payment year (e.g. performance threshold of 30 points, additional performance threshold of 80 points). CMS also includes a reminder that the applicable percentage is 7 percent for the 2021 MIPS payment year.

[Table 53](#) illustrates the changes in payment adjustments based on the final policies from the 2017 MIPS performance period and the 2018 MIPS performance period, and on the proposed policies for the 2019 MIPS performance period, as well as the statutorily required increase in the applicable percent.

CMS also provides three updated examples for the 2019 MIPS performance period to demonstrate scenarios in which MIPS eligible clinicians can achieve a final score at or above the performance threshold of 30 points for the 2019 MIPS performance period, starting on [p. 814](#). CMS notes that these examples are not intended to be exhaustive of the types of participants nor the opportunities for reaching and exceeding the performance threshold.

Third Party Intermediaries ([p. 819](#))

Third Party Intermediaries Definition ([p. 819](#))

At §414.1305, CMS proposes a new definition to define a 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, and PI performance categories. A QCDR, qualified registry, health IT vendor, or CMS-approved survey vendor are considered third party intermediaries. CMS also proposes to change the section heading at §414.1400 from “Third party data submissions” to “Third party intermediaries” to elucidate the definition and function of a third-party intermediary.

CMS also discusses here concerns about the ability of a non-U.S. based third party intermediary to participate in MIPS. ***CMS proposes to amend previously finalized policies at §414.1400(a)(4) to indicate that a third-party intermediary’s principle place of business and retention of associated CMS data must be within the U.S.***

CMS clarifies that:

- Third-party intermediaries that are authorized by CMS to submit data on behalf of MIPS eligible clinicians, groups or virtual groups have not otherwise been evaluated for the capabilities, quality, or any other features or its products.
- The U.S. Government and CMS do not endorse or recommend any third-party intermediary or its products.
- Prior to selecting or using any third-party intermediary or its products, MIPS eligible clinicians, groups or virtual groups should perform their own due diligence on the entity and its products, including contacting the entity directly to learn more about its products.

Certification (p. 821)

CMS proposes to amend §414.1400(a)(5) 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 previously finalized (82 FR 53807) that this certification must occur at the time of the submission and accompany the submission, but it has since discovered that it is not operationally feasible to include these requirements.

Qualified Clinical Data Registries (QCDRs) (p. 822)

Proposed Update to the Definition of a QCDR (p. 822)

Beginning with the 2022 MIPS payment year, CMS proposes to amend §414.1305 to modify the definition of a QCDR to state that the approved entity must have clinical expertise in medicine and quality measure development. Specifically, a QCDR would be defined as 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. As a part of the self-nomination process, CMS would look for entities that have quality improvement expertise and a clinical background. It would also follow up with the entity should it question these standards are met.

In addition, under §414.1400(b)(2)(ii), an entity that uses an external organization for purposes of data collection, calculation, or transmission may meet the definition of a QCDR as long as the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organization effective as of September 1 the year prior to the year for which the entity seeks to become a QCDR. Thus, CMS expects that entities without clinical expertise in medicine and quality measure development that want to become QCDRs would collaborate with other organizations with such expertise. However, such entities may seek to qualify directly as another type of third party intermediary, such as a qualified registry since becoming a registry does not require the level of measure development expertise that is needed to be a QCDR, since it develops its own measures.

CMS makes these proposals to ensure that QCDRs have access to clinical expertise in quality measurement and are able to provide and demonstrate an understanding of the clinical medicine, evidence-based gaps in care, and opportunities for improvement in the quality of care delivered to patients and priorities that are important to MIPS eligible clinicians. During the past two self-nomination periods, a large number of entities that have a predominantly technical background with limited understanding of medical quality metrics or the process for developing quality measures have sought approval as a QCDR. Some of these entities were developing QCDR measures without a complete understanding of measure constructs (e.g., what is required of a composite measure or what it means to risk-adjust), and in some instances, QCDRs were developing QCDR measures in clinical areas in which they did not have expertise. CMS is concerned that the QCDR measures submitted by such entities 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 specialty societies and other entities with clinical expertise. CMS does not believe these entities, in the absence of clinical expertise in quality measurement, meet the intent of QCDRs. Instead, CMS would like to ensure that QCDRs that participate in MIPS are first and foremost in the business to improve the quality of care clinicians provide to their patients through quality measurement and/or disease tracking.

Establishment of an Entity Seeking to Qualify as a QCDR (p. 824)

CMS proposes to re-designate §414.1400 (c)(2) as §414.1400(b)(2)(i) to state that beginning with the 2022 MIPS Payment Year, the QCDR must have at least 25 participants by January 1 of the year prior to the performance period. These participants would not need to use the QCDR to report MIPS data to CMS; rather, they need to submit data to the QCDR for quality improvement.

Current regulations state that the QCDR must have at least 25 participants by January 1 of the performance period. However, CMS is concerned that a QCDR's lack of preparedness to accept data from MIPS eligible clinicians and groups beginning on January 1 of the performance period may negatively impact a clinician's ability to use a QCDR to report, monitor the quality of care they provide to their patients (and act on these results) and may inadvertently increase clinician burden.

Self-Nomination Process ([p. 825](#))

Other than the changes proposed below, CMS does not propose any changes to its previously established policies regarding the simplified self-nomination process for existing QCDRs in MIPS that are in good standing and Web-based submission of self-nomination forms.

- Self-nomination period. ***CMS proposes that, beginning with the 2022 MIPS payment year, entities seeking to qualify as QCDRs must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year (e.g., or the CY 2020 performance period, the self-nomination period would begin on July 1st, 2019 and end on September 1st, 2019); must provide all information required by CMS at the time of self-nomination; and must provide any additional information requested by CMS during the review process.*** Currently, the self-nomination period is from September 1 until November 1. However, in order for CMS to process, review, and approve the QCDR measure submissions and provide QCDRs with sufficient time to respond to requests for information during the review process, while still meeting our goal to publish the list of approved QCDRs along with their approved QCDR measures prior to the start of the applicable performance period, CMS believes that an earlier self-nomination period is needed.
- Information Required at the Time of Self-Nomination ([p. 826](#)) Due to confusion on this issue, ***CMS proposes to update the regulations to state that QCDRs must include their CMS-assigned QCDR measure ID number when posting their approved QCDR measure specifications, and also when submitting data on the QCDR measures to us.***

QCDR Measure Requirements ([p. 827](#))

In addition to the QCDR measure criteria previously finalized at §414.1400(f), CMS proposes to apply select criteria used under the Call for Measures Process, as described in the CY 2018 QPP final rule (82 FR 53636). Specifically, 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 domain for patient and caregiver experience.***
- ***Measures that address efficiency, cost and resource use.***
- ***Measures that address significant variation in performance.***

As CMS gains additional experience with QCDRs in MIPS, it intends to further align these QCDR measure criteria with those of MIPS quality measures in future program years.

QCDRs Seeking Permission from Another QCDR To Use an Existing, Approved QCDR Measure ([p. 829](#))

In the CY 2018 QPP final rule (82 FR 53813), CMS finalized that beginning with the 2018 performance period, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. However, this policy has created unintended financial burden for QCDRs requesting permission from

other QCDRs who own QCDR measures, as some QCDRs charge a fee for the use of their QCDR measures. On the other hand, MIPS quality measures, while stewarded by specific specialty societies or organizations, are generally available for third party intermediaries, MIPS eligible clinicians, and groups to report on for purposes of MIPS without a fee for use.

CMS believes, that once a QCDR measure is approved for reporting in MIPS, it should be generally available for other QCDRs to report on for purposes of MIPS without a fee for use. As such, ***CMS proposes at §414.1400 (b)(3)(ii)(C) that beginning with the 2021 MIPS payment year, as a condition of a QCDR measure's approval for purposes of MIPS, the QCDR measure owner would be required to agree to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS and each applicable MIPS payment year. CMS also proposes that other QCDRs would be required to use the same CMS assigned QCDR measure ID.*** If a QCDR refuses to enter into such a license agreement, the QCDR measure would be rejected and another QCDR measure of similar clinical concept or topic may be approved in its place.

Qualified Registries (p. 830)

CMS refers readers to §414.1400 and the CY 2018 QPP final rule (82 FR 53815 through 53818) for its previously finalized policies regarding qualified registries.

Establishment of an Entity Seeking to Qualify as a Qualified Registry (p. 830)

Similar to changes proposed for QCDRs, ***CMS proposes to re-designate §414.1400(h)(2) as §414.1400(c)(2) to state that beginning with the 2022 MIPS Payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period*** (rather than January 1 of the performance period). These participants do not need to use the qualified registry to report MIPS data to us; rather, they need to submit data to the qualified registry for quality improvement.

Self-Nomination Period (p. 831)

CMS proposes that, beginning with the 2022 MIPS payment year, entities seeking to qualify as qualified registries must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year (e.g., or the CY 2020 performance period, the self-nomination period would begin on July 1st, 2019 and end on September 1st, 2019). Currently, the self-nomination period is from September 1 until November 1

Health IT Vendors or Other Authorized Third Parties That Obtain Data from MIPS Eligible Clinicians' Certified EHR Technology (CEHRT) (p. 832)

CMS proposes to codify the following previously finalized policies:

- ***HIT vendors that obtain data from a MIPS eligible clinician, like other third-party intermediaries, would have to meet all criteria designated by CMS as a condition of their qualification or approval to participate in MIPS as a third-party intermediary (at §414.1400(d))***
- ***HIT vendor means an entity that supports the HIT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT) (at §414.1305)***

CMS-Approved Survey Vendors (p. 833)

CMS proposes at §414.1400(e) to codify previously finalized criteria and requirements for a CMS-approved survey vendor to participate in MIPS. Entities seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data. CMS proposes several criteria that these survey vendors must comply with, which are outlined in this section.

Auditing of Third Party Intermediaries Submitting MIPS Data (p. 835)

CMS is not proposing any changes to these policies, which were finalized in the CY 2018 QPP final rule (82 FR 53819).

Remedial Action and Termination of Third Party Intermediaries (p. 835)

CMS proposes multiple technical changes to amend, clarify, and streamline its policies related to remedial action and termination. For example, CMS proposes to amend the timeframes by which a third-party intermediary must submit a Corrective Action Plan (CAP) or come into compliance. ***Specifically, it proposes §414.1400(f)(2), which requires third party intermediaries to submit a CAP or correct the deficiencies or data errors by the date specified by CMS.***

In the CY 2017 QPP final rule, CMS finalized its policy regarding data inaccuracies at §414.1400(k)(4). ***CMS proposes at §414.1400(f)(3) to expand data inaccuracies to include a determination by CMS that data is inaccurate, unusable, or otherwise compromised.*** However, CMS is not proposing to change the factors it may consider to make such a determination.

Public Reporting on Physician Compare (p. 838)

[Physician Compare](#) draws its operating authority from section 10331(a)(1) of the Affordable Care Act. CMS initiated a phased approach to publicly reporting performance scores that provide comparable information on quality and patient experience measures. A complete history of public reporting on Physician Compare is detailed in the CY 2016 PFS final rule (80 FR 71117 through 71122). More information about Physician Compare, including the history of public reporting and regular updates about what information is currently available, can also be accessed on the [Physician Compare Initiative website](#).

CMS will continue to rely on a phased approach to making this information public. CMS clarifies that although all information submitted under MIPS is technically available for public reporting, it does not mean all data under all performance categories will be included on either public-facing profile pages or the downloadable database. These data must meet the public reporting standards, first. CMS also is careful not to include too much information on public-facing profile pages so not to overwhelm website users. In addition, for each program year, CMS provides a 30-day preview period for any clinician or group with QPP data before the data are publicly reported on Physician Compare.

In the CY 2018 QPP final rule (82 FR 53823), CMS finalized a policy to publicly report on Physician Compare, either on profile pages or in the downloadable database, the final score for each MIPS eligible clinician and the performance of each MIPS eligible clinician for each performance category, and to periodically post aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category, as technically feasible, for all future years.

Quality (p. 840)

CMS previously finalized that it would not publicly report first year quality measures, meaning any measure in its first year of use in the quality performance category. ***CMS proposes to revise §414.1395(c) to indicate that it will not publicly report first year quality measures for the first two years a measure is in use in the quality performance category to encourage clinicians and groups to report new measures, get feedback on those measures, and learn from the early years of reporting measures before measure are made public.***

Cost (p. 841)

CMS previously finalized that it would not publicly report first year quality measures, meaning any measure in its first year of use in the quality performance category. ***CMS proposes to revise §414.1395(c) to indicate that it will not publicly report first year cost measures for the first two years a measure is in use in the cost performance category to help clinicians and groups get feedback on these measures and learn from the early years of these new measures being calculated.***

Improvement Activities (p. 841)

CMS previously finalized that for those eligible clinicians and groups that successfully meet the improvement activities performance category requirements, this information will be posted on Physician Compare as an indicator. It also finalized for all future years to publicly report first year activities if all other public reporting criteria are satisfied. No other changes to this category are being proposed.

Promoting Interoperability (PI) (p. 842)

In the CY 2018 QPP final rule (82 FR 53827), CMS finalized a policy to include an indicator on Physician Compare for any eligible clinician or group who successfully meets the PI performance category, as technically feasible, for all future years. “Successful” performance is defined as obtaining the base score of 50 percent (82 FR 53826). CMS also finalized a policy to include on Physician Compare, either on the profile pages or in the downloadable database, as technically feasible, additional information, including, but not limited to, objectives, activities, or measures specified in the CY 2018 QPP final rule (82 FR 53827; see 82 FR 53663 through 53688). CMS also finalized for all future years to publicly report first year PI objectives, activities, and measures if all other public reporting criteria are satisfied. In addition, it finalized that it would indicate “high” performance, as technically feasible and appropriate, in year two of the QPP (2018 data available for public reporting in late 2019). “High” performance is defined as obtaining a score of 100 percent (82 FR 53826 through 53827).

In response to user testing and in an effort to simplify this category, CMS proposes not to include the indicator of “high” performance and to maintain only an indicator for “successful” performance in the PI performance category beginning with year two of the QPP (2018 data available for public reporting in late 2019). CMS seeks comment on this proposal and on the type of EHR utilization performance information stakeholders would like CMS to consider adding to Physician Compare in the future.

Achievable Benchmark of Care (ABC™) (p. 843)

Background

In the CY 2018 QPP final rule (82 FR 53829), CMS finalized a policy to use the Achievable Benchmark of Care (ABC™) methodology to determine a benchmark for the quality, cost, improvement activities, and PI data, as feasible and appropriate, by measure and collection type for each year of the QPP based on the most recently available data each year. CMS also finalized a policy to use this benchmark as the basis of a 5-star rating for each available measure, as feasible and appropriate. For a detailed discussion of the ABC™ methodology, and more information about how this benchmark together with the equal ranges method is currently used to determine the 5- star rating system for Physician Compare, see the CY 2018 QPP final rule (82 FR 53827 through 53829). Additional information, including the Benchmark and Star Rating Fact Sheet, can be found on the [Physician Compare Initiative website](#).

Historical Benchmarks (p. 844)

CMS proposes to modify its existing policy to use the ABC™ methodology to determine benchmarks for the quality, cost, improvement activities, and PI performance categories based on historical data, as feasible and appropriate, by measure and collection type, beginning with year three of the QPP (2019 data available for public reporting in late 2020).

In the initial years of the QPP, CMS anticipated year-to-year changes in the measures available. As such, it finalized a policy to determine the benchmark using the most recently available data (82 FR 53829). This ensured that a benchmark could be calculated despite potential year-to-year measure changes, but it also meant that the benchmark was not known to clinicians and groups prior to the performance period. However, by year three of the program (2019 data available for public reporting in late 2020), CMS expects enough year-to-year stability in the measures available for reporting across all MIPS performance categories to use historical data to produce a reliable and statistically sound benchmark for most measures, by measure and collection type.

Under its proposal, benchmarks would be based on performance data from a baseline period or, if such data is not available, performance data from the performance period. The baseline period would be the 12-month calendar year that is 2 years prior to the applicable performance period. The benchmarks would be published prior to the start of the performance period, as technically feasible. For example, for the CY 2019 performance period, the benchmark developed using the ABC™ methodology would be calculated using CY 2017 performance period data and would be published by the start of CY 2019, as feasible and appropriate. If historical data is not available for a particular measure, we would indicate that and calculate the benchmark using performance data from the performance period.

This approach of utilizing historical data would be consistent with how the MIPS benchmarks are calculated for purposes of scoring the quality performance category. It also would provide clinicians with valuable information about the benchmark to meet to receive a 5-star rating on Physician Compare before data collection starts for the performance period.

QCDR Benchmarks (p. 845)

CMS proposes to extend the use of the ABC™ methodology and equal ranges method to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures, as feasible and appropriate, using current performance period data in year two of the QPP (2018 data available for public reporting in late 2019), and using historical benchmark data when possible as proposed above, beginning with year three of the QPP (2019 data available for public reporting in late 2020).

Currently, only MIPS measures are star rated on Physician Compare. QCDR measures are publicly reported as percent performance rates. As more QCDR measure data is available for public reporting and appreciating the value of star rating the measures presented to website users, CMS believes star rating the QCDR measures will greatly benefit patients and caregivers as they work to make informed health care decisions. CMS also believes that reporting all measure data in the same way will ease the burden of interpretation placed on site users and make the data more useful to them.

Voluntary Reporting (p. 846)

In the CY 2018 QPP final rule (82 FR 53830), CMS finalized a policy to make available for public reporting all data submitted voluntarily across all MIPS performance categories, regardless of collection type, by eligible clinicians and groups that are not subject to the MIPS payment adjustments, as technically feasible, for all future years. CMS also finalized that during the 30-day preview period, these eligible clinicians and groups may opt out of having their data publicly reported on Physician Compare (82 FR 53830). If they do not opt out, their data will be available for inclusion on Physician Compare if it meets all public reporting standards. No other changes are being proposed to this policy.

APM Data (p. 847)

In the CY 2018 QPP final rule (82 FR 53830), CMS finalized a policy to publicly report the names of eligible clinicians in Advanced APMs and the names and performance of Advanced APMs and APMs that are not

considered Advanced APMs related to the QPP, such as Track 1 Shared Savings Program Accountable Care Organizations (ACOs), as technically feasible, for all future years. CMS also finalized a policy to link clinicians and groups and the APMs they participate in on Physician Compare, as technically feasible. No other changes are being proposed to this policy.

Overview of the APM Incentive ([p. 848](#))

Definitions and Regulatory Text Changes ([p. 848](#))

CMS proposes to make a minor alteration to the list of definitions it uses for implementation of the APM Incentive Payment:

- ***Qualifying APM Participant:*** modify to provide that a QP is an eligible clinician determined by CMS to have met or exceeded the relevant QP Payment Amount or QP patient count threshold for the year based on participation in or with an ***APM Entity*** that is participating in an Advanced APM ([p. 849](#)). (The definition previously referred to an “Advanced APM Entity” which was a term eliminated in a previous rule).

Advanced APM Criteria

Use of CEHRT ([p. 850](#)). CMS previously finalized that in order to meet the “Use of CEHRT” Advanced APM criterion, an Advanced APM must require that at least 50 percent of eligible clinicians in each APM Entity use CEHRT to document and communicate clinical care with patients and other health care professionals ([p. 850](#)). In line with CMS’ heightened priority for interoperability, ***CMS proposes that beginning in CY 2019, in order to be an Advanced APM, the APM must require that at least 75 percent of eligible clinicians in each APM Entity use CEHRT to document and communicate clinical care with patients and other health care professionals ([p. 851](#)).***

MIPS Comparable Quality Measures ([p. 852](#)).

- ***“Evidence-based, reliable and valid”:*** CMS previously finalized that to be an Advanced APM one of the quality measures upon which the APM bases payment must have an evidence-based focus, be reliable, and meet at least one of the following criteria:
 - Used in the MIPS Quality Performance Category;
 - Endorsed by a consensus-based entity;
 - Developed under Social Security Act §1848(s) (i.e. the Secretary’s Annual Quality Measure Development Plan)
 - Submitted in response to the MIPS Call for Quality Measures; or
 - Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid ([p. 853](#))

CMS notes that it did not intend to convey that a measure on the MIPS final list or that was submitted in the MIPS Call for Quality Measures that is not evidence-based would meet the criterion. CMS states that the same is true for QCDR measures. A QCDR measure can be included if it is endorsed by a consensus-based entity or has independent verification or for CMS to make its own determination that the measure is evidence-based, reliable, and valid before considered a “MIPS-comparable measure” ([p. 854](#)). ***CMS acknowledges ambiguity in its finalized language and states that it will use the more permissive interpretation of the regulation text so that quality measures will meet the criterion if submitted if included in the Quality Measure Development plan (§1481(s)) or in response to the MIPS Call for Quality Measures ([p. 854](#)).***

However, beginning January 1, 2020, ***CMS proposes to change the regulation so that it states that at least one of the quality measures upon which an Advanced APM bases payment must be finalized on***

the MIPS final list of measures; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidence-based, reliable, and valid ([p. 855](#)).

- ***Outcome Measure Requirement:*** CMS previously finalized a requirement that an Advanced APM must base payment on at least one outcome measure, but the requirement does not apply if CMS determines that there are no available or applicable outcome measures in the MIPS quality measure lists for the Advanced APM in the first QP performance period. Current regulation does not require that the outcome measure be evidence-based, reliable, and valid. Effective January 1, 2020, ***CMS proposes to modify regulation to explicitly state that the outcome measure must be evidence-based, reliable, and valid unless there is no available or applicable outcome measure*** ([p. 856](#)).

Bearing Financial Risk for Monetary Losses ([p. 857](#)). CMS previously finalized two ways in which an APM can meet the Nominal Amount standard. An APM would meet the Nominal Amount standard if under the terms of the APM, the total amount that an APM Entity potentially owes CMS or forgoes is at least:

- ***Revenue-Based Standard:*** At least 8 percent of the average estimated total Medicare Parts A and B revenues of participating APM Entities. CMS previously sought comment on whether this revenue standard threshold should change for CY 2019 performance year (e.g. 15 percent of revenue or 10 percent so long as risk is at least equal to 1.5 percent of expected expenditures for which an APM Entity is responsible under the APM ([p. 857](#))). ***CMS proposes to maintain the generally applicable revenue-based standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities through QP Performance Period 2024*** ([p. 858](#)). ***CMS seeks comment on whether it should consider raising the nominal amount standard to 10 percent*** ([p. 859](#)).
- ***Benchmark-Based (Expenditure-based) Standard:*** For all QP performance periods, 3 percent of the expected expenditures for which an APM entity is responsible under the APM. (For episode payment models, “expected expenditures” means the target price for an episode). ***CMS seeks comment on whether it should increase the Expenditure-based Standard to 4 percent for QP performance period 2025 and later*** ([p. 859](#)).

Qualifying APM Participant (QP) and Partial QP Determinations ([p. 860](#))

QP Determination Claims Run Out. Medicare previously finalized that the QP Performance Period will run from January 1 through August 31 of the calendar that is 2 years prior to the payment year. CMS also finalized that it will make QP determinations at three separate snapshot dates (March 31, June 30, and August 31). CMS believes that providing eligible clinicians notification of their QP status more quickly after the snapshot dates is warranted to reduce burden on physicians. Therefore, ***CMS proposes that for each of the QP determination snapshot dates, CMS will allow for a 60-day claims run out (instead of CMS’ previous 90-days claims run out)***⁴⁹ ***before calculating the Threshold Scores so that the 3 QP determinations will be completed approximately 3 months after the end of that determination period*** ([p. 861](#)).

Partial QP Election to Report to MIPS. CMS previously finalized that following a determination that eligible clinicians in an APM Entity are Partial QPs, the APM Entity will make an election whether to report on applicable measures and activities as required under MIPS ([p. 862](#)). CMS notes that the APM Entity must opt-in to consider its participants MIPS eligible.

CMS also finalized that in cases where the Partial QP determination is made at the individual level, the eligible clinician will make the election whether to report on applicable measures and activities as required under MIPS

⁴⁹ CMS found that there was only a 0.5 percent difference in claims processing completeness when using 60 days instead of 90 days as a claims run out period ([p. 861](#)).

and as a result be subject to the MIPS reporting requirements and payment adjustment. In the absence of an affirmative election by the eligible clinician, CMS previously finalized that it would use the eligible clinician's actual MIPS reporting activity to determine whether to exclude the Partial QP from MIPS ([p. 863](#)). ***CMS proposes to revise this policy so that if the eligible clinician does not make any election, they will not be subject to the MIPS reporting requirements and payment adjustment*** ([p. 864](#)). CMS believes this will help avoid scenarios where an eligible clinician is inadvertently subject to MIPS requirements.

All-Payer Combination Option ([p. 867](#))

CMS restated the All-Payer Combination Option QP Thresholds:

- All-Payer Combination QP Payment Amount Thresholds: [Table 57](#)
- All-Payer Combination QP Patient Count Thresholds: [Table 58](#)

CMS also reviewed the policies previously finalized policies for:

- The Payer Initiated Process: [p. 870](#)
- The Eligible Clinician Initiated Process: [p. 871](#)
- QP Determinations Under the All-Payer Combination Option: [p. 872](#)

Other Payer Advanced APM Criteria. CMS reiterated its goal to align policies under the Medicare Option and All-Payer Combination Option.

- ***Investment Payments:*** For the Financial Risk Standard, CMS stated that it received stakeholder feedback that CMS should take into account “business risk” costs such as IT, personnel, and other administrative costs. ***CMS is not proposing to modify its Other Payer Advanced APM Financial Risk Standard*** ([p. 873](#)). CMS notes however that an Other Payer arrangement could be structured so that the APM provides an “investment payment” to the participating APM Entities to assist with the practice transformation needed to participate in the payment arrangement, which could be structured in various ways. CMS provided several examples:
 - It could be structured similarly to the Medicare ACO Investment model where expected shared savings payments were pre-paid to encourage new ACOs to form in rural and underserved areas.
 - It could be structured so that the payment is made specifically to encourage participating APM Entities to continue to make staffing, infrastructure, and operational investments as a means of practice transformation.
 - “It could have a different structure entirely.” ([p. 873](#))
- ***Use of CEHRT:*** In order to align with Advanced APM policies earlier in the rule, ***CMS proposes that beginning in CY 2020, in order to be an Other Payer Advanced APM, the APM must require that at least 75 percent of eligible clinicians in each APM Entity use CEHRT to document and communicate clinical care with patients and other health care professionals*** ([p. 875](#)).

CMS notes that it has received stakeholder input that because CEHRT use has become so commonplace, it might not be expressly required under Other Payer payment arrangements. ***CMS proposes to modify its current policy to offer flexibility by stating that a payer or eligible clinician must provide documentation to CMS that CEHRT is used to document and communicate clinical care under the payment arrangement (at least 50 percent of eligible clinicians in 2019; at least 75 percent of eligible clinicians in 2020 and later) regardless of whether such CEHRT use is explicitly required under the terms of the payment arrangement*** ([p. 876](#)). CMS states that documentation could come from a variety of sources, including the level of CEHRT use in a particular state Medicaid program, for instance, by presenting data from ONC showing CEHRT adoption rates for all physicians in that state; commercial payers could document that CEHRT adoption rates within their networks meet or exceed the

requirements. ***CMS states that in order to determine whether the CEHRT use criterion was met, it will consider data from a payer or eligible clinician*** ([p. 877](#)).

- ***MIPS Comparable Quality Measures***: CMS makes proposals to align with those made under the Advanced APM section for the “[MIPS Comparable Quality Measures](#)” criterion ([p. 880](#)). The policies are proposed for effective dates of January 1, 2020.
- ***Financial Risk for Monetary Losses***: CMS previously finalized a Revenue-based Standard for the Financial Risk criterion for Other Payer Advanced APMs for QP Performance Periods of 2019 and 2020 of 9 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities ([p. 883](#)). CMS would only use this standard for Other Payer arrangements where financial risk is expressly defined in terms of revenue for the payment arrangement ([p. 884](#)). ***CMS proposes to maintain the generally applicable Revenue-based Nominal Amount Standard at 8 percent of total combined revenues from a payer of providers and suppliers in participating APM Entities for QP Performance Periods 2019 through 2024*** ([p. 884](#)).

Other Payer Advanced APM Determinations.

- ***Multi-Year Payment Arrangements***: CMS previously sought comment on the current duration of payment arrangements and whether creating a multi-year determination process (as opposed to the annual process as finalized) would encourage the creation of more multi-year payment arrangements, including what types of information would need to be submitted after the first year to update Other Payer Advanced APM determinations ([p. 885](#)). After feedback, ***CMS proposes to maintain the annual submission process with modification (for both the Payer Initiated and Eligible Clinician Initiated Processes)*** ([p. 885](#)):
 - ***CMS proposes that beginning with 2019 and 2020 submission periods, after the first year that a payer, APM Entity, or eligible clinician (“requester”) submits a multi-year payment arrangement that CMS determines is an Other Payer Advanced APM, the requester would only need to submit information on relevant changes to the payment arrangement for each successive year for the remaining duration of the payment arrangement*** ([p. 886](#)).
 - ***CMS proposes that the multi-year Other Payer Advanced APM determination would remain in effect until the arrangement terminates or expires, but not longer than 5 years*** ([p. 887](#)).
- ***Payer Initiated Process- Remaining Other Payers***: CMS previously finalized that beginning prior to the 2019 QP Performance Period, CMS would allow for determination consideration, payment arrangements under Medicaid, Medicare Health Plans, and payment arrangements aligned with a CMS Multi-Payer Model. CMS also finalized that all other payers (including commercial and other private payers) can request determinations prior to the 2020 QP Performance Period ([p. 888](#)). CMS refers to these as the “Remaining Other Payers.” ***CMS is aligning the Payer Initiated Process for Remaining Other Payers with the previously finalized provisions for the Payer Initiated Process for Medicare, Medicare Health Plans, and CMS Multi-Payer Models*** ([p. 889](#)). CMS included previous policies and application to Remaining Other Payers for:
 - Guidance and Admission Forms: [p. 889](#)
 - Submission Period: [p. 890](#)
 - Timeline for Other Payer Advanced APM Determinations: [Table 59](#)
 - CMS Determination: [p. 891](#)
 - CMS Notification: [p. 892](#)
 - CMS Posting of Other Payer Advanced APMs: [p. 892](#)

- *Payer Initiated Process- CMS Multi-Payer Models: CMS proposes to eliminate the Payer Initiated Process and submission form that were specifically for CMS Multi-Payer Models (p. 893).* CMS believes these models can utilize the submission forms already in existence for other payers. CMS noted that the elimination of the form does not mean that it is prohibiting submissions on CMS Multi-Payer Models, just aligning the processes for the other payers.

Calculation of the All-Payer Combination Option Threshold Scores and QP Determinations.

- *Full TIN Determination Requests:* CMS previously finalized that an eligible clinician could request a QP determination and that an APM Entity could request a QP determination at the APM Entity level and where CMS received both requests, CMS would make the determination at both levels on the eligible clinician could become a QP on either determination (p. 894). CMS also requested input on whether it should include a third alternative whereby CMS would allow QP determinations at the TIN level when all clinicians who have reassigned billing rights to the TIN are included in a single APM Entity. ***CMS proposes to add the third alternative to allow requests for QP determinations at the TIN level where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity (p. 895).*** Therefore, this would be available to all TINs part in Full TIN APMs (e.g. the Medicare Shared Savings Program).
 - ***CMS proposes that it would assess QP status based on the most advantageous result for each individual eligible clinician (p. 895).***
 - ***CMS proposes to allow the TIN level requests for QP determinations only in instances where the entire TIN has met the Medicare threshold for the All-Payer Combination Option (p. 896).***
- *All-Payer Combination Payment Amount and Patient Count Thresholds.* CMS is concerned that there is confusion about the relationship between the payment amount and patient count thresholds in the context of the All-Payer Combination Option (p. 897). ***CMS reiterates its policy that the minimum Medicare threshold needed to qualify for QP determination for the All-Payer Combination option may be calculated based on either payment amount or patient count; while the All-Payer threshold (which includes Medicare data) can still be based on the payment amount or patient count regardless of how the Medicare threshold was calculated (p. 897).*** CMS is providing clarifying language updates to the regulations (p. 898).
- *Medicare Threshold Score Weighting for TIN Level All-Payer Combination Option Calculations:* CMS had previously finalized a weighting methodology to ensure that where eligible clinicians are assessed under the Medicare Option as an APM Entity group that the Medicare portion of their All-Payer calculation under the All-Payer Combination option would not be lower than the Medicare Threshold Score received for participation in the APM Entity group (p. 899). ***CMS proposes to extend this same weighting methodology to TIN-level Medicare Threshold Scores when a TIN is assessed under the Medicare Option as part of an APM Entity group and receives a Medicare Threshold Score at the APM Entity group level (p. 899).***

Quality Payment Program Technical Correction: Regulation Text Changes (p. 904)

This section discusses some technical revisions being made to regulations to correct several technical errors and to reconcile the text of several regulations with the final policies adopted through notice and comment rulemaking.

Requests for Information (p. 908)

Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers (p. 909)

Currently, Medicare- and Medicaid-participating providers and suppliers are at varying stages of adoption of health information technology (health IT). Many hospitals have adopted electronic health records (EHRs), and CMS has provided incentive payments to eligible hospitals, critical access hospitals (CAHs), and eligible professionals who have demonstrated meaningful use of certified EHR technology (CEHRT) under the Medicare EHR Incentive Program. As of 2015, 96 percent of Medicare- and Medicaid-participating non-Federal acute care hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care. While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many localities and regions throughout the Nation.

CMS is firmly committed to the use of certified health IT and interoperable EHR systems for electronic healthcare information exchange to effectively help hospitals and other Medicare- and Medicaid-participating providers and suppliers improve internal care delivery practices, support the exchange of important information across care team members during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). The Office of the National Coordinator for Health Information Technology (ONC) acts as the principal Federal entity charged with coordination of nationwide efforts to implement and use health information technology and the electronic exchange of health information on behalf of the Department of Health and Human Services.

In light of the widespread adoption of EHRs along with the increasing availability of health information exchange infrastructure predominantly among hospitals, CMS is interested in hearing from stakeholders on how it could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, CMS might consider revisions to the current CMS CoPs for hospitals, such as: requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested.

CMS specifically invites stakeholder feedback on the following questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information:

- **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?**
- **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, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-91), 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, implementing regulations related to the HIPAA privacy and security standards), 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?

CMS invites members of the public to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. CMS is particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. CMS also welcomes the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers. CMS has received stakeholder input through recent CMS Listening Sessions on the need to address health IT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and post-acute care providers, behavioral health providers, clinical laboratories and social service providers, and CMS would also welcome specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers as well.

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information (p. 918)

This CMS request for information (RFI) is a follow-up to [similar provisions included in the FY 2019 Inpatient Prospective Payment System \(IPPS\) proposed rule](#). In that discussion, CMS discussed its continued efforts to post charge data for hospitals and physicians on the CMS website as well as its general desire to improve transparency. CMS also [proposed, as part of that rule](#), to mandate that hospitals make their standard charges available via the internet in a machine-readable format, updated annually or more often as appropriate. While CMS stated that the proposal was directed at hospitals, **CMS stated that it encourages all providers and suppliers “to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be” and “to update this information at least annually, or more often as appropriate to reflect current charges (p. 919).**

CMS reiterated concerns from the FY 2018 IPPS proposed rule, specifically citing (p. 919):

- Patients being surprised by out-of-network bills for physicians (e.g. anesthesiologists and radiologists) who provide services at in-network hospitals;
- Patients being surprised by facility fees and physician fees for emergency room visits;
- Chargemaster data do not provide useful information for patients in determining what the patient is likely to pay for a particular service or hospital stay.

CMS is considering ways to improve the accessibility and usability of current charge information. In particular CMS asks a series of questions as part of this RFI (beginning on [p. 920](#)), including questions related to:

- How to define standard charges for various providers in various settings
- What types of information can providers and suppliers provide that would be most beneficial in enabling patients to use charge and cost information
- Whether providers and suppliers should be required to inform patients what the patient’s out-of-pocket costs will be prior to furnishing the service
- How Medigap coverage affects patient understanding of out-of-pocket costs before receipt of care

Collection of Information Requirements (p. 923)

As required under the Paperwork Reduction Act (PRA), CMS is soliciting public comment in advance of the following information collection requirements.

Proposed Information Collection Requirements (ICRs) (p. 924)

ICRs Regarding the Clinical Laboratory Fee Schedule (CLFS) (p. 925)

CMS’ aforementioned proposals regarding the CLFS may result in more data being reported. However, with regard to the CLFS-related requirements and burden, the agency notes that section 1834A(h)(2) of the Act provides that the Paperwork Reduction Act in chapter 35 of title 44 of the U.S.C. shall not apply to information collected under section 1834A of the Act (which is the new private payor rate-based CLFS).

ICRs Regarding Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (p. 927)

Consultations: CMS estimates it would take 2 minutes (0.033 hr) at \$200.54/hr for a family and general practitioner or 2 minutes at \$70.72/hr for a registered nurse to use a qualified CDSM to consult specified applicable AUC. In aggregate, CMS estimates an annual burden of 1,425,000 hours (43,181,818 consultations x 0.033 hr/consultation) at a cost of \$119,275,350 ($[0.1 \times 1,425,000 \text{ hr} \times \$200.54/\text{hr}] + [0.9 \times 1,425,000 \text{ hr} \times \$70.72/\text{hr}]$).

Annual Reporting: There is no need for review by OMB under the authority of the PRA; however, CMS assessed the impact and includes an analysis to this effect in the regulatory impact section below.

Significant Hardship Exception: The use of this process is not “information” as defined under 5 CFR 1320.3(h), and therefore, is exempt from requirements of the PRA.

Recordkeeping: CMS estimates that the average time for office clerical activities associated with this storage of information to be 10 minutes (0.167 hr) at \$17.25/hr for a medical secretary to perform 6,699 recordkeeping actions, since consultation will not take place in the year when a hardship is incurred and 2016 data from the Medicare EHR Incentive Program and the first 2019 payment year MIPS eligibility and special status file suggests this estimate of those seeking hardship (control number 0938-1314). In aggregate, CMS estimates an annual burden of 1,119 hours (6,699 recordkeeping activities x 0.167 hr) at a cost of \$19,303 (1,119 hr x \$17.25/hr).

ICRs Regarding the Medicare Shared Savings Program (p. 931)

CMS notes that section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the Shared Savings Program.

ICRs Regarding the Physician Self-Referral Law (p. 931)

While the writing and signature requirements are subject to the PRA, CMS contends that the associated burden is exempt under 5 CFR 1320.3(b)(2) given the time, effort, and financial resources necessary to comply with the writing and signature requirements would be incurred by persons without federal regulation during the normal course of their activities.

The Quality Payment Program (QPP) (p. 933)

[Table 62](#) presents a framework for understanding how the 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’ participation estimates are reflected in [Tables 65](#), [66](#), and [67](#) for the quality performance category, [Table 78](#) for the Promoting Interoperability performance category, and [Table 81](#) for the improvement activities performance category.

Quality Payment Program ICRs Regarding the Virtual Group Election (p. 942)

The virtual group election requirements and burden are currently approved by OMB.

Quality Payment Program ICRs Regarding Third-Party Reporting (p. 942)

[Table 63](#) represents the upper bound of qualified registry burden, with the potential for less additional MIPS burden if the registry already provides similar data submission services. [Table 64](#) shows the minimum and maximum burden on QCDRs and reflect adjustments due to review of self-nomination process and the number of respondents. The CMS-approved CAHPS for MIPS survey vendor requirements and burden are currently approved by OMB.

Quality Payment Program ICRs Regarding Data Submission (p. 952)

[Table 65](#) provides CMS’ estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the 2019 MIPS performance period. [Table 66](#) estimates the number of clinicians to submit data as individual clinicians via each collection type in Quality Payment Program Year 3. [Table 67](#) provides CMS’ estimated counts of groups or virtual groups to submit quality data on behalf of clinicians for each collection type in the 2019 MIPS performance period and reflects CMS’ assumption that the formation of virtual groups will reduce burden. [Table 68](#) provides CMS’ estimates of the burden associated with obtaining an account for the CMS Enterprise Portal (EIDM account). [Table 69](#) summarizes the range of total annual burden associated with clinicians submitting quality data via claims. [Table 70](#) provides CMS’ estimates of

the burden associated with MIPS CQM or QCDR reporting, which CMS expects to be the same regardless of whether the clinician is participating in MIPS as an individual or group. [Table 71](#) provides CMS' estimates of the burden associated with MIPS eCQM reporting. [Table 72](#) summarizes the burden for groups submitting to MIPS via the CMS Web Interface. [Table 74](#) estimates the burden for group registration for the CMS Web Interface, while [Table 75](#) estimates the burden for group registration for the CAHPS for MIPS survey.

Quality Payment Program ICRs Regarding the Nomination of Quality Measures (p. 979)

[Table 76](#) provides the estimated burden for the annual call for quality measures.

Quality Payment Program ICRs Regarding Promoting Interoperability Data (p. 982)

[Table 77](#) summarizes the burden for clinicians to apply for reweighting the Promoting Interoperability performance category to zero percent due to a significant hardship exception (including a significant hardship exception for small practices) or as a result of a decertification of an EHR. [Table 78](#) estimates the number of individual MIPS eligible clinicians and groups that will submit Promoting Interoperability performance data, while [Table 79](#) estimates the burden associated with submitting that data.

Quality Payment Program ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures (p. 988)

[Table 80](#) estimates the burden associated with the call for PI measures.

Quality Payment Program ICRs Regarding Improvement Activities Submission (p. 989)

[Table 81](#) estimates the number of organizations that will submit improvement activities on behalf of eligible clinicians, while [Table 82](#) estimates the burden for submitting such IAs.

Quality Payment Program ICRs Regarding the Nomination of Improvement Activities (p. 994)

[Table 83](#) estimates the burden for nominating IAs.

Quality Payment Program ICRs Regarding CMS Study on Factors Associated with Reporting Quality Measures (p. 997)

Because section 1848(s)(7) of the Act, as added by section 102 of the MACRA (Pub. L. 114-10) states that Chapter 35 of title 44, United States Code, shall not apply to the collection of information for the development of quality measures, CMS is not setting out such burden since the study shall inform the agency on the root causes of clinicians' performance measure data collection and data submission burdens and challenges that hinders accurate and timely quality measurement activities.

Quality Payment Program ICRs Regarding the Cost Performance Category (p. 997)

MIPS eligible clinicians are not required to provide any documentation as the cost performance category relies on administrative claims data.

Quality Payment Program ICRs Regarding Partial QP Elections (p. 998)

[Table 84](#) provides the estimated burden for partial QP election.

Quality Payment Program ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process and Eligible Clinician Initiated Process (p. 999)

[Table 87](#) provides the estimated burden for the submission of data for the all-payer QP determinations.

Quality Payment Program ICRs Regarding Voluntary Participants Election to Opt-Out of Performance Data Display on Physician Compare (p. 1006)

[Table 88](#) provides the estimated burden for clinicians and groups who will voluntarily participate in MIPS and will also elect not to participate in public reporting.

[Summary of Annual Quality Payment Program Burden Estimates \(p. 1007\)](#)

[Table 89](#) summarizes this proposed rule's burden estimates for the Quality Payment Program. [Table 90](#) provides the reasons for changes in the estimated burden for information collections in this proposed rule.

[Submission of PRA-Related Comments \(p. 1014\)](#)

CMS invites public comments on the aforementioned potential information collection requirements and will consider all ICR-related comments received.

Regulatory Impact Analysis (p. 1016)

[Overall Impact \(p. 1017\)](#)

CMS estimates that this rulemaking is "economically significant" as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. CMS notes that approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the Small Business Administration standards, and that there are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This proposed rule is considered an E.O. 13771 regulatory action because it is expected to result in regulatory costs. The estimated impact would be \$5 million in costs in 2019, \$4.114 billion in costs in 2020, and \$44 million in cost savings in 2021 and thereafter. Annualizing these costs and cost savings in perpetuity and discounting at 7 percent back to 2016, CMS estimates that this rule would generate \$174 million in annualized net costs for E.O. 13771 accounting purposes.

[Changes in Relative Value Unit \(RVU\) Impacts and Other PFS Impacts \(p. 1021\)](#)

CMS estimates the CY 2019 PFS conversion factor to be 36.0463, which reflects the budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) and the 0.25 percent update adjustment factor specified under section 1848(d)(18) of the Act. **CMS estimates the CY 2019 anesthesia conversion factor to be 22.2986**, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments. [Table 92](#) and [Table 93](#) present how CMS calculated the proposed PFS and Anesthesia conversion factors for 2019.

[Table 94](#) shows the payment impact on PFS services of the proposals contained in this proposed rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues would be different from those shown in the table. Column F shows the shows the estimated CY 2019 combined impact on total allowed charges of all the RVU changes by specialty. The most widespread specialty impacts of the proposed RVU changes are generally related to the changes to RVUs for specific services resulting from the Misvalued Code Initiative, including proposed RVUs for new and revised codes. Because office/outpatient E/M codes comprise a large volume of services in the PFS, much of the specialty level impacts are being driven by its proposal to establish a single payment rate for new patients and a single PFS rate for established patients for E/M visits levels 2-5 as well as other adjustments including: the E/M Multiple Procedure Payment Adjustment, the HCPCS G-code add-ons to recognize additional relative resources for certain kinds of visits, HCPCS G-codes to describe podiatric E/M visits, the technical adjustment to the PE methodology, and the HCPCS G-code for 30 minutes of prolonged services.

The estimated impacts for some specialties, including obstetrics/gynecology, urology, independent labs, and clinical psychologists, reflect increases relative to other physician specialties. These increases can largely be attributed to proposed increases in value for particular services, the proposed updates to supply and equipment pricing, and the proposed valuation of the E/M office visit codes that had a positive impact on specialties reporting a higher proportion of level 2 and level 3 office visits. Specialties such as OB/GYN and urology would

see an increase in payments from these proposals, due to a combination of single PFS rates for E/M visit levels and the add-on codes for inherent visit complexity.

The estimated impacts for several specialties, including allergy/immunology, diagnostic testing facilities, hematology/oncology, radiation therapy centers, and podiatry, reflect decreases in payments relative to payment to other physician specialties.

- Allergy/immunology experiences a decrease due to a reduction in PE RVUs based on updated supply pricing for certain codes frequently billed by this specialty.
- For the other specialties, these decreases can largely be attributed to proposed revaluation of individual procedures, proposed decreases in relative payment as a result of proposed updates to prices for medical supplies and equipment, and the continued implementation of previously finalized code-level reductions that are being phased-in over several years.
- For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the Clinical Laboratory Fee Schedule. As a result, the estimated 1 percent reduction for CY 2019 is only applicable to approximately 17 percent of the Medicare payment to these entities.
- Specialties such as podiatry and dermatology that would experience a decrease in payments are those that bill a large portion of E/M visits on the same day as procedures, and therefore would see a reduction based on the application of the E/M MPPR adjustments.
- Other specialties, such as rheumatology and hematology/oncology are estimated to experience a decrease in payments due to the E/M proposals because they may tend to bill greater proportion of level 4 and 5 E/M visits and the add-on codes for inherent visit complexity may not fully mitigate a reduction in their payments.

CMS reminds stakeholders that the estimated impacts are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under “downloads” on the [CY 2019 PFS proposed rule website](#). CMS selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties.

Effect of Changes Related to Telehealth (p. 1028)

CMS estimates there will only be a negligible impact on PFS expenditures from the proposed addition of two new codes, HCPCS codes G0513 and G0514, to the list of Medicare telehealth services.

Effect of Changes to Payment to Provider-Based Departments (PBDs) of Hospitals Paid under the PFS (p. 1029)

CMS notes that there will be no additional savings for CY 2019 relative to CY 2018 because its proposed PFS Relativity Adjuster of 40 percent maintains the current rate which was finalized for CY 2018.

Other Provisions of the Proposed Regulation (p. 1030)

Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-based Payments (p. 1030)

CMS cannot estimate the magnitude of savings over time attributable to [these proposals](#) because CMS cannot determine how many new drugs and biologicals subject to partial quarter pricing will appear on the ASP Drug Pricing files in the future or how many Part B claims for these products will be paid. This limitation also applies to contractor-priced drugs and biologicals that have HCPCS codes and are in their first quarter of sales. Finally, the claims volume for contractor-priced drugs and biologicals that are billed using miscellaneous or Not

Otherwise Classified codes, such as J3490 and J3590, cannot be quantified. Although CMS cannot estimate the overall savings to the Medicare Program or to beneficiaries, CMS would like to point out that this change in policy is likely to decrease copayments for individual beneficiaries who are prescribed new drugs. CMS does not anticipate that this change will result in payments amounts that are below acquisition cost or that the proposals will impair providers' or patients' access to Part B drugs.

Proposed Changes to the Regulations Associated with the Ambulance Fee Schedule (p. 1032)

CMS notes that there are no policy proposals associated with the self-implementing [legislative provisions](#) CMS is proposing to codify and no associated impact in this rule.

Clinical Laboratory Fee Schedule: Proposed Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory (p. 1033)

CMS estimates that its [proposal](#) could increase the number of laboratories required to report applicable information by an additional 835 laboratories. Presuming all 835 laboratories met all of the criteria necessary to receive applicable laboratory status, CMS estimates that an additional 250,500 records would be reported for the next data reporting period, or an increase in records reported of about 5 percent. CMS does not expect the additional reported data resulting from its proposed change will have a predictable, direct impact on CLFS rates.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services (p. 1037)

Impact of Consultations by Ordering Professionals (p. 1039)

CMS includes a proposal regarding who, when not personally performed by the ordering professional, may consult AUC through a qualified CDSM and still meet the requirements of its regulations. For the purposes of this analysis, CMS assumes that orders for advanced diagnostic imaging services would be placed by ordering professionals that are non-physician practitioners in the same percent as the numbers of non-physician practitioners are relative to the total number of non-institutional providers (that, is 40 percent). **CMS specifically solicits comment and data on alternative assumptions about the number of non-physician practitioners who order advanced imaging services.**

CMS also proposes that auxiliary personnel may perform the AUC consultation when under the direction of, and incident to, the ordering professional's services. Due to this proposed change, CMS estimates that the majority, or as many as 90 percent, of practices would employ the use of auxiliary personnel, working under the direction of the ordering professional, to interact with the CDSM for AUC consultation for advanced diagnostic imaging orders. CMS estimates a reduction in consultation burden from \$275,139,000 to \$122,508,675, which results in a proposed net burden reduction of \$152,630,325.

Impact of Significant Hardship Exceptions for Ordering Professionals (p. 1041)

CMS proposes to modify the significant hardship exception criteria to be specific to the Medicare AUC program and independent of other Medicare programs both in policy and process. CMS estimates the count of practitioners that will be ordering professionals under the AUC program to be 586,386. Given limitations in data, **CMS specifically request comments and data on the numbers of professionals in the specialties that actually order advanced imaging services.** CMS estimates that 6,699 ordering professionals who would self-attest to a significant hardship exception under the AUC program. If 6,699 separate ordering professionals require that a Medical Secretary perform the same clerical activity to store documentation supporting the self-attestation of a significant hardship on an annual basis, then this equates to a cost of approximately \$38,596 per year. **CMS seeks comment to inform these burden estimates.**

Impact of Consultations beyond the Impact to Ordering Professionals ([p. 1044](#))

Transfers from Ordering Professionals to Qualified CDSMs and EHR Systems ([p. 1045](#))

CMS estimates impact on the workflow of the AUC consultation that represents the acquisition cost, training, and maintenance of a qualified CDSM. CMS assumes three potential scenarios as low, medium, and higher burden assessments of this consultation requirement. First, CMS assumes that some number of ordering professionals consults a qualified CDSM available free of charge. Second, CMS assumes that some number purchase a qualified CDSM to integrate within an existing EHR system. Third, CMS assumes that some do not currently have an EHR system and, as a result of the statutory requirement to consult with AUC, would purchase an EHR system with an integrated qualified CDSM to consult specified applicable AUC for the purposes of this program

- In the lowest estimate of burden, CMS believes it is reasonable to estimate that as many as 75 percent of an assumed annual 40,000,000 orders for advanced diagnostic imaging services could occur at no additional cost beyond the time and effort to perform the consultation.
- For the medium estimate, CMS estimates that the time and effort to purchase, install, train, and maintain a qualified CDSM integrated into an EHR system to be \$394,770,600. **CMS seeks comment on the assumptions used to develop this estimate.** However, is also reasonable to assume that some ordering professionals may not need additional training in using a qualified CDSM because the EHR Incentive Program required CDS as a core measure, which may yield lower costs and burden to learn to incorporate decision support into the ordering workflow through shorter training times.
- For the higher estimate, CMS estimates a total one-time cost of \$963,208,359.20 in EHR system and integrated qualified CDSM infrastructure, or annualized cost over 5 years of \$192,641,671.84/year. **CMS seeks comment and information about the assumptions used to develop this estimate.** These estimates might be viewed as an upper bound of the impact of this program beyond consultation with a free tool and note that at the time of publication there were three free tools available as indicated on the [CMS website](#).

Impact to Medicare Beneficiaries ([p. 1050](#))

Additionally, CMS believes that the additional 2-minute consultation will impact the Medicare beneficiary when their advanced diagnostic imaging service is ordered by the ordering professional by introducing additional time to their office visit, leading to a burden estimate of \$68,001,000 per year. CMS notes that there could be process improvements that increase efficiency, which CMS estimates could offset the estimated burden by \$34,000,500 annually, but notes that it does not presently have a concrete solution and that **CMS is seeking comment on this analysis to inform future rulemaking.**

Considering the Impact of Claims-Based Reporting ([p. 1051](#))

CMS believes the proposal described in this proposed rule minimizes burden and maximizes efficiency by reporting through established coding methods, to include G-codes and modifiers, to report the required AUC information on Medicare claims.

Impact on Transmitting Order for Advanced Diagnostic Imaging Services ([p. 1052](#))

CMS estimates that including AUC consultation information on the order to the furnishing professional or facility would lead to total annual burden of \$114,540,000.

Impact on CDSM Developers ([p. 1052](#))

While CMS does not propose to require the use of a unique consultation identifier (UCI), CMS provides detail on its assessment of costs that would be incurred by CDSM developers under such a policy starting on [p. 1052](#).

Impact of Expanding Applicable Setting on Furnishing Professionals and Facilities ([p. 1054](#))

CMS proposes to add independent diagnostic testing facilities to the definition of applicable settings under this program. CMS estimates that 1 percent of advanced diagnostic imaging services will be furnished by independent diagnostic testing facilities.

CMS assumes that the majority of furnishing professionals and facilities will work to alter billing practices through automation processes that accommodate AUC consultation information when furnishing advanced diagnostic imaging services to Medicare beneficiaries. Therefore, CMS believes a transfer of costs and benefits will be made from furnishing professionals and facilities to medical billing companies to create, test, and implement changes in billing practice for all affected furnishing professionals and facilities. CMS estimates that the one-time update to implement an automated billing solution will cost \$1,740,640,000.

The Congressional Budget Office estimates that section 218 of the PAMA would save approximately \$200,000,000 in benefit dollars over 10 years from FY 2014 through 2024, which could be the result of identification of outlier ordering professionals and also includes section 218(a) of the PAMA—a payment deduction for computed tomography equipment that is not up to a current technology standard. Because CMS has not yet proposed a mechanism or calculation for outlier ordering professional identification and prior authorization, CMS is unable to quantify that impact at this time.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services ([p. 1058](#))

CMS discusses some evidence suggesting the potential for savings based on the use of AUC, but also concerns with extrapolating findings to the Medicare population. Taken together, these concerns will form the basis for CMS' continued examination of the impact of this and future rulemaking to maximize the benefits of this program. Additionally, CMS notes that some ordering professionals may find benefits to the patients they serve and provides a few examples.

Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) ([p. 1062](#))

CMS is proposing to align the eQMs available for Medicaid EPs in 2019 with those available for MIPS eligible clinicians for the CY 2019 performance period. CMS anticipates that this proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant. CMS expects that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2019 to maintain current eQM lists and specifications. CMS is also proposing changes to the EHR reporting periods under the Medicaid PI Program, and to provide states flexibility to set alternative, earlier final deadlines for EHR or eQM reporting periods. CMS expects that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems to meet specifications for the proposed reporting periods. Finally, CMS is proposing changes to the EP Meaningful Use Objectives and Measures. These proposed amendments are expected to reduce provider burden. Again, CMS expects that any changes these proposals might require to state systems would be minimal. State expenditures to make any such changes would also be eligible for 90 percent enhanced federal financial participation.

Medicare Shared Savings Program ([p. 1064](#))

Both of CMS' [proposed policies](#) are generally expected to have a minimal impact on affected ACOs.

Physician Self-Referral Law ([p. 1065](#))

CMS is proposing [regulatory updates](#) to implement the provisions of section 50404 of the BBA of 2018 pertaining to the writing and signature requirements in certain compensation arrangement exceptions to the statute's referral and billing prohibitions. CMS does not anticipate that it would have an impact. CMS expects that the proposal regarding temporary non-compliance with signature arrangements would reduce burden by giving parties additional time to obtain all required signatures.

Changes Due to Updates to the Quality Payment Program ([p. 1065](#))

CMS presents the overall and incremental impacts to the expected QPs and associated APM incentive payments. CMS notes that final data sets including data from the first performance period were not available in time to incorporate into this analysis. If technically feasible, CMS intends to use data from the CY 2017 MIPS performance period in the final rule.

Estimated Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs ([p. 1066](#))

CMS estimates that approximately 8,100 additional eligible clinicians in 8 TINs would become QPs if its policies are finalized representing TIN level QP determinations under the All-Payer Combination Option, and would qualify for approximately \$27 million in APM incentive payments for the 2021 payment year.

Overall, CMS estimates that between 160,000 and 215,000 eligible clinicians would become QPs, therefore be excluded from MIPS, and qualify for the lump sum incentive payment based on 5 percent of their Part B allowable charges for covered professional services in the preceding year. CMS estimates that the aggregate total of the APM incentive payment of 5 percent of Part B allowed charges for QPs would be between approximately \$600 and \$800 million for the 2021 payment year. These estimates include qualification based on the Medicare Only Option and the All-Payer Combination Option.

Estimated Number of Clinicians Eligible for MIPS Eligibility ([p. 1070](#))

CMS provides information on estimated MIPS eligibility and participation based on eligibility status on [Table 96](#). In [Table 97](#), CMS provides estimates on how each proposed eligibility policy affects the estimated number of MIPS eligible clinicians. In total, CMS includes 591,010 MIPS eligible clinicians as the baseline in its scoring model, against which policy changes are assessed. After all policy changes are included, CMS estimates that there will be 650,165 MIPS eligible clinicians for the 2019 MIPS performance period.

Estimated Impacts on Payments to MIPS Eligible Clinicians ([p. 1079](#))

CMS' impact analysis looks at the total effect of the proposed MIPS policy changes on the MIPS final score and payment adjustment for CY 2019 MIPS performance period/CY 2021 MIPS payment year. The estimated payment impacts presented in this proposed rule reflect averages by practice size based on Medicare utilization. CMS does not provide estimates by specialty. The payment impact for a MIPS eligible clinician could vary from the average and would depend on the combination of services that the MIPS eligible clinician furnishes. The average percentage change in total revenues would be less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems that would not be affected by MIPS payment adjustment factors. CMS notes that it is unable to assess performance for virtual groups as an entity due to lack of detailed performance information. CMS details its assumptions and limitations that apply to its methodology for estimating payment impacts starting on [p. 1080](#) and on [p. 1098](#). CMS notes that, while it applied a 90 percent participation assumption for clinicians in all practice sizes and an alternative of 80 percent participation because participation in legacy programs, CMS believes that the percentage of eligible clinicians participating in MIPS will increase under the proposed policy changes, so CMS did not apply a participation assumption.

Using the assumptions noted above, CMS' model estimates that \$372 million would be redistributed through budget neutrality and that the maximum positive payment adjustments are 5.6 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. [Table 98](#) shows the impact of the payments by practice size and whether the clinicians are expected to submit data to MIPS (based on whether they submitted data to either PQRS or the Medicare or Medicaid EHR Incentive program or if they are facility-based). [Table 98](#) also shows that 96.1 percent of MIPS eligible clinicians that participate in MIPS are expected to receive positive or neutral payment adjustments. Among those who CMS estimates would not submit data to MIPS, 88 percent are in small practices (28,096 out of 31,921 clinicians).

CMS plans to update these numbers in the final rule when CMS has actual MIPS participation for the 2017 MIPS performance period.

However, due to many limitations, CMS notes that there is considerable uncertainty around its estimates that is difficult to quantify in detail ([p. 1099](#)).

Potential Costs of Compliance with the Promoting Interoperability and Improvement Activities Performance Categories for Eligible Clinicians ([p. 1094](#))

Potential Costs of Compliance with Promoting Interoperability Performance Category ([p. 1095](#))

As discussed in the Collection of Information Requirements section, CMS assumes a slight decrease in overall information collection burden costs for the Promoting Interoperability performance category related to having fewer measures to submit. Although CMS' proposal would require some investment in systems updates, its existing policy is that 2015 Edition CEHRT will be required beginning with the 2019 MIPS performance period/2021 MIPS payment year. Therefore, CMS does not anticipate any additional costs due to this regulation.

Potential Costs of Compliance with Improvement Activities Performance Category ([p. 1095](#))

Given the lack of comprehensive historical data for improvement activities, and due to the unavailability of MIPS CY 2017 performance period data in time for this proposed rule, CMS does not know which improvement activities clinicians have elected. As a result, it is difficult to quantify the costs, cost savings, and benefits associated implementation of improvement activities. CMS will report the costs and benefits of implementing the improvement activities for the final rule if the performance data are received in time.

CMS believes the overall potential cost of compliance would not increase because of this proposed rule. Similarly, CMS believes that third parties who submit data on behalf of clinicians who prepared to submit data in the transition year will not incur additional costs as a result of this proposed rule. ***CMS request comments that provide additional information that would enable CMS to quantify the costs, costs savings, and benefits associated with implementation of improvement activities in the inventory.***

With respect to CMS proposals regarding the CMS study on burdens associated with reporting quality measures for each MIPS performance period, CMS estimates total estimated annual cost burden of \$10,116.

Alternatives Considered ([p. 1100](#))

For purposes of the payment impact on the Quality Payment Program, CMS views the performance threshold and the additional performance threshold to be the critical factors affecting the distribution of payment adjustments under the Quality Payment Program, and the alternatives that CMS considered focus on those policies. CMS ran estimates with varying performance thresholds and additional performance threshold.

- In the model with a performance threshold of 30 and an additional performance threshold of 70, CMS estimates that \$372 million will be redistributed through budget neutrality, there will be a maximum payment adjustment of 4.3 percent, and 8.7 percent of MIPS eligible clinicians will receive a negative payment adjustment.
- In the model with a performance threshold of 25 and an additional performance threshold of 80, CMS estimates that \$340 million will be redistributed through budget neutrality, there will be a maximum payment adjustment of 5.4 percent, and 6.9 percent of MIPS eligible clinicians will receive a negative payment adjustment.
- In the model with a performance threshold of 35 and an additional performance threshold of 80, CMS estimates that \$408 million will be redistributed through budget neutrality, there will be a maximum payment adjustment of 5.8 percent, and 10.9 percent of MIPS eligible clinicians will receive a negative payment adjustment.

CMS also ran estimates on the potential change in population if CMS set the third low volume threshold set at 100 as an alternative to 200 covered services. CMS estimates that 50,260 clinicians would elect to opt-in for a total population of 658,400.

CMS also estimated the effect of applying the opt-in policy without adding the third low-volume threshold criterion. CMS estimates that 19,621 clinicians would elect to opt-in for a total population of 627,761.

Impact on Beneficiaries and Other Impacts (p. 1101)

In general, CMS believes that many of the proposed changes in this rule, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare providers and beneficiaries.

Evaluation and Management Documentation (p. 1101)

CMS estimates that the evaluation and management (E/M) visit documentation changes proposed may significantly reduce the amount of time practitioners spend documenting these services. For a full-time practitioner whose panel of patients is 40 percent Medicare (60 percent other payers), CMS estimates approximately 51 hours saved per year. However, given ongoing documentation requirements, CMS believes the total amount of time practitioners spend on E/M visit documentation may remain high, despite the time savings that CMS estimates in this section could result from its E/M documentation proposals. **CMS welcomes public comments on its assumptions for the estimated reduction in documentation burden related to these proposals.**

Modernizing Medicare Physician Payment by Recognizing Communication Technology- Based Services (p. 1103)

CMS has several proposals for modernizing Medicare physician payment for communication technology-based services. CMS estimates that usage of these services will result in fewer than 1 million visits in the first year but will eventually result in more than 19 million visits per year, ultimately increasing payments under the PFS by about 0.2 percent. In order to maintain budget neutrality in setting proposed rates for CY 2019, CMS assumed the number of services that would result in a 0.2 percent reduction in the proposed conversion factor. CMS is also proposing to make separate payment for these services when furnished by RHCs and FQHCs. CMS estimates that the impact of this proposal would be less than \$1 million in additional Medicare spending in the first year and could eventually result in up to \$20 million in spending per year in future years.

Outpatient Therapy Services (p. 1105)

CMS is also proposing to end functional reporting for outpatient therapy services. CMS calculated that therapists in private practice (TPPs) would have saved between 128,804 and 193,206 hours (or 7,728,211 to 11,592,317 minutes) collectively in CY 2017 if the functional reporting requirements had not been in place. CMS believes this is a reasonable projection for the potential savings to TPPs, physicians and certain nonphysician practitioners in future years if CMS finalize its proposal. CMS calculated additional savings for providers of outpatient therapy services such as hospitals, SNFs and rehabilitation agencies, with its data indicating that therapy providers would have collectively saved between 242,116 to 363,174 hours (or 14,526,961 to 21,790,442 minutes) for CY 2017 if the functional reporting requirements had not been effective during that year.

Physician Supervision of Diagnostic Imaging Procedures (p. 1107)

CMS believes that the proposed changes to the physician supervision requirements for RAs furnishing diagnostic imaging procedures in this proposed rule may significantly reduce burden for physicians. However, CMS is not able to quantify the amount of time potentially saved by physicians and practitioners under its proposal to now require direct supervision of diagnostic imaging procedures done by RAs.

Beneficiary Liability (p. 1108)

Many proposed policy changes could result in a change in beneficiary liability as it relates to coinsurance and provides an example on [p. 1108](#).

Impact on Beneficiaries in the Quality Payment Program (p. 1109)

There are several changes in this rule that would have an effect on beneficiaries. In general, CMS believes that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the Physician Fee Schedule, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries, and specifically highlights the proposed addition of patient-reported outcome measures and changes to the Promoting Interoperability performance category.

Impact on Other Health Care Programs and Providers (p. 1109)

CMS estimates that CY 2019 Quality Payment Program will not have a significant economic effect on eligible clinicians and groups and believes that MIPS policies, along with increasing participation in APMs over time may succeed in improving quality and reducing costs. This may in turn result in beneficial effects on both patients and some clinicians, and CMS intends to continue focusing on clinician-driven, patient-centered care.

Estimating Regulatory Familiarization Costs (p. 1110)

CMS estimates that the total cost of reviewing this regulation is \$5,105,275 (\$859.04 x 5,943 reviewers).