

Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019

A SIDE-BY-SIDE COMPARISON OF KEY PROVISIONS FROM THE PROPOSED AND FINAL RULES FOR CY 2019

Overview

On November 1, 2018, the Centers for Medicare and Medicaid Services (CMS) released the [CY 2019 Medicare Physician Fee Schedule Final Rule and Interim Final Rule](#).

This major final rule includes updates to payment policies and payment rates for services furnished under the Medicare Physician Fee Schedule (PFS) on or after January 1, 2019, as well as provisions related to the 2019 Quality Payment Program (QPP). This final rule also addresses a subset of changes to the Medicare Shared Savings Program for Accountable Care Organizations (ACOs) proposed in the August 2018 proposed rule “[Medicare Shared Savings Program; Accountable Care Organizations--Pathways to Success](#),” as well as certain other revisions designed to update program policies under the Shared Savings Program.

The interim final rule implements amendments made by the SUPPORT for Patients and Communities Act to the Medicare telehealth provisions in the Social Security Act and regarding permissible telehealth originating sites for purposes of treatment of a substance use disorder or a co-occurring mental health disorder for telehealth services furnished on or after July 1, 2019 to an individual with a substance use disorder diagnosis.

Hart Health Strategies, Inc. has prepared the below “side-by-side” comparison of the proposed and final provisions with the goal of helping organizations better understand how CMS modified its proposals in response to stakeholder feedback. Page numbers and hyperlinks throughout the summary refer to the display version of the final rule, which has been posted to our website. A table of contents is also provided to help you more easily navigate the summary. To go directly to a specific section of the rule, please click on the page number listed in the table of contents.

Unless otherwise noted, these regulations are effective on January 1, 2019. CMS will accept comments on the interim final rule provisions through **December 31, 2018**.



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Provisions of the Final Rule for the PFS

Topic	Proposed Rule	Final Rule
Determination of Practice Expense Relative Value Units (PE RVUs)		
General	CMS reviews the step-by-step PE RVU methodology.	<p>CMS again reviewed the step-by-step PE RVU methodology beginning on p. 11.</p> <p>Pharmacists. CMS received a request that it begin including pharmacists as “active qualified health care providers” for purposes of calculating physician PE direct costs. CMS replied it is not aware of any policy that would prohibit CMS from including “costs in the direct PE input database used to develop PE RVUs for individual services, to the extent that inclusion of such costs would not lead to duplicative payments. <i>CMS requested input on the typical clinical labor costs involving pharmacists for particular PFS services</i> (p. 13)</p> <p>New Survey Data. CMS received requests that it consider a new national all-specialty PE/HR survey given how dated the current information is (p. 15). CMS agreed that a “routinely updated source of information” would be preferable and stated that it has engaged the RAND Corporation as a contractor “to explore the feasibility of updating the data used in the development of PE/RVUs) (p. 16).</p> <p>EMTALA-mandated Uncompensated Care. CMS received a request that it study indirect PE incurred by emergency departments, including EMTALA-mandated uncompensated care. The commenter stated that “emergency physicians are not able to schedule their patients and therefore cannot maximize the use of staff and resource, and that there are costs associated with being open and having to pay shift differentials over nights, weekends, and holidays.” CMS stated that it will take the information into consideration for future rulemaking (p. 16).</p>
Specialty-Specific PE/HR Data	<p>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,</p> <p>CMS proposed the following crosswalks:</p> <ul style="list-style-type: none"> Hospitalists (cross-walked to Emergency Medicine) 	<p><i>CMS finalized the crosswalks for Hospitalists and Advanced Heart Failure and Transplant Cardiology as proposed</i> (p. 18)</p>

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	<ul style="list-style-type: none"> Advanced Heart Failure and Transplant Cardiology (cross-walked to Cardiology) 	<p>PT/INR Monitoring Services. CMS also received a comment expressing concern about the PE/HR assigned to home PT/INR monitoring services because the services are provided by entities that are enrolled as independent testing facilities because there is no other specialty enrollment designation that better describes the suppliers and that these services are more therapeutic than diagnostic. The request recommended CMS consider a home PT/INR monitoring specialty distinct from independent testing facilities <i>and</i> to use either the Pathology or All Physicians specialty as a proxy for PE/HR. CMS stated that it would consider the proxy in future rulemaking and provided instructions for requesting new specialty designations (p. 17).</p>
Low Volume Codes	<p>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.</p> <p>CMS proposed the addition of 28 additional low volume codes to the list and makes “expected specialty” assignments for them.</p>	<p>CMS restates the 28 codes proposed for addition to the list of Low Volume Services in Table 1. <i>CMS finalized the addition of the 28 codes proposed for addition to the list of Low Volume Services</i> (p. 27).</p> <p>For several codes, while CMS finalized their inclusion on the Low Volume Code list, <i>CMS finalized a different “expected specialty” than either as proposed or currently assigned</i> (p. 25):</p> <ul style="list-style-type: none"> CPT 70577 (<i>Mri brain w/o dye</i>): CMS changed the “expected specialty” from Diagnostic Radiology to Neurosurgery CPT 70588 (<i>Mri brain w/ dye</i>): CMS changed the “expected specialty” from Diagnostic Radiology to Neurosurgery CPT 74235 (<i>Remove esophagus obstruction</i>): Changed “expected specialty” from Gastroenterology to Diagnostic Radiology CPT 75810 (<i>Vein x-ray spleen-liver</i>): Changed “expected specialty” from Diagnostic Radiology to Interventional Radiology CPT 78282 (<i>Gi protein loss exam</i>): Changed “expected specialty” from Diagnostic Radiology to Nuclear Medicine CPT 79300 (<i>Nuclr rx interstit colloid</i>): Changed “expected specialty” from Diagnostic Radiology to Nuclear Medicine CPT 33251 (<i>Incisional Electrophysiologic Procedures on the Heart and Pericardium</i>): Changed “expected specialty” from Cardiac Surgery to Thoracic Surgery as the “expected specialty” (p. 26). <p>In addition, <i>CMS finalized the addition of the following codes to the Low Volume List:</i></p>

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<p>Equipment Costs</p>	<p>Equipment Utilization Rate Assumption: CMS requested stakeholder submission of data to illustrate an alternative equipment utilization rate assumption.</p> <p>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. However, 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> <p>Interest Rates. CMS proposes no changes to equipment interest rates.</p>	<ul style="list-style-type: none"> • CPT 22857 (<i>Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), since interspace, lumbar</i>) and assigned orthopaedic surgery as the specialty (p. 25). • CPT 32654 (<i>Thoracoscopy (Video-assisted thoracic surgery [VATS]) on the Lungs and Pleura</i>) and assigned Thoracic Surgery as the “expected specialty” (p. 26). <p>CPT 33251 (<i>Incisional Electrophysiologic Procedures on the Heart and Pericardium</i>) and assigned Thoracic Surgery as the “expected specialty” (p. 26).</p> <p>In response to stakeholder comments, CMS stated that it continues to believe that certain highly technical pieces of equipment and equipment rooms are “less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure and are typically available for other patients even when one member of clinical staff may be occupied with a preservice or postservice task related to the procedure.” (p. 38).</p> <p>In response to comments suggesting that CMS rely on the “market-based research into equipment and supply pricing” that CMS had conducted would help inform more appropriate maintenance cost assumptions. However, CMS replied that the contractors that conducted the market-based study researched commercial pricing of supplies and equipment, but that it did not research equipment maintenance rates (p. 39).</p> <p>CMS published the interest rates in Table 4.</p>
<p>Direct PE Inputs for Specific Services</p>	<p>Standardization of Clinical Labor Tasks:</p> <p>Pathology Services: CMS does not believe that clinical labor tasks associated with pathology services would be dependent on number of blocks or batch size and continues to believe these values “accurately reflect the typical time it takes to perform these clinical labor tasks.”</p> <p>RUC PE worksheet: 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>	<p>CMS did not readdress this issue.</p>

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	<p>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.” 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> <p>Equipment Recommendation for Scope Systems: 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> <p>CMS is delaying general proposals for further changes to scope equipment until CY 2020. CMS proposes several specific updates:</p> <ul style="list-style-type: none"> • 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) <p>Technical Directions to Direct PE Input Database and Supporting Files: CMS proposes to correct “clerical” inconsistencies in the direct PE database, including to refine the quantity of minimum multi-specialty visit packs</p> <p>Updates to Prices for Existing Direct PE Inputs: Market-based Supply and Equipment Pricing Update: CMS reviewed its market research process and contractor activity and after reviewing the information provided new data from the contractor:</p>	<p><i>CMS did not finalize this proposal in its entirety</i> stating that it agreed with stakeholders “that the old clinical labor task is adequately accounted for by being divided into the new activity codes.” (p. 45). However, CMS states that there were instances where CMS found “that several of the codes did not include the old clinical labor task ‘Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocol by radiologist’ on a prior version of the PE worksheet” and in addition, several codes that contained CA014 for <i>Confirm order, protocol exam</i> did not contain any clinical labor for CA007 (<i>Review patient clinical extant information and questionnaire</i>), and <i>in these cases, CMS finalized its proposal</i> (p. 46).</p> <p>CMS stated that it continues to look forward to receiving “detailed recommendations” regarding scope equipment items that would be typically required and pricing information for each scope category (p. 49).</p> <p>CMS again acknowledged that the RUC has convened a Scope Equipment Reorganization workgroup, which was part of the rationale for the delay until 2020 (p. 51). CMS stated that it continues to believe that the scope pricing proposals should be delayed until CY 2020 so that it can incorporate the input from the workgroup (p. 52).</p> <p>CMS agreed with commenters that it was inappropriate to remove the SA048 supply pack from CPT 43200 (<i>Esophagoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)</i>) (p. 60). <i>CMS otherwise finalized the policy as proposed</i> (p. 61).</p> <p>CMS noted that it received many comments expressing concern about the transparency of the data used for medical equipment and supply</p>

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	<ul style="list-style-type: none"> • CMS proposed to adopt the updated direct PE input prices for supplies and equipment as recommended in the report and moving away from pricing data “that is more than a decade old.” • CMS proposed to phase in use of new direct PE input pricing over a four year period: <ul style="list-style-type: none"> ○ 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 proposed to fully implement those prices with no transition (because there is no current price) • 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 proposed it will be fully implemented in the year adopted without being phased-in. • 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 proposed 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. • CMS proposed to phase in any updated pricing established during the 4 year transition for very commonly used supplies and items included 	<p>pricing and that the data are not representative of small practices (p. 79). CMS provided its rationale as to why it believed the StrategyGen was the best option beginning on p. 80. CMS also believes that the large sample size used in StrategyGen negates commenters concern about whether the data is representative of small practices (p. 81). CMS also acknowledged that there were errors in the proposed rule that led to confusion about how GSA data was used as an input. CMS clarifies how the GSA pricing info was used beginning on p. 83. CMS also stated that the “current RUC process, while indispensable, does not provide for comprehensive pricing updates.” (p. 84). CMS also highlighted that detractors of the StrategyGen data did not identify other sources of pricing information, and rather, just suggested that CMS continue to rely on invoice submissions and review of individual codes through the RUC process (p. 88). Based on some data and invoices submitted on individual codes, CMS did update pricing information. These codes can be found in Table 9.</p> <p><i>CMS finalized the phase-in policy</i> (p. 88). CMS also believes that the four year transition allows more opportunities for public comment and submission of additional data (p. 87).</p> <p><i>CMS finalized this policy</i> (p. 93).</p> <p><i>CMS finalized this policy</i> (p. 93).</p> <p><i>CMS finalized this policy</i> (p. 93).</p> <p><i>CMS finalized this policy</i> (p. 93).</p>

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<u>Adjustment to the Allocation of Indirect PE for Some Office-based Services</u>	<p>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> <ul style="list-style-type: none"> 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): CPT 95165 and 95004 <p>Updates to Prices for Existing Direct PE Inputs: Breast Biopsy Software (EQ370): CMS received a request to update the pricing for Breast Biopsy software (EQ370) equipment. CMS does not propose to update the price or add the software to certain CPT codes citing its previous rationale that the current equipment attributed to the codes serves a similar clinical function. However, CMS proposed to change the name of EQ370 from “Breast Biopsy software” to “Breast MRI computer aided detection and biopsy guidance software.”</p> <p>Updates to prices for Existing Direct PE Inputs: Invoice Submission: 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>	<p>CMS restated its concern and request for comment on the impact the policies could have on these codes but <i>did not directly address these codes in this section, but rather, generally finalized its policy</i> (p. 93).</p> <p>CMS finalized its proposal to not update the price of Breast Biopsy Software (EQ370). However, <i>CMS received input and agrees that CAD Software equipment (ED058) is synonymous with Breast Biopsy software (EQ370). Therefore, CMS updated the pricing of ED058 and is deleting EQ370</i> (p. 100).</p> <p>CMS reiterated this policy (p. 101).</p>
	CMS proposes to continue its second year transition to this process for allocating indirect PE.	CMS stated that it received no comments on this, and <i>CMS finalized as proposed</i> (p. 102).

Determination of Malpractice Relative Value Units (RVUs)

<p>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. 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. 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 continued 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 cross-walked for categorization into CMS</p>	<p>CMS stated that it received “a few comments” on this topic and that it will consider the input in future rulemaking and for the required CY 2020 update (p. 104).</p>
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	specialty codes in order to develop the specialty-level risk factors and the MP RVUs.	
Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services		
Background	CMS acknowledged concerns about statutory restrictions on Medicare telehealth services. It 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.” This would be a separate category of services not subject to the statutory telehealth restrictions because CMS does not define them as telehealth services.	CMS reiterated its interpretation that these “communication technology-based services” are not “telehealth” services and “will be paid under the PFS like other physicians’ services” (p. 108).
Proposed Communication Technology-Based Services	<p>Brief Communication Technology-based Service (e.g. Virtual Check-in) (GHC11): 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> <p>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. CMS proposes the code values in the Valuation of Specific Codes section of the proposed rule.</p> <p>The proposed code is GVC11 (<i>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</i>)</p>	<p>CMS finalized its proposal to make separate payment for this service (p. 110; p. 119).</p> <p>CMS finalized the valuation of HCPCS G2012 as proposed (p. 117). See Valuation of Specific Codes section.</p> <p>CMS stated that the HCPCS code in the proposed rule was a placeholder and the finalized code will be HCPCS G2012 (<i>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</i>) (p. 110). CMS reiterates that the code requires direct interaction between the patient and the billing practitioner (p. 111). CMS received comments that the service be allowed to be billed by physical therapists. CMS reiterated that the code can only be reported by those that are allowed to furnish E/M services (p. 118).</p>

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	<p>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> <p>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.</p> <p>CMS proposes that this could only be used for established patients.</p> <p>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</p> <p>CMS seeks comment on what types of communication technology are utilized by professionals furnishing these services.</p> <p>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> <p>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> <p>CMS seeks comment on how clinicians can best document the medical necessity of this service.</p>	<p><i>CMS finalized and reiterated this requirement (p. 112).</i></p> <p><i>CMS finalized and reiterated this requirement (p. 112).</i></p> <p><i>CMS finalized the policy limiting the use of this code to established patients.</i> CMS defers to the CPT definition of “established patient” (i.e., “one who has received professional services from the physician or qualified health care professional or another physician or qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past 3 years” (p. 114).</p> <p><i>CMS finalized the descriptor language stating, “nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment” (p. 116).</i></p> <p>CMS received comments requesting that it not be overly prescriptive about what technology can be used and that technology is evolving rapidly. <i>CMS finalized allowing “audio-only real-time telephone interactions in addition to synchronous, two-way audio interactions that are enhanced with video or other kinds of data transmission” (p. 111).</i></p> <p><i>CMS finalized a policy that requires verbal consent of the patient be noted in the medical record for each billed service (p. 112).</i> CMS received requests to waive patient cost-sharing for this service, but CMS replied that it does not have the statutory authority (p. 118).</p> <p><i>CMS is not implementing a frequency limitation (p. 115).</i> CMS states that it will monitor utilization of the code to determine whether frequency limitations are necessary in the future (p. 111; p. 115).</p> <p>CMS reiterated that, like all other MPFS services, the service must be medically reasonable and necessary (p. 111; p. 117). CMS stated that it does “not want to impose undue administrative burden likely to discourage appropriate provision of these services, and are <i>therefore</i></p>

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	<p>Remote Evaluation of Pre-Recorded Patient Information (GRAS1): CMS proposed a specific code that describes remote professional evaluation of patient-transmitted information conducted via pre-recorded “store and forward” video or image technology.</p> <p>The code is GRAS1 (<i>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</i>). This would be a stand-alone service “that could be separately billed to the extend 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> <p>CMS proposes the code values in the Valuation of Specific Codes section of the proposed rule.</p> <p>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> <p>Interprofessional Internet Consultation: CMS proposed to begin separately paying for CPT codes (99446-9) describing interprofessional consultations for which CMS declined to make separate payment in the past. These 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.”</p> <ul style="list-style-type: none"> • CPT 99446 (<i>Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a</i> 	<p><i>not requiring any service-specific documentation requirements for this service.”</i> (p. 117).</p> <p>CMS finalized its proposal to pay separately for this service. CMS notes that it will monitor utilization of the code and reiterated that its use must be medically reasonable and necessary (p. 123; p. 127).</p> <p>The finalized code and descriptor are as follows: G2010 (<i>Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with 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</i>) (p. 123). CMS finalized that “follow-up” could take place via phone call, audio/video communication, secure text messaging, email, or patient portal communication (noting that there is no reference to “verbal” in the descriptor when referring to “follow-up”) (p. 126).</p> <p>CMS finalized the valuation of HCPCS G2010 as proposed (p. 125). See Valuation of Specific Codes section.</p> <p>CMS agreed with the commenters that suggested that it is more appropriate to limit use of the code to established patients, and thus, CMS finalized that G2010 is only for use with established patients (p. 124). In addition, CMS finalized requiring beneficiary consent could be verbal or written, “including electronic confirmation that is noted in the medical record for each billed service” (p. 125).</p> <p>CMS finalized payment for these codes (p. 137). CMS stated that it will monitor utilization of the interprofessional consultation codes and make adjustments in future rulemaking if needed (p. 134). CMS clarified that “the billing of these services should be limited to those practitioners that can independently bill Medicare for E/M visits, as interprofessional consultations are primarily for the ongoing evaluation and management of the patient, including collaborative medical decision making among practitioners,” and that the agency is “not finalizing any expansion of these services beyond their current scope.” (p. 136). (Note on RHCs/FQHCs: In a separate section of the rule CMS reminded stakeholders that RHC AIR and FQHC PPS payments include</p>

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	<p><i>verbal and written report to the patient's treating/requesting physician or other qualified health care professional; <u>5-10 minutes of medical consultative discussion and review</u>)</i></p> <ul style="list-style-type: none"> • CPT 99447 (<i>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; <u>11-20 minutes of medical consultative discussion and review</u>)</i>) • CPT 99448 (<i>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; <u>21-30 minutes of medical consultative discussion and review</u>)</i>) • CPT 99449 (<i>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; <u>31 minutes or more of medical consultative discussion and review</u>)</i>) <p>CMS also proposed to begin separately paying for two new codes (994X0 and 994X6) to describe additional consultative services.</p> <ul style="list-style-type: none"> • CPT 99451 (<i>Interprofessional telephone/Internet/electronic health record referral service(s) provided by a <u>treating/requesting</u> physician or qualified health care professional, <u>30 minutes</u>)</i>) • CPT 99452 (<i>Interprofessional telephone/Internet/electronic health record assessment and management service provided by a <u>consultative</u> physician including a written report to the patient's <u>treating/requesting</u> physician or other qualified health care professional, <u>5 or more minutes of medical consultative time</u>)</i>) <p>CMS proposed the code values in the Valuation of Specific Codes section of the proposed rule.</p> <p>CMS proposed 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> <p>CMS also seeks comment on its assumption that these are separately identifiable services attributable to a single beneficiary.</p>	<p>"all costs associated with a billable visits, and therefore consultations with other practitioners are not separately billable" (p. 763)).</p> <p>See Valuation of Specific Codes section of the rule.</p> <p><i>CMS finalized that patient verbal request is required and must be noted in the medical record for each service</i> (p. 136). CMS received requests to waive patient cost-sharing for this service, but CMS replied that it does not have the statutory authority (p. 135).</p>

Topic	Proposed Rule	Final Rule
Medicare Telehealth Services	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.”	
	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.	CMS stated that it appreciated feedback on how to address program integrity concerns but stated that “adding additional billing requirements may inhibit uptake for these services.” (p. 134).
	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).	CMS reiterated its policy to accept requests to add services to the list of Medicare Telehealth Services by February 10 th (p. 139).
	CMS proposed to add G0513 (<i>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)</i>) to the telehealth list on a Category 1 basis for 2019.	CMS finalized the addition of this code to the telehealth list (p. 149).
	CMS proposes to add G0514 (<i>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)</i>) to the telehealth list on a Category 1 basis for 2019.	CMS finalized the addition of this code to the telehealth list (p. 149).
	CMS declined to add the following requests to the list of telehealth services: <ul style="list-style-type: none"> Chronic Care Remote Physiologic Monitoring (CPT 99453, 99454, 99457) Interprofessional Internet Consultation (CPT 99451, 99452) Initial Hospital Care Services (CPT 99221-99223) <p>CMS also declined to change the requirements for the following codes:</p> <ul style="list-style-type: none"> Subsequent Hospital Care Services (CPT 99231-99233) Subsequent Nursing Facility Care Services (CPT 99307-99310) 	<p>CMS maintained its policies on these codes (p. 149).</p> <p>CMS maintained its policies on these codes (p. 149).</p> <p>In addition, CMS received a comment that it conduct a demo to evaluate the clinical benefit of PTs, OTs, and SLPs furnishing telehealth</p>

Topic	Proposed Rule	Final Rule
<p>Bundled Payment for Substance Use</p>	<p>CMS cited evidence that routine counseling can increase the effectiveness of treatment for substance abuse disorders (both with or without medication assisted treatment (MAT)). CMS believes that creating a bundled episode of</p>	<ul style="list-style-type: none"> • Requiring that no originating site facility fee should be paid in instances when the individual’s home is the originating site. • Allowing the Secretary to implement amendments in this section under an Interim Final Rule. <p>Therefore, <u>CMS is issuing an interim final rule with comment period to implement the requirements of the SUPPORT Act as described above (p. 157).</u></p> <ul style="list-style-type: none"> • <u>CMS adds the home of an individual as a permissible originating site for telehealth services furnished on or after July 1, 2019 to individuals with a substance use disorder diagnosis for purposes of treatment of a substance abuse disorder or a co-occurring mental health disorder.</u> • <u>Telehealth geographic requirements do not apply to telehealth services furnished on or after July 1, 2019 to individuals with a substance use disorder diagnosis for treatment of a substance use disorder or a co-occurring mental health disorder at an originating site (other than a renal dialysis facility).</u> <p>CMS highlighted that the SUPPORT Act did not amend the limitation of telehealth services to those that are on the Medicare telehealth list (p. 157).</p> <p>Medicare Payment for Certain Services Furnished by Opioid Treatment Programs (OTP)- Request for Information. CMS highlights that the SUPPORT Act creates a new Medicare benefit category for “opioid use disorder treatment services furnished by OTPs” under Medicare Part B, effective January 1, 2020 (p. 158). <u>CMS is requesting input regarding services furnished by OTPs, payment for these services, and additional conditions for Medicare participation for OTPs that would be useful for future rulemaking (p. 159).</u></p> <p><u>RHCs/FQHCs.</u> The support act provides extra payments to RHCs and FQHCs for services furnished for the treatment of opioid use disorders under certain circumstances. <u>CMS, with HHS, states that guidance implementing this provision “will be forthcoming.” (p. 765).</u></p> <p>CMS stated that it received several comments in response to this. CMS received comments stating. Concern that the format of the bundled episode of care could fail to take into account the variability of patient</p>

Topic	Proposed Rule	Final Rule
Disorders Comment Solicitation	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 CMS sought comment on creating a bundled payment of this type.	needs and the fact that treatment is often ongoing and does not have a definitive end point. CMS acknowledge this issues although stated that it does not believe it precludes payment bundles or global periods in this arena. CMS stated that its in future rulemaking that its intention is to increase access to necessary care. <u>CMS requested additional information it should consider in future rulemaking on payment structure and amounts for substance abuse treatment “that account for ongoing treatment and wide variability in patient needs for treatment of SUDs while improving access to care (p. 162).</u>

Potentially Misvalued Services under the PFS

CY 2019 Identification and Review of Potentially Misvalued Services	<p>Public Nomination</p> <p>For submissions 1 and 2, 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> <p><u>Submission 1</u></p>	<p>CMS reminded stakeholders that public nominations for misvalued codes for the following rulemaking cycle must be received by February 10th (p. 173). In CMS’ discussion of the codes, it is worth noting that CMS repeatedly stated that recent RUC review of a code should be a preclusion from being considered “potentially misvalued” (p. 178; p. 181).</p> <p>CMS acknowledged comments received criticizing the transparency of the submission and that the nomination letter was not made available. CMS replied that it believes it sufficiently summarized the contents of the letter (p. 173). CMS however notes that it posted the submission letter on the CMS website. The link shows that the submission was from Anthem (who cited data from an Urban Institute study to support the nomination of these codes as potentially misvalued).</p> <p>CMS noted that, “As previously indicated, <u>in the proposed rule we publish</u> the list of codes nominated as potentially misvalued, which allows the public the opportunity to comment on these codes; then, <u>in the final rule, we finalize</u> our list of potentially misvalued codes.” (p. 174). (NOTE: CMS completely ignores what it actually said in the proposed rule and contradicts itself between the proposed and final rule: “We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year’s PFS <u>proposed rule</u>, we <u>publish</u> the list of nominated codes <u>and indicate whether we proposed each nominated code as a potentially misvalued code</u>. The public has the</p>
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Topic	Proposed Rule	Final Rule
	<ul style="list-style-type: none"> CPT 27130 (<i>Total hip arthroplasty</i>) CPT 27447 (<i>Total knee arthroplasty</i>) CPT 43239 (<i>Egd biopsy single/multiple</i>) CPT 45385 (<i>Colonoscopy w/lesion removal</i>) CPT 70450 (<i>CT head w/o contrast</i>) CPT 93000 (<i>Electrocardiogram complete</i>) CPT 93306 (<i>Tte w/doppler complete</i>) <p><u>Submission 2</u></p> <ul style="list-style-type: none"> CPT 92992 (<i>Atrial septectomy or septostomy; transvenous method, balloon</i>) CPT 92993 (<i>Atrial septectomy or septostomy; blade method</i>) 	<p>opportunity to comment on these and all other proposed potentially misvalued codes. In that year’s final rule, we finalize our list of potentially misvalued codes.” (p. 101 of the proposed rule). In the proposed rule, CMS did not indicate whether it proposed the codes as potentially misvalued).</p> <ul style="list-style-type: none"> CPT 27130 (<i>Total hip arthroplasty</i>): CMS finalized the addition of this code to the list of potentially misvalued services (even though it did not affirmatively propose to do such in the proposed rule) (p. 182). (Additional discussion on p. 177) CPT 27447 (<i>Total knee arthroplasty</i>): CMS finalized the addition of this code to the list of potentially misvalued services (even though it did not affirmatively propose to do such in the proposed rule) (p. 182). (Additional discussion on p. 177). CPT 43239 (<i>Egd biopsy single/multiple</i>): CMS finalized the addition of this code to the list of potentially misvalued services (even though it did not affirmatively propose to do such in the proposed rule) (p. 182). (Additional discussion on p. 178) CPT 45385 (<i>Colonoscopy w/lesion removal</i>): CMS finalized the addition of this code to the list of potentially misvalued services (even though it did not affirmatively propose to do such in the proposed rule) (p. 182). Additional discussion on p. 178). CPT 70450 (<i>CT head w/o contrast</i>): CMS finalized the addition of this code to the list of potentially misvalued services (even though it did not affirmatively propose to do such in the proposed rule) (p. 182). (Additional discussion on p. 178; p. 179) CPT 93000 (<i>Electrocardiogram complete</i>): CMS finalized the addition of this code to the list of potentially misvalued services (even though it did not affirmatively propose to do such in the proposed rule) (p. 182). (Additional discussion on p. 180). CPT 93306 (<i>Tte w/doppler complete</i>): CMS finalized the addition of this code to the list of potentially misvalued services (even though it did not affirmatively propose to do such in the proposed rule) (p. 182). (Additional discussion on p. 180; p. 181). <p>CMS did not add these codes to the list of potentially misvalued codes given the impending review of these codes by the RUC (p. 183).</p> <p>CMS made no additional comments on code screens.</p>

Topic	Proposed Rule	Final Rule
	<p>Code Screens: CMS makes no mention of adding any additional screens or codes via its screens to the Potentially Misvalued Code initiative.</p> <p>Update on the Global Surgery Data Collection: 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 (<i>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</i>) 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. CMS continues to seek input on:</p> <ul style="list-style-type: none"> • How it can encourage reporting to ensure the validity of the data “without imposing an undue burden.” • Whether it needs to “do more to make practitioners aware of their obligation.” • Whether it should consider implementation of an “enforcement mechanism.” • Whether it is reasonable to assume that many visits are not being furnished (or whether there is an alternate explanation) • 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) • Whether the post-op visits are being delivered after the end of the global period and being reported and paid for separately • How to approach 10-day globals for which the preliminary data suggests post-op visits are rarely performed • Whether it should consider changing the global period and reviewing the code valuation • Whether it should consider requiring the use of modifiers regardless of whether a transfer of care is formalized 	<p>CMS stated that it will evaluate the comments received and “consider whether to propose action at a future date” and will “consider other actions to make sure affected practitioners are aware of the requirement” (p. 186). CMS also noted that MedPAC submitted support for converting all 10- and 90-day global codes to 0-day globals and revaluing them as such.</p>

Radiologist Assistants

Radiologist Assistants

CMS proposes 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

CMS finalized this policy with refinements ([p. 190](#)). CMS finalized its proposed revisions at §410.32 and adding a new paragraph (b)(4) that states that diagnostic tests that are performed by a registered

Topic	Proposed Rule	Final Rule
	rules. Specifically, CMS proposes 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.	<p>radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.</p> <p>CMS notes that it will be updating guidance contained in Pub. 100-04, Medicare Claims Processing Manual, Chapter 23 (available on the CMS website) (p. 189).</p>

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

Payment Mechanism & PFS Relativity Adjuster

In creating this new payment mechanism, CMS sought to ensure that the relativity in OPPS payment rates was maintained under the relative payment system of the MPFS. CMS had established a transitional policy of site-specific rates under the MPFS for the technical component (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.”

As it continues to explore other options to improve payment accuracy, CMS proposed to continue instructing nonexcepted off-campus PBDs to bill for nonexcepted items and services on an institutional claim to bill using the ~PN modifier.

CMS found that its updated analysis supports maintaining a PFS Relativity Adjuster of 40 percent for CY 2019. CMS proposed 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.”

CMS proposed maintaining its previously finalized policies for nonexcepted off-campus PBDs for supervision rules, beneficiary cost-sharing, and geographic adjustments.

CMS noted that as part of its continued analysis that it is “also analyzing PFS claims data to identify patterns of services furnished together on the same day” (p. 218). CMS also stated that it continues to be interested in feedback and is looking for recommendations “for ways in which CMS can improve pricing and transparency with regard to differences in payment rates across sites of service (p. 219).

CMS did not explicitly finalize continued use of the ~PN Modifier, but implicitly discusses its continued use in CY 2019 and going forward.

CMS finalized the PFS Relativity Adjuster at 40 percent “for 2019 and beyond until there is an appropriate reason and process for implementing an alternative” (p. 213).

CMS finalized these policies (p. 214).

Valuation of Specific Codes for CY 2019

CMS outlines proposed direct practice expense refinements for CY 2019 for the following services:

CMS outlines finalized direct practice expense refinements for CY 2019 for the following services:

Topic	Proposed Rule	Final Rule
	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • 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)

Topic	Proposed Rule	Final Rule
	<ul style="list-style-type: none"> • 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 GVCI1) • 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) 	<ul style="list-style-type: none"> • 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 GVCI1) • 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)

Topic	Proposed Rule	Final Rule
	<ul style="list-style-type: none"> Comment Solicitation on Superficial Radiation Treatment Planning and Management 	<ul style="list-style-type: none"> Comment Solicitation on Superficial Radiation Treatment Planning and Management

Evaluation & Management (E/M) Visits

[E/M Documentation Guidelines](#)

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. CMS proposed 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.

Lifting Restrictions Related to E/M Documentation:

- [Eliminating Extra Documentation Requirements for Home Visits](#) (CPT Codes 99341 – 99350): CMS proposed removing the requirement that the medical record document the medical necessity of furnishing the visit in the home rather than the office.
- [Eliminating Prohibition on Billing Same-Day Visits by Practitioners of the Same Group and Specialty](#): 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 solicited 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. CMS also seeks input on whether it should alternatively create exceptions or otherwise modify the manual provision rather than eliminate it. CMS requests examples of where the current instruction is not clinically appropriate.

"For CY 2019 and 2020, we will continue the current coding and payment structure for E/M office/outpatient visits, and therefore practitioners should continue to use either the 1995 or 1997 versions of the E/M guidelines to document E/M office outpatient visits billed to Medicare for 2019 and 2020 (with the exception of our final policy to eliminate redundant data recording.) ([p. 554](#)). CMS noted that it intends "to engage in further discussions with the public over the next several years to potentially further refine our policies for 2021 ([p. 569](#)).

CMS finalized this proposal effective January 1, 2019 ([p. 552](#); [p. 555](#)).

CMS made no policy changes but thanks commenters for the input and will "consider this issue further for potential future rulemaking." ([p. 557](#)).

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	<p>Documentation Changes for Office or Other Outpatient E/M Visits and Home Visits:</p> <ul style="list-style-type: none"> • <u>Providing Choices in Documentation – Medical Decision Making, Time, or Current Framework:</u> In order to determine the appropriate level of E/M visit, CMS proposed to allow practitioners to choose between: <ul style="list-style-type: none"> – Medical Decision Making (MDM); – Time; or – 1995 or 1997 Guidelines <p>For medical review, CMS proposes to apply “a <u>minimum documentation standard</u>” 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. 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.</p> <ul style="list-style-type: none"> – <u>Current Framework:</u> CMS’ proposed documentation for any level 2 through 5 visit would include: 	<p>CMS received comments both for and against allowing choice in documentation method for office/outpatient E/M visits (p. 566).</p> <p><u>In Favor:</u></p> <ul style="list-style-type: none"> • Choice/flexibility • MedPAC recommended paying based on time alone (p. 567). <p><u>Against/Concerns:</u></p> <ul style="list-style-type: none"> • Introduces too much variation in medical record format and content • Too many potential frameworks for use by auditors • Lack of clarity about whether the choice of documentation method is made on a case-by-case basis. • Time alone is not accurate measure of visit complexity • Time could be subject to gaming • Lack of detail on time thresholds and documentation requirements <p>Nonetheless, <i>for CY 2021, CMS will allow flexibility on how office/outpatient levels (levels 2 – 5) are documented by allowing practitioners to choose between current framework, MDM, or time. For level 5 visits, practitioners can use the current framework <u>or</u> the “current definition” of level 5 MDM; <u>or</u>, if using time, it requires documentation of the medical necessity of the visit and “that the billing practitioner personally spent at least the typical time associated with the level 5 CPT code that is reported face-to-face (40 minutes for an established patient and 60 minutes for a new patient.”</i> (p. 568; p. 570).</p> <p>CMS received comments expressing concern that a “minimum documentation standard” would result in “inadequate documentation for patient care, legal and other purposes.” Commenters also stated that there was an overestimation of the burden reduction that accompanies this proposal (and might even increase burden) (p. 566). However,</p>

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	<ul style="list-style-type: none"> ▪ 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) <p>– <u>MDM Only</u>: Medicare will require only documentation supporting straightforward MDM measured by minimal problems, data review, and risk (two of these three). CMS solicits comments on whether and how guidelines for MDM might be changed in subsequent years.</p> <p>– <u>Time</u>: 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> <p>For those documenting E/M visit levels using time, CMS proposes:</p> <ul style="list-style-type: none"> ▪ 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 ▪ 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 rate for Levels 2-5 is 31 minutes for an established patient and 38 minutes for a new patient ▪ 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). ▪ CMS cites an additional approach which would be to 	<ul style="list-style-type: none"> • <i>For CY 2021, when using <u>current framework</u> or <u>MDM</u> for Levels 2 – 4, CMS finalized a minimum documentation standard associated with E/M office/outpatient level 2 visits (p. 568; p. 570).</i> • <i>For CY 2021 when using <u>time</u> for Levels 2-4, CMS will require documentation that the visit was medically reasonable and necessary and that the billing practitioner spent the “current typical time” for the CPT code reported (p. 569).</i>

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	<p>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> <ul style="list-style-type: none"> ▪ 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>Additional Information:</p> <ul style="list-style-type: none"> ▪ 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).” ▪ CMS requests input on whether the 1995 and 1997 guidelines are adequate on their own or whether they need to be supplemented. <ul style="list-style-type: none"> • <i>Removing Redundancy in E/M Visit Documentation:</i> CMS attempts to further simplify documentation of <u>history and exam</u> for <u>established</u> 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-documenting a defined list of required elements such as review of a specified number of systems and family/social history.” <p>CMS is also seeking comment on whether it could implement a similar provision for <u>MDM</u> or for <u>new</u> patients (for instance when prior data is available through an interoperable EHR or other source).</p> <p>CMS proposed that for <u>new</u> and <u>established</u> patients, practitioners would no longer be required to re-enter</p>	<p>CMS stated that it received information on the Marshfield point system, but most comments suggested that it should not be used as a replacement. CMS also received comments about additional information that could be used to support different visit levels (e.g. HCC scores as is done in MA) (p. 570).</p> <p>CMS received comments regarding updates to MDM and how H&P might be incorporated into MDM (p. 570).</p> <p><i>CMS finalized this proposal effective January 1, 2019</i> (p. 572). Under these current rules, if relevant information is already in the medical record, the clinician is allowed to focus documentation on “what has changed since the last visit, or on pertinent items that have not changed, and need not re-record the defined list of required elements if there is evidence that the practitioner reviewed the previous information and updated as needed. Practitioners should still review prior data, update as necessary, and indicate in the medical record that they have done so.”</p> <p>CMS stated that it will review input received to see whether there are additional documentation relief steps the agency can take under <u>MDM</u> or for <u>new</u> patients (p. 573).</p>

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	<p>information in the medical record regarding the <u>chief complaint</u> and <u>history</u> already entered by ancillary staff or the beneficiary.</p> <ul style="list-style-type: none"> • <i>Podiatry Visits</i>: 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” CMS proposes to use “substantially the same” documentation standards as proposed for other office/outpatient E/M visits. With respect to time, CMS requests input on what the total time would be for payment for the proposed new podiatry G-codes. 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>Minimizing Documentation Requirements by Simplifying Payment Amounts¹:</p> <ul style="list-style-type: none"> • CMS proposed to pay a single payment rate for Levels 2 through 5 E/M visits by developing a single set of RVUs for new patient Levels 2 through 5 and established patients Levels 2 through 5. • CMS proposed 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><i>CMS finalized this proposal effective January 1, 2019 (p. 574).</i> CMS states that the clinician “may simply indicate in the medical record that he or she reviewed and verified this information.”</p> <p><i>CMS did not finalize its proposal to create new codes to describe podiatric E/M visits (p. 576).</i> Given that CMS did not finalize the podiatry E/M codes, CMS did not have to address the documentation standards for those codes (p. 576).</p> <p>CMS acknowledged that most commenters opposed this proposal (p. 581). Most commenters also requested that CMS refrain from making changes base on the ongoing work being done in this area by the CPT/RUC Workgroup (p. 582). (CMS noted that the 2 year delay provides time for CMS to respond to the CPT/RUC developments (p. 584). The area in which CMS agreed with commenters was that they failed to account for “resource costs for the most complex patients” (p. 582). Therefore, <i>CMS finalized for CY 2021 a single payment rate for office/outpatient levels 2-4 and will maintain a separate payment rate for Level 5 (p. 583). CMS will develop the 2021 values/payments based on the inputs listed in Table 21.</i></p> <p>CMS acknowledges that changes could be made prior to implementation in 2021, but as a point of reference shows that under the new policy (using</p>

¹ Note that CMS makes reference to the departure between the policies finalized and what had been proposed: “After considering the comments, especially those suggesting that implementation of significant payment and coding changes requires time for practitioners, vendors, health systems, and other stakeholders to prepare, we are finalizing modified changes in payment coding, and associated documentation rules for E/M office/outpatient visits for 2021. These changes, detailed below, incorporate many significant changes from our proposals based on suggestions from the many comments we received.” (p. 553).

Topic	Proposed Rule	Final Rule
	<p>Recognizing the Resource Costs for Different Types of E/M Visits:</p> <ul style="list-style-type: none"> <p><u>Accounting for E/M Resource Overlap Between Stand-alone Visits and Global Periods:</u> 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.” CMS also proposed 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> <p>CMS also proposed 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.</p> <p><u>HCPCS G Code Add-ons to Recognize Additional Relative Resources for Certain Kinds of Visits:</u> 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> <ul style="list-style-type: none"> <p><u>Primary Care Visits:</u> CMS proposes a HCPCS G-code add-on that can be billed with the E/M code set to adjust payment</p> 	<p>2018 data inputs), a new patient visit level 2-4 would be \$130: (as opposed to the estimated payment level of \$135 in the proposed rule for collapsed visit levels 2-5). (A level 4 new patient visit would be paid at approximately 77.8% of its current reimbursement of \$167).</p> <p>An established patients visit level 2-4 would be \$90 (as opposed to the estimated payment level of \$93 (based on CY 2018 CF) in the proposed rule for collapsed visit levels 2-5). (A level 4 established patient visit would be paid at approximately 82.5% of its current reimbursement of \$109).</p> <p>CMS did not finalize its proposal to apply an MPPR to separately identifiable office/outpatient E/M visits furnished on the same day as a global procedure (p. 592). However, CMS did state that it continues to have “significant concerns about the appropriate payment when codes with global periods, especially 0 and 10-day global periods, are billed on the same day as an E/M visit” (p. 590) and that CMS is “not persuaded by the statements that the RUC process has achieved this goal” (that overlapping resources have been accounted for) (p. 591).</p> <p>CMS notes that part of its approach to budget neutrality was accomplished by the reductions associated with the MPPR policy. Now that is not finalizing the MPPR policy. CMS notes that in some cases it has “proposed and finalized inputs for particular services that are designed to maintain the overall RVUs for those services despite changes in coding.” CMS also states, “We also note that while it has been our standard practice to avoid scaling the full set of work RVUs to maintain budget neutrality, we could also consider that alternative given the significance of office/outpatient visit codes in PFS relativity. Were we to consider either of these alternative approaches for 2021, we would address them through future rulemaking.” (p. 630).</p> <p>CMS finalized for CY 2021 the use of the add-on codes for services “inherent in visits for primary care and particular kinds of specialized medical care” (p. 553; p. 584; p. 607).</p>

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	<p>to account for additional costs beyond the typical resources accounted for in the single payment rate for Levels 2 through 5.</p> <ul style="list-style-type: none"> ▪ 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)): <ul style="list-style-type: none"> – Proposed wRVU: 0.07 – Proposed Physician Time: 1.75 minutes – Proposed PE RVU: 0.07 – Proposed MP RVU: 0.01 ▪ CMS states that it anticipates GPC1X “would be billed with every primary care-focused E/M visit for an established patient” ▪ 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.” ▪ CMS proposes to allow for GPC1X to be billed along with the proposed new code for prolonged E/M services. – <u>Specialty Visits</u>: CMS proposes the creation of a HCPCS G-code to be reported with an E/M for additional resource costs for specialty visits. <ul style="list-style-type: none"> ▪ GCG0X (Visit complexity inherent to evaluation and 	<p><i>For 2021, CMS finalized the primary care add-on code and descriptor as GPC1X (placeholder code)(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 level 2 through 4 office/outpatient evaluation and management visit, new or established) (p. 609).</i> The inputs used for valuation as finalized (now altered to match the inputs for the specialty add-on code (p.609):</p> <ul style="list-style-type: none"> • Physician Time: 8.25 minutes • wRVU: 0.25 • MP RVU: 0.02 <p>CMS states that “we would expect that most practitioners enrolled in such specialties as family medicine, internal medicine, pediatrics, and geriatrics would be billing the primary care visit complexity add-on with every office office/outpatient E/M visit.” (p. 600). CMS further states that while medical necessity must still be documented, “the appropriateness of using the primary care add-on to the visit would not necessitate additional documentation.” (p. 601).</p> <p>CMS noted that the agency believes “that in almost all cases where physicians and other professionals are furnishing primary care, information already in the medical record or on the claim, such as physician specialty, diagnosis codes, other service codes billed (chronic care or transitional care management services), or patient relationship codes would serve as sufficient documentation that the furnished visit met the primary care description.” (p. 600). CMS also continues to believe that there are scenarios where a specialist provides primary care and provides a cardiologist example on p. 602).</p> <p>CMS notes that there are some instances in which it will be appropriate to bill both the primary care and non-procedural specialized care add-on codes together (p. 610).</p> <p>CMS references to this code are all now to “inherent complexity associated with non-procedural specialty care visits” (p. 604).</p>

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	<p>management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care (add-on code, list separately in addition to an evaluation and management visit))</p>	<p><i>For 2021, CMS finalized the “non-procedural specialized care complexity adjustment” code and descriptor as: GCG0X (place holder code) (Visit complexity inherent to evaluation and management associated with nonprocedural specialty care including endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonology centered care. (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established) (p. 609). CMS stated that it did not include descriptor references to “specialty care that routinely involves significant procedural interventions, such as interventional radiology and dermatology, since we do not agree with commenters that these kinds of specialty care are routinely considered to be “non-procedural specialist care.” (p. 608).</i></p> <p>CMS acknowledged the comments citing the concern that the add-on code is contradictory to the statutory provisions that prohibit payment differentials for the same service based on specialty (p. 605). <i>CMS states that “[t]hese codes are neither required nor restricted by physician specialty, though we acknowledge that, like many other physicians’ services for which payment is made under the PFS, they are specifically intended to describe services that clinicians practicing in some specialties are more likely to perform than those in other specialties.” (p. 553).</i></p> <p>CMS also states that “in almost all cases where physicians and other professionals are furnishing specialty care that is centered around separately reportable office/outpatient visit codes (as opposed to procedural codes with global periods for example), information already in the medical record or in the claims history for that practitioner, such as physician specialty diagnosis codes, and/or other service codes billed (chemotherapy administration) would serve as sufficient documentation that the furnished visit met the description of non-procedural specialty care.” (p. 605). CMS further states that it “would expect that most practitioners enrolled in the specialties used as descriptive examples in the proposed descriptor would report the complexity add-on with every office/outpatient E/M visit.” (p. 606). (CMS provides an oncology example on p. 606). Since CMS contemplates that a physician might not be enrolled in a specialty listed in the descriptor, but still be providing care related to that list of clinical issues that “some degree of visit-specific documentation</p>

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	<ul style="list-style-type: none"> ▪ CMS proposes a crosswalk to CPT 90785 (Interactive complexity) <ul style="list-style-type: none"> – wRVU: 0.25 – PE RVU: 0.07 – MP RVU: 0.01 – Physician Time: 8.25 minutes – <u>Proposed HCPCS G-Code to Describe Podiatric E/M Visits:</u> CMS proposes 2 HCPCS G-codes for podiatric E/M visits. <ul style="list-style-type: none"> ▪ GPD0X (Podiatry services, medical examination and evaluation with initiation of diagnostic and treatment program, new patient) <ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> ▪ Proposed wRVU: 0.85 ▪ Proposed Physician Time: 21.60 minutes ▪ Proposed Direct PE Inputs: \$17.07 • <u>Proposed Adjustment to the PE/HR Calculation:</u> CMS proposed a technical modification to the PE methodology “to stabilize the allocation of indirect PE for visit services.” CMS proposed 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). • <u>Proposed HCPCS G-Code for Prolonged Services:</u> CMS proposes a HCPCS G-code add-on for prolonged face-to-face services. It proposes to add GPR01 (<i>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</i> 	<p>might be necessary for purposes of demonstrating that the add-on code was reported appropriately (p. 607).</p> <p>The inputs used for valuation as finalized (p. 609):</p> <ul style="list-style-type: none"> • Physician Time: 8.25 minutes • wRVU: 0.25 • MP RVU: 0.02 <p>RHCs/FQHCs. In a separate section of the rule, CMS clarifies that the two new add-on codes for inherent complexity are for practitioners billing under the Medicare Physician Fee Schedule and therefore are not usable for RHCs and FQHCs (p. 763).</p> <p><i>CMS did not finalize its proposal to create separate podiatric E/M visit codes</i> (p. 612; p. 613). CMS noted however that their proposal was not meant to prohibit podiatrists from reporting office/outpatient visit codes where those codes “more accurately described visits with particular patients or, more broadly, visits generally furnished by particular podiatrists.” (p. 613).</p> <p><i>CMS did not finalize this proposal citing the “broad ramifications” it would have had</i> (p. 616).</p> <p>CMS has changed its reference to “Extended Visit Services” (p. 616; p. 619) given that CPT descriptors describe “prolonged services” as something that would happen less often than this code has been contemplated for use. <i>For 2021, CMS finalized the use of the code (along with the inputs as proposed)</i></p>

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	<p><i>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.</i></p> <p><i>Proposal Impacts.</i> CMS conducted an analysis to determine the impact of the E/M proposals on each specialty.</p> <ul style="list-style-type: none"> • 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) <p><i>Emergency Department and Other E/M Visit Settings:</i></p> <ul style="list-style-type: none"> • CMS does not propose changes to the emergency department E/M code set. • CMS seeks comment on whether it should make changes to other settings in future years. 	<p><i>for use with office/outpatient E/M visit levels 2 - 4</i> (p. 618; p. 619). CMS stated that it believes that “30 additional minutes (which, in accordance with CPT coding conventions for timed codes, can be reported after 15 additional minutes is spent with the patient) is an appropriate interval of time after which to reflect the additional resource costs associated with patient visits that require more time than is typical for the visit.” (p. 619). To ensure that the Extended Visit Services code complements the single payment proposal for levels 2 – 4, <i>CMS will use a single number of minutes for purposes of reporting time-based add-on codes: the weighted average of “typical” times associated with each of the codes that comprise the single payment rate</i> (p. 621). Therefore, <i>CMS finalized a code descriptor for the Extended Visit Code to describe a single range of minutes that “applies to the overall duration of face-to-face time during the visit, without regard to which level 2, 3, or 4 E/M office/outpatient visit was reported” (i.e. 34 – 69 minutes for established patients; and 38 – 89 minutes for new patients of face-to-face time)</i> (p. 622). CMS created a chart to articulate the time thresholds (including scenarios where you would alternatively bill a level 5 and the current prolonged services code in Table 24A. <i>CMS finalized the Extended Visit Service code and descriptor as: GPRO1 (Extended time for evaluation and management service(s) in the office or other outpatient setting, when the visit requires direct patient contact of 34-69 total face-to-face minutes overall for an existing patient or 38-89 minutes for a new patient (List separately in addition to code for level 2 through 4 office or other outpatient Evaluation and Management service))</i> (p. 623).</p> <p><i>CMS includes the specialty level impacts of the E/M coding and payment policies (based on inputs as though it were implemented in 2019) in Table 24C.</i> (This includes collapsing the payment levels for 2-4; keeping level 5 intact, and adopting the primary care and non-procedural specialized care add-on codes. CMS does not mention the inclusion of the Extended Visit Service in this impact table) (p. 629).</p> <p>CMS states that it has received additional feedback through its efforts with ONC to suggest that the ED codes “may benefit from a coding or payment compression into fewer levels of codes, or that documentation rules may</p>

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		need to be reduced or altered.” (p. 631). CMS stated that, as in the proposed rule discussion, it is taking a “step-wise approach” and limiting its proposals this year to office/outpatient E/M visits, but that it might consider expanding its efforts “to additional sections of the E/M visit code set in future years.” CMS stated it will take the feedback it received into consideration for future rulemaking (p. 633).

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Teaching Physician Documentation Requirements for Evaluation and Management Services		
	<p>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.</p> <ul style="list-style-type: none"> For <u>procedural services</u>, the participation of the teaching physician can be demonstrated by the notes in the medical records made by a physician, resident, or nurse. For <u>E/M visits</u>, the teaching physician is required to “<u>personally document</u> their participation in the medical record.” <p>CMS proposed 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 proposed that the medical record must document that the teaching physician was present at the time the service is furnished. The revised paragraph in the regulations will specify that the presence of the teaching physician during <u>procedures</u> and <u>evaluation and management services</u> may be demonstrated by the notes in the medical records made by a physician, resident, or nurse. The changes include:</p> <ul style="list-style-type: none"> Deleting regulatory language that states that the <u>teaching physician</u> 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 <u>extent of the teaching physician’s participation</u> in the review and direction of services furnished to each beneficiary (and that the extent of participation may be demonstrated in notes in the medical record made by a <u>physician, resident, or nurse</u>) 	<p>CMS received comments for and against the proposal with some stating that teaching physicians should continue to be responsible for documenting their physical presence and that the change could shift burden to the residents and nurses (p. 637). Nonetheless, <i>CMS finalized the changes as proposed</i> (p. 638). CMS stated that “the teaching physician continues to be responsible for reviewing and verifying the accuracy of notations previously included by residents and members of the medical team, along with further documenting the medical record if the notations previously provided did not accurately demonstrate the teaching physician’s involvement in an E/M service.”</p>

GPCI Comment Solicitation

CMS seeks comments on potential sources of data for commercial rent for use in the next GPCI update.

CMS stated that it received a few comments and will consider the information for future rulemaking (particularly for CY 2020 statutorily required GPCI updated) ([p. 639](#)).

Therapy Services

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

Section 50202 of the BBA of 2018 repealed the application of the Medicare outpatient therapy caps and the therapy cap exceptions process. 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 in order for Medicare to pay for the services. CMS implemented this provision by continuing to use the KX modifier.² 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.

No changes from the proposed rule.

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.

[Payment for Outpatient PT and OT Services](#)

Section 53107 of the BBA provides for payment of outpatient therapy services furnished on or after January 1, 2022, in whole or in part by a therapy assistant. Specifically, it provides for payment of those services at

CMS finalized these policies with modification ([p. 659](#)).

² 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](#))

**Furnished by
Therapy
Assistants**

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 and when payment is made based on the PFS. The reduced payment rate is not applicable to outpatient therapy services furnished by critical access hospitals.

Implementation of the payment reduction authorized under section 53107 of the BBA requires CMS to establish a new modifier 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).

CMS proposes 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 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.

CMS also proposes 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). The two new therapy modifiers would be used to identify services furnished in whole or in part by a PTA or an OTA; and, these new therapy modifiers would be used instead of the GP and GO modifiers that are currently used 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.

CMS finalized the establishment of two new modifiers, one to identify services furnished in whole or in part by PTAs and the other to identify services furnished in whole or in part by OTAs.

CMS finalized its proposal to define PTAs and OTAs as those individuals meeting the personnel qualifications set forth in part 484. However, CMS notes that, effective January 13, 2018, the personnel qualifications for PTAs and OTAs were moved from §484.4 and redesignated without changes at §§484.115(g) and (i), respectively. ([p. 649](#))

Instead of finalizing the new modifiers to identify services furnished by PTAs and OTAs as *therapy* modifiers, ***CMS is adopting a final policy to use these new modifiers as a payment modifier that will be appended on the same line of service with the respective PT or OT therapy modifier.*** This modified approach allows CMS to proceed without making the proposed revisions to the current descriptors for the three therapy modifiers – GP, GO and GN.

CMS finalized the new payment modifiers as follows:

- ***CQ Modifier:*** Outpatient physical therapy services furnished in whole or in part by a physical therapist assistant.
- ***CO Modifier:*** Outpatient occupational therapy services furnished in whole or in part by an occupational therapy assistant.

These new modifiers cannot be used on the line of service of the professional claim when the rendering NPI is a physician or an NPP.

CMS is not revising the three therapy modifiers as proposed. Instead, they will continue in effect, unmodified, as follows:

- ***GP*** – services delivered under an outpatient physical therapy plan of care.
- ***GO*** – services delivered under an outpatient occupational therapy plan of care.
- ***GN*** – services delivered under an outpatient speech-language pathology plan of care.

Instead of finalizing its proposed definition of a service that is furnished in whole or in part by a PTA or OTA as a service for which any minute of a therapeutic service is furnished by a PTA or OTA, ***CMS finalized a de minimis standard under which a service is furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA.***

CMS proposes 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.

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.

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.

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 it was meant to apply when a PTA or OTA is

CMS anticipates addressing application of the therapy assistant modifiers and the 10 percent standard more specifically, including their application for different scenarios and types of services, in rulemaking for CY 2020.

CMS plans to revise its manual provisions at Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, section 230, as appropriate, to reference the new CQ and CO modifiers that will be used to identify services furnished in whole or in part by a PTA or OTA starting in CY 2020.

involved in providing some or all of the therapeutic portions of an outpatient therapy service. Thus, CMS proposes 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.

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.

Functional Reporting Modification

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. CMS proposes to discontinue the functional reporting requirements for services furnished on or after January 1, 2019.

Specifically, CMS proposes 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.

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.

CMS finalized its proposals with modification, as detailed below ([p. 664](#)).

CMS finalized these changes as proposed ([p. 664](#)). Specifically, CMS is removing the following regulatory requirements:

- ***Conditions of payment at §§410.59(a)(4), 410.60(a)(4), 410.62(a)(4), and 410.105(d) 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 at §410.61(c) for outpatient PT, OT, and SLP services and at §410.105(c)(1)(ii) for the PT, OT, and SLP services in CORFs.***

CMS finalized this proposal with modifications ([p. 665](#)). CMS is ending the

- 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.

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. Instead of deleting the HCPCS G-codes effective for CY 2019 as proposed, **CMS finalized a modification to retain the set of 42 non-payable HCPCS G-codes until CY 2020.** This delay will:

- Allow time to update billing systems and policies.
- Avoid a situation where claims that inadvertently contain any of these G-codes during CY 2019 can be processed, and are not unnecessarily returned or rejected.
- Allow physical and occupational therapists to report six of these non-payable HCPCS G-codes and the measures developed from them for purposes of meeting the MIPS program requirements.

CMS also intends to revise its manuals regarding the application of the functional reporting requirements in its IOM, Pub. 100-02, Medicare Benefits Policy Manual, Chapters 12 and 15, and Pub. 100-04, Medicare Claims Processing Manual, Chapter 5.

Therapy KX Threshold Amounts

Not discussed in the proposed rule.

Under current law, the KX modifier thresholds are updated each year based on the Medicare Economic Index (MEI). They are calculated by updating the previous year's amount by the MEI for the upcoming calendar year and rounding to the nearest \$10.00.

Based on the above calculation, the CY 2019 KX threshold amount is \$2,040 for PT and SLP services combined and \$2,040 for OT services.

For CY 2018 through CY 2028, the MR threshold is \$3,000 for PT and SLP services combined and \$3,000 for OT services, as specified by law.

Additional detail on how expenses are applied toward these threshold amounts can be found on [p. 665](#) – [p. 667](#).

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

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.

Effective January 1, 2019, Wholesale Acquisition Cost (WAC)-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3 percent add-on in place of the 6 percent add-on that is currently being used. CMS will also permit Medicare Administrative Contractors (MACs) to use an add-on percentage of up to 3 percent for WAC-based payments for new drugs ([p. 679](#)).

CMS notes interest in striking a balance between concerns about providers' overhead costs and concerns about addressing financial incentives that may lead to excessive drug use. However, the agency is concerned that the add-on is based on an undiscounted list price, which contributes to excessive add-on payments, particularly for expensive new drugs and is not tied to any other factors, such as actual market cost, administrative complexity of ordering the drug, or additional overhead costs ([p. 672](#)).

Potential Model for Radiation Therapy

Among other things, the Patient Access and Medicare Protection Act (PAMPA) (Pub. L. 114-115, enacted December 28, 2015) required the Secretary of Health and Human Services to submit to Congress a report on the development of an episodic APM for payment under the Medicare program under title XVIII of the Act for radiation therapy (RT) services furnished in non-facility settings ("Report to Congress"). As part of that report, CMS discussed the current status of RT services and payment, and reviewed model design considerations for a potential APM for RT services.

Prior to issuing the report, CMS' Innovation Center conducted an environmental scan of current evidence, held a public listening session, and collected comments from RT stakeholders about a potential APM. CMS demonstrated that episode payment models can be a tool for improving care and reducing expenditures. Based on the report and other reasons, CMS believes that radiation oncology is a promising area of health care for bundled payments and will continue to use public information regarding commercial initiatives, as well as stakeholder feedback to help inform the development, implementation, and refinement of design and testing of a potential model that tests payment for RT services under the authority of section 1115A of the Act.

Other Provisions of the Proposed Rule

Clinical Laboratory Fee Schedule

Topic	Proposed Rule	Final Rule
Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory		
	<p>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.</p> <p>CMS also welcomes comments on its proposal to modify the definition of applicable laboratory to exclude MA plan payments under Part C as Medicare revenues.</p>	<p><i>CMS finalized its proposal to modify the definition of applicable laboratory to exclude MA plan revenues from total Medicare revenues (the denominator of the majority of Medicare revenues threshold), and revised paragraph (3) of the definition of applicable laboratory at §414.502, accordingly (p. 698).</i> As suggested by commenters, CMS will consider excluding Medicare Part D revenues from total Medicare revenues for future refinements to the CLFS, if such payments are related to laboratory testing. (p. 698).</p>

Solicitation of Public Comments on Other Approaches to Defining Applicable Laboratory

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).

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

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.

CMS finalized the use of the Form CMS-1450 14x TOB to define applicable laboratories. More specifically, CMS finalized modification of the definition of applicable laboratory to also include 14X TOB revenues. CMS revised paragraph (2) of the definition of applicable laboratory at §414.502, accordingly (p. 716).

With regard to legality issues, CMS believes using the 14x TOB to define applicable laboratory is consistent with the statute. CMS stated its belief that using Form CMS-1450 14x TOB provides a means of distinguishing services furnished by a hospital outreach laboratory from other services furnished and billed by a hospital using the same NPI. CMS notes that the statute specifically directs the agency to identify applicable “laboratories” and not “providers” or “suppliers.” Hospital outreach laboratories without unique NPIs furnish clinical laboratory tests paid under the CLFS and PFS, albeit to Medicare beneficiaries who are not hospital patients, thus, CMS believes such laboratories, should not be exempt from reporting the applicable data merely due to their shared use of a billing entity with a hospital (p. 713).

As discussed in the rule, many commenters did not support using the CLIA certificate to define applicable laboratory because of the administrative complexity associated with this approach. Commenters stated that the CLIA certificate has no relationship to actual laboratory revenues, like the NPI does, and therefore, laboratories would need to develop their own mechanisms to attribute Medicare revenues to the CLIA certificate. In addition, one commenter stated that it is unlikely that a single CLIA certificate would be assigned to both its outreach laboratory (non-patients) and its laboratory that provides testing for its hospital inpatients and hospital outpatients. CMS noted that in cases in which a hospital owns and operates multiple outreach laboratories at different locations, the administrative burden of attributing Medicare revenues to the CLIA certificate would be even more substantial as there could be several CLIA certificates assigned under the same NPI (p. 717).

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

Decreasing the Low Expenditure Threshold

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: (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

Many commenters were opposed to reducing the low expenditure threshold because of the administrative burden it would place on physician office laboratories and small independent laboratories. CMS stated that it will consider the commenters’ input regarding the low expenditure threshold as it continues to evaluate and refine Medicare CLFS payment policy in the future (p. 725).

A few commenters suggested alternative approaches to lowering the low expenditure threshold that involve collecting data for physician office dependent tests and allowing laboratories to voluntarily report applicable information,

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.

whereas others suggested that CMS permit voluntary reporting so that laboratories that do not meet the current low expenditure threshold may report applicable information if they choose to. CMS stated that it has addressed these approaches in the past, including voluntary reporting, which it does not believe is consistent with the statute ([p. 725](#)).

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.

While several commenters did not support raising the low expenditure threshold given concerns that it would further reduce the amount of applicable information reported from small laboratories, a few suggested postponing changes to allow the program to mature. CMS stated it will consider the commenters input on increasing the low expenditure threshold as it continues to evaluate and refine Medicare CLFS payment policy in the future, but make no changes to this policy at this time ([p. 729](#)).

Changes to the Regulation Associated with the Ambulance Fee Schedule

The Medicare Improvements for Patients and Providers Act of 2009 (MIPPA) established ground ambulance payment increases. 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.

CMS finalized its proposal without modification ([p. 742](#)).

The Medicare Prescription Drug, Improvement and Modernization of 2003 (MMA) provided for a “Super Rural Bonus” previously determined to be 22.6%. 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. CMS plans to continue to apply the 22.6 percent Super Rural Bonus through December 31, 2022.

CMS finalized its proposal without modification ([p. 744](#)).

The American Taxpayer Relief Act of 2012 (ATRA) included a provision that reduced payments for ambulance services for non-emergency basic life support services involving transport of an individual with ESRD for renal

CMS finalized its proposal without modification ([p. 746](#)).

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, but then temporarily modified by the Balanced Budget Act of 2018 (BBA), to 23 percent for services for services on or after October 1, 2018. 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.

Rural Health Clinics (RHCS) and Federally Qualified Health Centers (FQHCS)

Proposed Rule

Final Rule

Payment for Care Management Services

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 additional service to the rules for BHI).

CMS finalized its proposal ([p. 764](#)).

Communication Technology-Based Services and Remote Evaluation

CMS referred 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. 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.” However, if there is no RHC or FQHC “billable visit” the costs are not part of the payment. Therefore, CMS proposed 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.

CMS finalized its proposal ([p. 764](#)). CMS clarified that a subsequent emergency room visit would not negate the ability for the RHC or FQHC to bill for the visit as long as it otherwise does not result in a follow-up within the given timeframe at the RHC or FQHC (in which case the communications technology-based service would be bundled) ([p. 761](#)). CMS reminded stakeholders that it does not have the authority to waive beneficiary coinsurance and that “RHCs and FQHCs should inform their patients that coinsurance applies, and provide information on the availability of assistance to qualified patients in meeting their cost sharing obligations, or any other programs to provide financial assistance, if applicable.” ([p. 758](#)).

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.

CMS finalized HCPCS G0071 (Virtual Communication Services) ([p. 764](#)).

CMS proposes to waive the RHC and FQHC face-to-face requirements for G0071.

CMS finalized this proposal ([p. 764](#)).

Telehealth Services. CMS also received a comment asking whether CMS had the authority to allow FQHCs to serve as *distant site providers* for telehealth services to beneficiaries. CMS reminded stakeholders that the communications-based technology services it proposed for use in FQHCs are distinct from Medicare

telehealth services ([p. 756](#)). But regarding Medicare telehealth services, CMS also reminds stakeholders that RHCs and FQHCs are statutorily allowed to be *originating sites*; however, CMS does not have the authority to allow RHCs or FQHCs to *furnish* (and bill for) distant site telehealth services ([p. 756](#)).

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Topic	Proposed Rule	Final Rule
Proposals for Continuing Implementation		
Background	<p>Section 218(b) of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113-93, enacted April 1, 2014) added a new section 1834(q) of the Act directing CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. In the CY 2018 PFS final rule (82 FR 53190), CMS established that the Medicare AUC program for advanced diagnostic imaging services would begin on January 1, 2020 with a year-long educational and operations testing period during which time AUC consultation information is expected to be reported on claims, but claims will not be denied for failure to include proper AUC consultation information. Under the program, ordering professionals must consult AUC for every applicable imaging service furnished in an applicable setting and paid under an applicable payment system unless a statutory exception applies. 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. More information is available here.</p> <p>CMS will continue to post information on its website for this program, accessible here.</p>	
Expanding Applicable Settings	<p>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).</p> <p>CMS invites comments on this proposal and on the possible inclusion of any other applicable settings.</p>	<p><i>CMS finalized this expansion as proposed (p. 777).</i></p> <p>CMS disagrees that this expanded definition will add complexity as CMS seeks consistency in applying its regulations across outpatient settings in which outpatient advanced diagnostic imaging services are furnished, and would be concerned with applying these requirements in different settings along different timelines.</p> <p>Because CMS did not propose adding other settings to this definition, it will not expand it further in this final rule, but will continue to monitor claims for advanced diagnostic imaging services across the Medicare program.</p>
Consultations by Ordering Professionals	<p>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</p>	<p><i>Based on the public comments received, CMS does not believe it would be appropriate to move forward with the proposal to specify the scope of individuals who can perform the AUC consultation as auxiliary personnel. It is modifying its proposal in response to comments, and conforming the regulation at §414.94(j)(2), to specify that, when not personally performed by the ordering</i></p>

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.

professional, the consultation with a qualified CDSM may be performed by clinical staff under the direction of the ordering professional.

CMS has used the term clinical staff elsewhere in the Medicare program to identify the individuals that may perform care management services including chronic care management (CCM), behavioral health integration (BHI) and transitional care management (TCM) services. These services involve some non-face-to-face services along with clinical activities around the care plan and communication and coordination with the patient's other healthcare professionals.

CMS believes that allowing clinical staff to perform the AUC consultation under the direction of the ordering professional is a better fit with the AUC program than its proposal, and is responsive to public comments asserting that the concept of "incident to" is not relevant in the context of the AUC program. The finalized policy will allow the AUC consultation to be performed by clinical staff under the direction of the ordering professional, which further reflects a balance between those commenters who wanted only the ordering professional to perform the consultation and those who suggested CMS should allow the consultation to be delegated. Clinical staff will have a level of knowledge that allows for effective communication of advanced diagnostic imaging orders, interaction with AUC, and engagement with the ordering professional, while they remain under the direction of the ordering professional ([p. 785](#)).

**Reporting AUC
Consultation
Information**

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. 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, OPFS or ASC payment system). As such, claims from both furnishing professionals and facilities must include AUC consultation information (i.e., 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).

CMS finalized these policies without modification ([p. 788](#)).

Some stakeholders opposed the requirement to report AUC consultation information on all claims, specifically the facility claims. CMS recognized that the technical component (TC) or facility portion of an applicable imaging service is frequently furnished and billed by a different entity than the professional component (PC) portion of the service. CMS does not currently do any matching or comparison of separate claims for the PC and TC or facility portion of an advanced diagnostic imaging service. Rather, it processes these separate claims individually, and has no immediate plans to begin doing otherwise for purposes of the AUC program. CMS hopes to learn more about the implementation of this program, including issues such as these commenters have raised, during the educational and operations testing period.

**Claims-based
Reporting**

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.

Based on public comments, CMS finalized this proposal to use G-codes and modifiers to report consultation information on claims (p. 798). CMS appreciates that commenters pointed out concerns and technical issues regarding this approach and will work to address them during implementation In this section.

In this section, CMS summarizes alternatives it has considered for reporting the AUC consultation information on the Medicare claim, including: assigning a G-code for every qualified CDSM with a code descriptor containing the name of the qualified CDSM and the use of modifiers that would appear on the same line as the CPT code that identifies the specific billed service; and the use of a unique consultation identifier (UCI) that would include an indication of AUC adherence, non-adherence and not applicable responses. While the UCI option would allow for direct mapping from a single AUC consultation to embedded information within a CDSM, this approach would not identify whether an AUC consultation was performed for each applicable imaging service reported on a claim form, or be useful for purposes of identifying outlier ordering professionals. Following internal consideration, CMS has concluded that the UCI approach is not feasible at this time and discusses some of these hurdles in this section of the rule. CMS prefers to use coding structures that are already in place (e.g., G-codes and modifiers), but will consider future opportunities to use a UCI and looks forward to continued engagement with and feedback from stakeholders.

CMS agrees with commenters that G-codes and modifiers may not be the ideal solution. However, it is important that CMS prepare stakeholders for the method of reporting in the immediate years of the program and CMS is optimistic that it can issue G-codes in a timely manner upon qualifying new CDSMs. CMS will look into the benefits and potential problems of using CPT codes to describe which qualified CDSM was consulted. An initial concern of CMS', in addition to timing to accommodate the start of the AUC program, is whether CPT code descriptors could be changed quickly enough to accommodate newly qualified CDSMs and whether CPT codes would be set aside for future use.

CMS also notes here that it will work with the appropriate stakeholders to identify a possible future location for a UCI to be appended to claims. It is not committing to using the UCI at this time, but is open to exploring the possibility of developing a UCI that could be appended to claims in the future. CMS will also work to better understand and identify a potentially appropriate place on the furnishing facility claim to include the ordering professional's NPI, and to understand whether changes to that claim form may be needed. In the short term, it will consider other implementation options so that fields on the claims are not used improperly.

**Significant
Hardship
Exception**

For CY 2019, CMS proposes to adjust the significant hardship exception requirements under the AUC program, at §414.94(i)(3) of its regulations, 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.

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 such attestation would be supported with documentation of the significant hardship. Ordering professionals would communicate that 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 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.

Finally, CMS clarifies here that It is the responsibility of the ordering professional to consult AUC and to provide that consultation information to the furnishing professional; and it is the responsibility of the furnishing professional and facility to accurately report that information on claims for applicable imaging services.

CMS finalized these policies as proposed (p. 812).

In response to requests for additional exceptions, CMS notes it does not have the authority to include exceptions to the AUC program beyond the scope of those specified in section 1834(q)(4)(C) of the Act.

Some commenters requested clarification around what constitutes an emergency medical condition, suggesting that CMS revise the regulatory language to allow exceptions when an emergency medical condition is suspected for cases in which clinicians, in their best judgment, believe a patient may be experiencing a medical emergency at the time of order. CMS responded that the regulation reflects the current statutory language and that CMS will not amend its regulation in response to these comments. As stated in earlier rulemaking, CMS agrees that exceptions granted for an individual with an emergency medical condition include instances where an emergency medical condition is suspected, but not yet confirmed. This may include, for example, instances of severe pain or severe allergic reactions. In these instances, the exception is applicable even if it is determined later that the patient did not in fact have an emergency medical condition.

CMS disagrees with commenters that inclusion of significant hardship information on each imaging order and subsequent claim imposes extensive burden. Furthermore, CMS believes that a blanket exception for a specific period of time for ordering professionals based on a single significant hardship attestation would introduce a level of complexity and burden to the process that was not identified by requestors.

In this section, CMS responds to stakeholder concerns that the AUC program is duplicative of the QPP by noting that there are specific and distinct differences between the programs. The AUC program was established to promote appropriate use of advanced diagnostic imaging and improve ordering patterns for these services through the consultation of AUC with real time reporting requirements and payment implications. While some components of the QPP can involve using AUC and clinical decision support, their use is not mandatory, and the QPP provides numerous options for participation across all MIPS performance categories. In contrast, consultation with AUC using a CDSM is required for each

order for an applicable imaging service furnished in an applicable setting and paid under an applicable payment system under the AUC program.

Identification of Outliers

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 the prior authorization process specified at Section 1834(q)(5) of the Act when ordering advanced diagnostic imaging services. Specifically, it solicits comments on the data elements and thresholds that CMS should consider when identifying outliers.

CMS appreciates the feedback received from public commenters expects to solicit additional public comment to inform its methodology through rulemaking before finalizing its approach ([p. 812](#)). 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 our outlier methodology. Since it intends to evaluate claims data to inform its methodology, 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)

Topic	Proposed Rule	Final Rule
eCQM Reporting Requirements for EPs under the Medicaid Promoting Interoperability Program for 2019		
	<p>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.</p> <p>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.</p> <p>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. 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</p>	<p><i>CMS finalized without change its proposal to amend the list of available eCQMs for the CY 2019 performance period.</i> To keep eCQM specifications current and minimize complexity, CMS aligned the eCQMs available for Medicaid EPs in 2019 with those available for MIPS eligible clinicians for the CY 2019 performance period. Specifically, the eCQMs available for Medicaid EPs in 2019 will 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 (p. 818).</p> <p>While CMS did not propose to include the e-specified measures within the Adult Core Set and Child Core Set that are not also on the MIPS eCQM list for eCQM reporting in the Medicaid Promoting Interoperability Program in 2019, the agency intends to reevaluate whether to add these measures when proposing eCQM reporting requirements for the Medicaid Promoting Interoperability Program for 2020 and beyond (p. 819).</p> <p><i>CMS finalized its proposal that for 2019, Medicaid EPs will report on any six eCQMs that are relevant to the EP's scope of practice, regardless of whether they report via attestation or electronically. CMS also finalized the proposal that for 2019 the Medicaid Promoting Interoperability Program will 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) (p. 821).</i> As a reminder, CMS' policy continues to allow Medicaid EPs to report eCQMs with zero in the</p>

identify which of the available measures are high priority measures, but invites comment on other possibilities for 2019:

- 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 (i.e., an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure)
- 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. These include:
 - CMS2: Preventive Care and Screening: Screening for Depression and Follow-Up Plan
 - CMS4: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment
 - CMS122: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%)
 - CMS125: Breast Cancer Screening
 - CMS128: Anti-depressant Medication Management
 - CMS136: Follow-Up Care for Children Prescribed ADHD Medication (ADD)
 - CMS153: Chlamydia Screening for Women
 - CMS155: Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents
 - CMS165: Controlling High Blood Pressure
- 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

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.

CMS also proposes that the eQM 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.

denominator, which indicates that they have no data on that eQM in their EHR from the reporting period. Therefore, if fewer than six measures are relevant to a Medicaid EP's scope of practice, he or she may submit "zero denominator" eQMs that his or her CEHRT is able to calculate to meet the requirement to report six measures. Of note for specialty physicians, CMS now explains that if no outcome or high priority measures apply to a Medicaid EP's scope of practice and there is no data for any of the outcome or high priority measures reportable by his or her CEHRT, he or she may report on six non-outcome and non-high priority measures that are applicable to his or her scope of practice.

Regarding CMS' proposal to allow states to indicate which eQMs are high priority measures for that state's Medicaid agency, the agency finalized it without modification ([p. 822](#)).

Despite the majority of commenters calling for a 90-day reporting period, CMS finalized without change its proposal that the eQM reporting period for EPs in the Medicaid Promoting Interoperability Program will 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 ([p. 823](#)). The eQM reporting period for Medicaid EPs demonstrating meaningful use for the first time, which was established in the Stage 3 final rule, will remain any continuous 90-day period (80 FR 62892).

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

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). 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 finalized its proposal to amend §495.4 to provide that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program will 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 states can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. CMS also finalized its proposal 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 states can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021 (p. 827).

In addition, CMS finalized its proposal 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 the agency, through their State Medicaid HIT Plan (SMHP). 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 (p. 827).

Revisions to Stage 3 Meaningful Use Measures for Medicaid EPs

[Change to Objective 6 \(Coordination of Care through Patient Engagement\)](#)

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.

CMS finalized without change the proposal to amend §495.24(d)(6)(i) so 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) will remain 5 percent for 2019 and subsequent years (p. 832).

[Change to the Syndromic Surveillance Reporting Measure](#)

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.

CMS finalized without change the proposal 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 (p. 834). The new objective will also include any other setting from which ambulatory syndromic surveillance data are collected by the state or local public health agency. CMS explained that the change does not alter the exclusion for this measure at §495.24(d)(8)(i)(C)(2)(i),

for EPs who are not in a category of health care providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system, as defined by the state or local public health agency. Furthermore, this does not create any requirements for syndromic surveillance registries to include all EPs. Additionally, under the specifications for the 2015 Edition of CEHRT for syndromic surveillance, it is possible that an EP could own CEHRT and submit syndromic surveillance in a format that is not accepted by the local jurisdiction. In this case, the EP may take an exclusion for syndromic surveillance.

Medicare Shared Savings Program Quality Measures

Topic	Proposed Rule	Final Rule
	In August 2018, CMS issued the “ Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success ” proposed rule (referred to as the “August 2018 proposed rule”), which addressed a number of proposed policy changes including redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; revisions to ensure rigorous benchmarking; and policies promoting use of interoperable electronic health record technology among ACO providers/suppliers. Later in this final rule (see Appendix A), CMS finalizes multiple proposals from the August 2018 proposed rule.	
	In this section of the rule, CMS addresses quality reporting for the Shared Savings Program and certain other issues. Starting with the 2018 performance period, the quality performance category under the Merit-based Incentive Payment System (MIPS) APM Scoring Standard for MIPS eligible clinicians participating in a Shared Savings Program ACO includes measures collected through the CMS Web Interface and the CAHPS for ACOs survey measures.	
	<i>In this section of the rule, CMS finalizes its proposal to eliminate 9 measures and to add 2 measures to the Shared Savings Program quality measure set. In a separate section of the rule, CMS finalizes the removal of ACO-11-Percent of Primary Care Physicians Who Successfully Meet Meaningful Use Requirements. The net result of the final policies included in this final rule is a set of 23 measures on which ACOs’ quality performance will be assessed for performance years during 2019 and subsequent performance years (compared to 31 measures used in 2018). Table 26 shows the Shared Savings quality measure set finalized in this rule for performance years during 2019 and subsequent performance years, including the phase-in schedule for these measures. Table 27 provides a summary of the number of measures by domain and the total points and domain weights that will be used for scoring purposes under the changes to the quality measure set finalized in this rule.</i>	
	Later in this rule (see Appendix A), CMS discusses its proposal to remove the ACO-11-Use of Certified EHR Technology measure.	

Changes to the CAHPS Measure Set

Under this proposal, CMS would add the following CAHPS for ACOs SSMS to the quality measure set for the MSSP. These measures, which are already collected for informational purposes only, would be pay-for-reporting for two years (2019 and 2020) and then phase into pay-for-performance beginning in 2021:

- [ACO-45: CAHPS: Courteous and Helpful Office Staff](#)
- [ACO-46: CAHPS: Care Coordination](#)

CMS finalized these new measures, as proposed ([p. 848](#)).

The CAHPS for ACO survey is focused on beneficiaries’ experience of care received from clinicians in ambulatory care settings. CMS currently excludes beneficiaries from CAHPS sampling if 100 percent of their primary care service visits were performed in an institutional setting (as determined using HCPCS codes). ***However, after reviewing its current CAHPS sampling***

Additionally, CMS solicits comment on potentially converting ACO-7: Health and Functional Status SSM to pay-for-performance in the future and feedback on possible options for enhancing the collection of health and functional status data.

process, starting with the CAHPS sample for performance year 2018, CMS will also begin excluding beneficiaries if their last primary care service visit (as determined using HCPCS codes) during the sampling timeframe was performed in an institutional setting (p. 850). CMS believes this change will help to ensure that beneficiaries who are residing in institutional settings are appropriately excluded from CAHPS sampling.

CMS highlights concerns raised about adding ACO-7-Health and Functional Status as a pay-for-performance measure in future years since the measure is largely outside of the physician's control and agree. CMS will consider this feedback as it conducts additional work to analyze the implications of adding a scored health and functional status measure to the ACO quality measure set in the future.

Changes to the CMS Web Interface and Claims-Based Quality Measure Sets

Claims-Based Measures

To reduce the burden on ACOs and their providers, 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.

This proposed reduction in the number of measures aligns with proposed changes to the CMS Web Interface measures that are reported under MIPS. Because these measures are claims-based measures and do not impose any reporting burden on ACOs, CMS intends to continue to provide information to ACOs on their performance on these measures for use in their quality improvement activities through a new quarterly claims-based quality outcome report that ACOs began receiving in August 2018.

CMS finalized its decision to remove ACO-35, ACO-36, and ACO-37 from the Shared Savings Program quality measure set effective for quality reporting for performance years during 2019 (p. 856)

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.

CMS also 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. The SNFQRP measure differs from [ACO-35](#), which CMS is removing, since it looks only at unplanned, potentially preventable readmissions for Medicare FFS beneficiaries within 30 days of discharge to a lower level of care from a SNF, while [ACO-35](#) assesses hospital readmissions from a SNF, that occur within 30 days following discharge from a hospital for beneficiaries admitted to a SNF after hospital discharge.

CMS also finalized its proposal to remove ACO-44 from the Shared Savings Program quality measure set effective for quality reporting for performance years during 2019 (p. 857).

The majority of commenters were opposed to potentially adding the SNFQRP measure to the Shared Savings Program quality measure set. CMS will consider this feedback prior to making any future proposals (p. 859).

[Web Interface Measures](#)

CMS previously 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 the proposed MIPS quality measures in this rule.

Based on the changes being finalized in [Tables A, C and D](#) of [Appendix 1: Finalized MIPS Quality Measures](#) of this final rule, ACOs will no longer be responsible for reporting the measures proposed for removal for purposes of the Shared Savings Program starting with reporting for performance years during 2019 (p. 859).³

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: Medication Reconciliation Post-Discharge](#)
- [ACO-15: Pneumonia Vaccination Status for Older Adult](#)
- [ACO-16: Preventive Care and Screening: Body Mass Index Screening and Follow Up](#)
- [ACO-41: Diabetes: Eye Exam](#)
- [ACO-30: Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic](#)

³ Note that CMS does not specifically address [ACO-13: Falls: Screening for Future Fall Risk](#) in the final rule; however, this measure is listed in [Table 26](#), which shows the finalized Shared Savings quality measure set for 2019.

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

- ACO-47: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

CMS did not adopt its proposal to add ACO-47 because the measure steward believes it is not implementable at this time. Shared Savings Program ACOs will not be responsible for reporting this measure starting with quality reporting for performance years during 2019 (p. 860).

Physician Self-Referral Law

Topic	Proposed Rule	Final Rule
	<p>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. Because the BBA 2018 provisions are nearly identical, CMS believes no additional changes to the regulation are necessary.</p> <p>Compensation Arrangement Exceptions: CMS proposes a new special rule on compensation arrangements:</p> <ul style="list-style-type: none"> • 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.” • CMS has existing special rules related to temporary non-compliance with the Stark signature requirement. 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. <p>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.</p> <p>CMS also 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>	<p>CMS maintained its policy given that no changes were proposed.</p> <p><i>CMS finalized its proposal (p. 868).</i></p> <p><i>CMS finalized its proposal (p. 868).</i></p> <p><i>CMS reiterated this policy on p. 869.</i></p>

- **Annual Update to the Stark/Self-Referral Code list.**

The revised January 1, 2019 list of codes subject to the self-referral regulations will be available on [the CMS Physician Self-Referral website](#).

CY 2019 Updates to the Quality Payment Program

Topic	Proposed Rule	Final Rule
MIPS Program Details		
<u>MIPS Eligible Clinicians</u>	<p>CMS proposes to amend §414.1305 to modify the definition of a MIPS eligible clinician to include, beginning with the 2021 MIPS payment year:</p> <ul style="list-style-type: none"> • 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. <p>CMS proposed to include these additional clinicians in the MIPS eligible clinician definition if they had at least 6 MIPS quality measures available to them.</p> <p>In addition, CMS requests comments on:</p> <ul style="list-style-type: none"> • 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. 	<p><i>CMS finalized a modification to its proposal to amend §414.1305 to revise the definition of a MIPS eligible clinician to include, beginning with the 2021 MIPS payment year, the following:</i></p> <ul style="list-style-type: none"> • <i>Physical therapists</i> • <i>Occupational therapists</i> • <i>Qualified speech-language pathologists</i> • <i>Qualified audiologists (as defined in section 1861(II)(3)(B) of the Act)</i> • <i>Clinical psychologists (as defined by the Secretary for purposes of section 1861(ii) of the Act)</i> • <i>Registered dietitians or nutrition professionals</i> • <i>A group that includes such clinicians</i> (p. 906) <p>CMS did not finalize the inclusion of clinical social workers and certified nurse-midwives since they do not have sufficient relevant quality measures at this time and because of other participation challenges. However, CMS will consider these professionals in the future.</p> <p>CMS encourages clinicians who are not eligible to participate in MIPS to voluntarily report on applicable measures and activities for MIPS. The data received will not be used to assess performance for the purpose of the MIPS payment adjustment; however, these clinicians will have the opportunity to access feedback on their submitted MIPS data.</p> <p>As noted in Appendix A, CMS will automatically assign a zero percent weighting for the Promoting Interoperability (PI) performance category, which will be reweighted to the quality performance category for these new types of MIPS eligible clinicians. If the clinician chooses to report as part of a group, then under the policy CMS established previously (82 FR 53687), all of the MIPS eligible clinicians in the group must qualify for a zero percent weighting in order for the Promoting Interoperability performance category to be reweighted in the final score.</p>

CMS disagrees with public commenters that the expansion of the MIPS eligible clinician type will decrease the number of small practices. As defined at §414.1305, a small practice is a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period. This definition currently includes both eligible clinicians and *MIPS* eligible clinicians, and therefore, the expansion of the MIPS eligible clinician definition should not negatively impact a practice's ability to be considered a small practice ([p. 992](#)).

CMS finalized this unified MIPS determination period as proposed ([p. 917](#)).

CMS intends to provide eligibility determinations as close to the beginning of the performance period as feasible. CMS also is working to provide the quarterly snapshots, if feasible. These would be provided for informational use only and the final eligibility determination would not be made until after a reconciliation of the first and second segment of the MIPS determination period.

An individual eligible clinician or group that is identified as not exceeding the low-volume threshold or as having special status during the first segment of the MIPS determination period will continue to be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period.

Also, an individual eligible clinician or group for which the unique billing TIN and NPI combination is established during the second segment of the MIPS determination period will be assessed based solely on the results of that segment.

CMS clarifies that it did not propose to utilize the MIPS determination period for “facility-based” determinations. For the facility-based determination, CMS will only use the first segment of the MIPS determination period because the performance period for measures in the Hospital Value-Based Purchasing (VBP) program overlaps in part with that determination period. If CMS were to use the second segment, it could not be assured that the clinician actually worked in the hospital on which their MIPS score would be based during that time.

It is important to note that during the final 3 months of the calendar year in which the performance period occurs, in general, CMS does not believe it would be feasible for many MIPS eligible clinicians who join an existing practice (existing TIN) or join a newly formed practice (new TIN) to participate in MIPS as individuals. For more information on the proposed reweighting policies for MIPS

MIPS Determination Period

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 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 (e.g. rural area is defined as a ZIP code designated as rural, using the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available).

eligible clinicians who join an existing practice or join a newly formed practice during this timeframe, click [here](#).

Low-Volume Threshold

Amendments to Comply with the Bipartisan Budget Act of 2018: To comply with the Bipartisan Budget Act (BBA) 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.

MIPS Program Details:

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.

Amendments to Comply with the Bipartisan Budget Act of 2018:

CMS finalized this policy as proposed ([p. 921](#)). A clinician may identify and monitor a claim to distinguish covered professional services from Part B items and services by calculating one professional claim line with positive allowed charges to be considered one covered professional service.

MIPS Program Details:

CMS finalized these policies as proposed ([p. 922](#)).

- 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.

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

For the 2019 performance year and future years, CMS also proposes to add one additional criterion to the low-volume threshold determination:

- 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)

Low-Volume Threshold Opt-in:

- CMS proposes to modify §414.1310(b)(1)(iii) to provide that beginning with the 2019 performance year, if an eligible clinician or group meets or exceeds at least one, but not all, of the low-

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

CMS finalized this policy as proposed ([p. 932](#)). Setting the third criterion at 200 or fewer covered professional services, combined with CMS' proposed policy with respect to opting in to MIPS, ensures that a significant number of eligible clinicians have the ability to opt-in if they wish to participate in MIPS. CMS estimates no additional clinicians would be excluded as a result of this third criterion because a clinician that cares for at least 200 beneficiaries would have at least 100 or 200 services; however, it estimates 27,903 clinicians would opt-in with the low-volume threshold at 200 services, as compared to 12,242 clinicians if CMS did not add the third criterion.

CMS presents data in [Figure 1](#) in response to concerns that the proposed low-volume threshold limits the number of clinicians in the budget neutral pool and effectively precludes MIPS eligible clinicians with good performance from earning more than a nominal payment adjustment. The data show that while lowering the low-volume threshold would increase the number of MIPS eligible clinicians and the dollars available in the budget neutral pool (\$131M), it would have minimal impact on the maximum possible positive payment adjustment.

CMS also clarified here that, in general, allowed charges refers to the maximum amount Medicare will pay for a covered professional service under the PFS, which is the PFS fee schedule amount reduced by the applicable beneficiary co-payment. For purposes of MIPS low-volume threshold determinations, allowed charges are calculated before any Multiple Procedure Payment Reduction is applied.

Low-Volume Threshold Opt-in: *CMS finalized these policies as proposed* ([p. 949](#)). In response to concerns that the opt-in may reduce the amount of positive MIPS payment adjustment factors for clinicians who are required to participate since additional clinicians who voluntarily opt-in are likely to be above the MIPS threshold, CMS ran models based on Year 1 data to evaluate the impact of this

volume threshold determinations (and would otherwise be excluded from MIPS), then such eligible individual or group may choose to opt-in to MIPS. This policy would not apply to individual eligible clinicians and groups who do not exceed any of the low-volume threshold criteria, who would be excluded from MIPS participation without the ability to opt-in to MIPS.

- A clinician or group 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.
 - For individual eligible clinicians and groups to make an election to opt-in or voluntarily report to MIPS, they will 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 eligible clinician has elected to participate in MIPS, the decision to opt-in to MIPS will be irrevocable and cannot be changed for the applicable performance period.
 - Clinicians who do not decide to opt-in to MIPS will remain excluded and may choose to voluntarily report. Such clinicians will not receive a MIPS payment adjustment factor.
 - APM Entities also would be required to make a definitive choice at the APM Entity level to opt-in to participate in MIPS via a similar election process.
- 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 and subject to payment adjustments.
- A virtual group election would constitute a low-volume threshold opt-in for any prospective member of the virtual group (solo practitioner or group) that exceeds at least one, but not all, of the low-volume threshold criteria. As a result of the virtual group election, any such solo practitioner or group will 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.

policy. It revealed a very modest impact to the payment adjustment irrespective of the opt-in assumption used. See [Figure 2](#) for the model by option.

In response to other concerns, CMS noted it does not believe that it has the flexibility to allow *any* clinician who wishes to participate in MIPS to opt-in nor to retroactively apply the opt-in policy to the 2018 MIPS performance period.

Some commenters sought clarification on the deadline to opt-in. CMS would like to create a process for eligible clinicians who wish to opt-in to MIPS that is the least burdensome, but also provides the clinician with the most flexibility. It is exploring if it can operationally allow clinicians to opt-in at any time prior to the submission period and will provide further guidance via subregulatory guidance if this becomes available.

CMS also clarifies here that in instances where a third party intermediary is representing a MIPS eligible clinician, the third party intermediary must be able to transmit the clinician's opt-in decision to CMS.

In the [Regulatory Impact Analysis](#), CMS estimates clinician eligibility as follows:

- Eligible because they exceed all three criteria of the low-volume threshold and are not otherwise excluded (770,000)
- Eligible because they exceed at least one, but not all, of the low-volume threshold criteria and elect to opt-in (28,000 for a total MIPS eligible clinician population of approximately 798,000)
- Potentially eligible if they either did group reporting or elected to opt-in (390,000)
- Excluded because they do not exceed any of the low-volume threshold criteria (78,000)
- Excluded due to non-eligible specialty, newly enrolled, or QP status (209,000)

Part B Services Subject to MIPS Payment Adjustment: CMS proposes to amend §414.1405(e) to modify the application of both the MIPS adjustment factor and, if applicable, the additional MIPS adjustment factor so that beginning with the 2017 performance year/2019 MIPS payment year, these adjustment factors will apply to Part B payments for covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by the MIPS eligible clinician during the year. CMS is making this change beginning with the first MIPS payment year and notes that these adjustment factors will not apply to Part B drugs and other items furnished by a MIPS eligible clinician, but will apply to covered professional services furnished by a MIPS eligible clinician.

Part B Services Subject to MIPS Payment Adjustment: *CMS finalized this policy as proposed (p. 951).*

Partial QPs

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 finalized this policy [later in this rule](#). That section of the rule also eliminates the scenario in which affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period will constitute an explicit election to report under MIPS for eligible clinicians who are determined to be Partial QPs individually and make no explicit election to either report to MIPS or be excluded from MIPS. CMS believes this change is necessary because 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, it is not 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.

CMS also clarifies that affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period does not constitute an explicit election to report under MIPS 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.

Group Reporting

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);

CMS received many comments on group reporting and will take them into consideration for future rulemaking.

- 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

Virtual Groups

CMS proposes to continue its previously established virtual group policies for the 2022 MIPS Payment year and future years with the following modifications:

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. A designated virtual group representative must submit an election, on behalf of the solo practitioners and groups that compose a virtual group, to participate in MIPS as a virtual group for a performance period. CMS anticipates that a virtual group representative will make the election via a web-based system developed by CMS.

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

Virtual Group Election Process: *CMS finalized this policy as proposed* ([p. 960](#)).

Virtual Group Eligibility Determinations: *CMS finalized these policies as proposed* ([p. 966](#)).

**MIPS
Performance
Period**

would be determined in accordance with the MIPS determination period.

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)

CMS finalized these policies as proposed ([p. 977](#)). CMS does not believe that it would be in the best interest of MIPS eligible clinicians to have less than a full calendar year performance period for the quality and cost performance categories for the 2022 MIPS payment year and future years. A full calendar year performance period is consistent with how many of the measures used in the program were designed to be reported and performed.

CMS also believes that benchmarks based on data from a 90-day performance period would be less reliable than those based on a full calendar year because fewer reported instances would meet the case minimum needed to be included in the benchmarks. This would also cause some measures to not have an available benchmark that could be used for scoring. In addition, using a 90-day performance period would not allow the creation of benchmarks from more current data since CMS would still need to wait until the end of the data submission period before it could create the benchmarks based on data submitted by all MIPS eligible clinicians. To publish historical benchmarks prior to the beginning of the performance period, CMS would still need to use data from two years prior to the performance period (four years prior to the MIPS payment year).

CMS also notes in this section that operationally its goal is to provide as much continuous submission opportunity as we can support in the future, including allowing clinicians to submit data during the performance period, as feasible. The ability to receive more frequent and continuous submissions will further CMS' ability to provide more frequent feedback to MIPS eligible clinicians.

**MIPS
Performance
Category
Measures and
Activities**

Collection Types, Submission Types and Submitter Types:

- CMS proposes to revise and define new terminology at §414.1305 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

Collection Types, Submission Types and Submitter Types:

CMS finalized these definitions as proposed ([p. 982](#)).

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 submission (which allows users to transmit data through a computer-to-computer interaction, such as an 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.

Performance Category Measures and Reporting:

Facility-Based Data Submissions

CMS proposed at §414.1325(a)(2)(ii) that there is no data submission requirement for the quality or cost performance category, as applicable, for MIPS eligible clinicians and groups that are scored under the facility-based measurement scoring methodology described in §414.1380(e).

Claims Submission

CMS proposes to amend §414.1325(c)(1) to limit the Medicare Part B claims quality measure collection type to small practices beginning with the 2019 performance period and to allow clinicians in small practices to report claims as a group.

Performance Category Measures and Reporting:

Facility-Based Data Submissions

CMS finalized this policy as proposed (p. 996). See section on [Facility-Based Scoring](#) for more information.

Claims submission

CMS finalized this policy as proposed (p. 996). CMS recognizes public concerns about limiting claims reporting and the burden this could pose on certain clinicians who have traditionally relied on claims-based measures. At the same time, CMS reiterates its belief that it's important to move away from manual methods of reporting, that it has been signaling it would do this for many year, and the fact that approximately 69% of the Medicare Part B claims measures are topped out.

CMS also clarifies that non-small practices that do not wish to enter into an arrangement with a third party intermediary can use the MIPS CQM collection type and either login and upload their data or use the direct submission type for the quality performance category, which is a flexibility offered under MIPS that was not available under the legacy programs. These submission types do not require the usage of a third party intermediary; however, there are certain technical capabilities that a practice must have to submit data in this manner. Additional details on the form and manner requirements of these submission types is available [here](#).

In response to a question about how CMS would determine that a claims submission is intended for group reporting if the group only submits data for the

quality performance category of MIPS, CMS also clarifies that in this scenario, it would calculate the quality performance category for the practice as both a group and as individuals and will apply the quality category score that is the greater of the two. CMS considered requiring an election for assessment as a group, but believes this would be unduly burdensome on small practices.

Web Interface

- 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 since it was designed as a method for quality submissions only. For those using the Web Interface for quality, Improvement Activities and Promoting Interoperability data could be submitted 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).
- CMS also solicits comment on expanding the core set of measures available via the Web Interface to include other specialty specific measures (such as surgery).

Submission Deadline

CMS proposes a number of other technical revisions to §414.1325 to outline data submission deadlines for all submission types for individual eligible clinicians and groups for all performance categories, and to allow flexibility for CMS to alter submission deadlines for the direct, login and upload, the CMS Web Interface, and login and attest submission types. CMS anticipates that in scenarios where the March 31st deadline falls on a weekend or holiday, it will extend the submission period to the next business day (i.e., Monday). There also may be instances where due to unforeseen technical issues, the submission system may be inaccessible for a period of time, in which case CMS will extend the submission period to account for this lost time, to the extent feasible.

CMS also proposes to align the deadline for the Web Interface submission types with all other submission type deadlines.

Web Interface

CMS finalized these policies as proposed ([p. 996](#)).

CMS clarifies that groups that elect to utilize the CMS Web Interface can still submit improvement activities or promoting interoperability data via direct and log in and upload, if they choose not to utilize the login and attest submission type.

CMS also notes here that it received many comments on expanding the scope of practices that can utilize the Web Interface and will take them into consideration for future rulemaking.

The following tables summarize individual and group submission types beginning with the 2019 MIPS performance period:

- **[TABLE 32: Data Submission Types for MIPS Eligible Clinicians Reporting as Individuals](#)**
- **[TABLE 33: Data Submission Types for MIPS Eligible Clinicians Reporting as Groups](#)**

Submission Deadline

CMS finalized these policies as proposed ([p. 1000](#)).

**Quality
Performance
Category**

CMS also proposes a number of other technical revisions to §414.1325 to more clearly and concisely reflect previously established policies.

Contribution to Final Score: Using authority granted under the Bipartisan Budget Act of 2018, CMS proposes at §414.1330(b)(3) to weight the quality performance category at 45 percent for the 2019 performance year.

Quality Data Submission Criteria:

CMS did not propose any changes to the quality data submission criteria or data completeness criteria for the 2021 MIPS payment year, but proposed changes to existing and additional related terminology.

Submission Criteria for Groups Reporting Quality Measures, Excluding CMS Web Interface Measures and the CAHPS for MIPS Survey Measure

To account for terminology changes in this rule, CMS proposed to revise §414.1335(a)(1) to state that data would be collected for the following collection types: Medicare Part B claims measures; MIPS CQMs; eCQMs; or QCDR measures. Codified at §414.1335(a)(1)(i), MIPS eligible clinicians and groups must submit data on at least six measures, including at least one outcome measure.

Beginning with the 2019 performance year, CMS proposes to amend §414.1335(a)(1)(ii) to clarify 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, they must report on each measure that is applicable.

Contribution to Final Score: CMS finalized these policies as proposed (p. 1000).

Several commenters did not support the proposed reduction of the quality performance category weight to 45 percent from 50 percent for the third year of MIPS, noting that adjusting the weight downward sends the wrong message to physicians regarding quality of care and that de-emphasizing quality runs contrary to the aim of reforming toward a value-based system, leads to less stability with the program and adds complexity. CMS believes that it is measuring value by rewarding performance in quality while keeping down costs and that clinicians can influence the cost of services that they do not personally perform by improving care management with other clinicians and avoiding unnecessary services.

Quality Data Submission Criteria: CMS finalized these clarifications as proposed (p. 1007).

CMS clarifies here that if a MIPS eligible clinician chooses to report only on a specialty or subspecialty measure set and reports on less than 6 quality measures through either the MIPS CQM or Medicare Part B claims collection types, they will be subjected to the measure validation process that will validate whether the clinician actually had less than 6 measures available or applicable to their scope of practice. If a MIPS eligible clinician chooses to report via the QCDR measure collection type, they will be required to meet the reporting requirement of 6 quality measures. If a MIPS eligible clinician reports fewer than 6 quality measures through a QCDR, they will receive zero points for each unreported quality measure.

In response to concerns about the full calendar year performance period being paired with a 60 percent data completeness requirement, CMS notes its interest in incorporating higher data completeness thresholds in future years to ensure more accurate assessments and avoid measure selection bias, but believes this should be done in a gradual manner to ensure the requirement is achievable by all MIPS eligible clinicians. CMS also supports a longer performance period because it is less confusing for clinicians, because larger sample sizes provide more accurate and actionable information, and because its consistent with how many of the measures used in the program were designed to be performed and reported.

[Tables 34](#) and [35](#) summarize the data completeness requirements and submission criteria by collection type for individual clinicians and groups.

Selection of MIPS Quality Measures for Individual MIPS Eligible Clinicians and Groups Under the Annual List of Quality Measures Available for MIPS Assessment:

Addition/Removal of Measures

For the 2019 MIPS performance period, CMS proposes to:

- Add 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;
- Remove 34 quality measures

[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.

Selection of MIPS Quality Measures for Individual MIPS Eligible Clinicians and Groups Under the Annual List of Quality Measures Available for MIPS Assessment:

Addition/Removal of Measures

For the 2019 MIPS performance period, CMS finalized the following updates:

- ***Adding 8 new MIPS quality measures that include 4 patient reported outcome measures, 6 high priority measures, and 2 measures on important clinical topics in the Meaningful Measures framework. CMS did not finalize the following measures, as proposed:***
 - ***Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future***
 - ***Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication***
- ***Removing 26 quality measures. CMS did NOT finalize the removal of the following measures for 2019:***
 - ***12: Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation***
 - ***48: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years***
 - ***154: Falls: Risk Assessment***
 - ***155: Falls: Plan of Care***
 - ***185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use. CMS is removing the claims version of this measure, but not the MIPS CQM (registry) version.***
 - ***318: Falls: Screening for Future Fall Risk***
 - ***375: Functional Status Assessment for Total Knee Replacement***
 - ***386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences***

[Appendix 1, Table Group A](#): New MIPS quality measures finalized for inclusion in MIPS for the 2019 performance period and future years

[Appendix 1, Table Group B](#): Finalized new and modified quality measure specialty sets.

[Appendix 1, Table Group C](#): Measures finalized for removal for 2019.

[Appendix 1, Table Group D](#): Quality measures with finalized substantive changes for 2019.

Through subregulatory guidance, CMS will categorize quality measures by the 19 Meaningful Measure areas as identified on the [Meaningful Measures Initiative website](#) for guidance purposes only.

In response to concerns that the current timeline for the release of measure specifications in December is overly burdensome and does not allow adequate time to build and test systems prior to reporting measures on January 1, CMS clarified that it is not technically feasible to release the MIPS quality measure specifications until the final rule is published. However, it will take these concerns into account as it considers the operational feasibility of releasing the MIPS quality measure specifications earlier than December. For Year 2 of the program there was a delay in posting the measures within the QPP Explore Measures Tool due to technical difficulties. However, the measure specifications were made available on the QPP Program resource library prior to the beginning of the performance period. CMS will continue to post the year 3 measure specifications on the QPP resource library prior to the beginning of the performance period and will make every effort to update the QPP Explore Measures Tool with the year 3 measures prior to the performance period, or as close to the beginning of the performance period as technically feasible.

CMS Web Interface Measures

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).

CMS Web Interface Measures

CMS thank stakeholders for their comments, and will consider it for future rulemaking ([p. 1019](#)).

High Priority Measure Definition

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.

High Priority Measure Definition

CMS finalized this policy as proposed ([p. 1027](#)) In response to concerns about the potential unintended consequences of revising the definition of high-priority measures to include opioid related quality measures, CMS clarified that its intention is not to create barriers for seriously ill patients receiving appropriate pain management. CMS encourages appropriate treatment, but also encourages proper monitoring, management, follow-up, and education of patients. CMS believes it is important to consider patients such as those receiving hospice and palliative care, and will discuss with measure stewards of opioid-related measures whether exceptions for such patients may be appropriate.

Topped Out Measures

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 4-year 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. However, CMS would also consider retaining the measure if there are compelling reasons as to

Topped Out Measures

CMS finalized this policy as proposed ([p. 1033](#)). Many commenters did not support this proposal to remove extremely topped out measures and requested more time and data to determine if measures are truly topped out. CMS did not agree with these concerns. The benchmarks used to identify measures for removal are reflective of the performance of those clinicians who have reported on the measure and will continue to do so should the measure be available in the program. Thus, CMS does not believe there will be variances in the high performing data submitted if the measure is retained.

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. When a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period. Because QCDRs have more flexibility to develop innovative measures, CMS believes there is limited value in maintaining topped out QCDR measures in MIPS.

Removal of Quality Measures

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

CMS also noted its appreciation for feedback suggesting that it defer to measure developers and national endorsement organizations to define which measures are topped out. It will take this suggestion in to future consideration.

Responding to concerns about excluding QCDR measures from the topped out timeline, CMS noted that the process and timeline for QCDR measure consideration and the criteria for approval is different than MIPS measures. QCDRs are expected to be nimble and innovative enough to develop QCDR measures that are robust in their quality action and demonstrate a performance gap. CMS also did not agree with commenters that recommended that topped out QCDR measures should be retained in the program for a minimum number of years. CMS believes this may inadvertently impact a high performing clinician who may not receive a high score when compared to other clinicians reporting on the same measure. CMS also does not believe that the removal of topped out QCDR measures would impact the number of available specialty-specific measures since QCDR measures are reviewed and approved on a more accelerated timeline in comparison to the MIPS quality measures.

Removal of Quality Measures

CMS finalized this policy as proposed ([p. 1039](#)). CMS understands that there are some process measures that are valuable, but believes it's important that they address one of the high priority areas and demonstrate a performance gap in order to be meaningful. CMS also understands that important quality of care aspects may only be captured by some topped out process measures, and encourage clinicians to continue to measure and monitor their progress in these areas; however, it does not believe that these measures provide value or should be tied to a pay for performance program such as MIPS.

CMS clarifies that it will only propose the removal of MIPS quality measures through formal notice-and-comment rulemaking, and that this annual process will provide stakeholders with sufficient notice and opportunity to voice their concerns on specific measure removals through the public comment process

In response to a request that CMS evaluate measures for removal based on the collection type, CMS noted that in instances where a new measure does not have eCQM available as a collection type, CMS decided not to remove the existing (duplicative) measure for the eCQM collection type only. CMS refers readers to [Appendix 1](#): Finalized Quality Measures of this final rule for additional detail on these eCQMs.

Categorizing Measures by Value

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.

CMS thanks commenters for their input and may take this input into consideration in future years ([p. 1040](#)).

**Cost
Performance
Category**

Contribution to Final Score: Section 51003(a)(1)(C) of the Bipartisan Budget Act of 2018 amended section 1848(q)(5)(E)(i)(II)(bb) of the Act such 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. In accordance with this amendment, 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.

Contribution to Final Score: *CMS finalized this policy as proposed* ([p. 1045](#)) despite various concerns about this policy and requests that CMS not increase the weight of this category until clinicians have had more time to learn about the new episode-based measures; until sufficient episode groups exist for additional specialties; and until CMS can address issues of social and complexity risk factors and of clinical risk adjustment for measures in areas such as oncology. CMS noted that since the weight of the cost category is still required to be 30 percent beginning with the 2024 MIPS payment year, it is necessary to begin adjusting the weight gradually. In regards to concerns about the episode-based cost measures, CMS believes that stakeholders had the opportunity to gain experience with the new measures through field testing in the fall of 2017. CMS will continue to aim to increase the number of clinicians who are measured in the cost performance category by developing more episode-based measures that cover additional types of clinicians and specialties.

CMS also will continue to investigate ways to best accommodate the issue of clinical and social risk adjustment in measures contained in the cost performance category. All measures included in the cost performance category are adjusted for clinical risk. CMS also adopted a complex patient bonus at the final score level that adjusts again for patient clinical complexity as well as some elements of social complexity. CMS will continue to consider ways to offer actionable feedback on cost measures to clinicians in the future.

Cost Criteria:

Episode-Based Measures Proposed for the 2019 and Future Performance Periods

Following the successful field testing and review through the Measures Application Partnership (MAP) process⁴, CMS proposes to add the following eight episode-based measures as cost measures for the 2019 MIPS performance period and future performance periods:

- Procedural
 - Elective Outpatient PCI
 - Knee Arthroplasty

Cost Criteria:

Episode-Based Measures Proposed for the 2019 and Future Performance Periods
CMS finalized these measures, as proposed, which are listed in [Table 36](#) ([p. 1069](#)).

CMS disagreed with concerns about the premature implementation of these measures, noting that the extensive field testing activities conducted in the fall of 2017 in combination with future education and outreach will help to ensure clinicians will understand these episode-based measures and what actions they could take to improve their performance in the measures. In response to requests for better and more detailed feedback on cost measures, CMS notes it's

⁴ All of these episode-based measures were considered by the National Quality Forum (NQF)-convened MAP, and were all conditionally supported by the MAP, with the recommendation of obtaining NQF endorsement. CMS intend to submit these episode-based measures to NQF for endorsement in the future.

- Revascularization for Lower Extremity Chronic Critical Limb Ischemia
- Routine Cataract Removal with IOL Implantation
- Screening/Surveillance Colonoscopy
- Acute Inpatient Medical Condition
 - Intracranial Hemorrhage or Cerebral Infarction
 - Simple Pneumonia with Hospitalization
 - STEMI with PCI

CMS would also retain the Medicare Spending Per Beneficiary (MSPB) measure and the Total Per Capita Cost measure.

continuing to conduct user research about what is valuable within information provided historically. CMS is committed to maturing the feedback experience for year 2 and may consider providing beneficiary-level data on cost measures in the future.

In response to concerns that measures for certain specialties have not yet been included, CMS noted that Section 1848(r)(2)(D)(i)(I) of the Act requires it to establish care episode groups and patient condition groups, which account for a target of an estimated one half of expenditures under parts A and B with such target increasing over time as appropriate. While CMS has developed some episode-based measures to target that goal, it will continue that work while also considering the important issue of measuring both cost and quality.

In response to concerns about the Simple Pneumonia with Hospitalization episode, CMS clarified that the costs associated with the hospice setting are not assigned to the episode.

CMS also agreed with a request to exclude Implantable Cardioverter Defibrillator (ICD) implantation MS-DRGs (222-227) from the Elective Outpatient PCI and STEMI with PCI measures as these are more likely to be elective ICD placements. Excluding these would ensure there are no adverse incentives to providing a service that is both covered and clinically indicated. CMS believes it is appropriate to assign services that are part of an admission for MI or HF, while excluding services that are elective. To maintain a consistent framework across all measures, CMS is implementing this revision where relevant in STEMI with PCI, Elective Outpatient PCI, and Revascularization for Lower Extremity Chronic Critical Limb Ischemia.

In response to opposition to the continued inclusion of the Total per Capita Cost measure and the MSPB measure in the cost performance category, CMS continues to believe that these measures are tested and reliable for Medicare populations and provide an important measurement of clinician cost performance. CMS notes that both of these measures are being refined as part of the measure maintenance and re-evaluation process, incorporating substantial stakeholder input.

Responding to concerns about risk and specialty adjustments, CMS reiterated its concern about holding clinicians to different standards for the outcomes of their patients with social risk factors because it does not want to mask potential disparities. CMS will continue to consider options to account for social risk factors that would allow us to view disparities and potentially incentivize improvement in care for patients and beneficiaries.

Reliability

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 beginning with the 2019 MIPS performance period.

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

CMS seeks comments on an alternative case minimum of 30 for both TIN/NPIs and TINs for the Simple Pneumonia with Hospitalization measure.

Attribution

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. 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.

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.

Improvement Activities Performance Category

Submission Criteria: 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.

Reliability

CMS finalized these policies as proposed ([p. 1075](#)). It will take comments received on expanding the performance period for measures in the cost performance category into account for future rulemaking.

[Table 37](#) presents the percentage of TINs and TIN/NPIs with 0.4 or higher reliability, as well as the mean reliability for the subset of TINs and TIN/NPIs who met the finalized case minimums for each of the episode-based cost measures.

In regards to the alternative case minimum of 30 for the Simple Pneumonia with Hospitalization measure, CMS notes that this would give the measure slightly higher reliability. However, CMS believes that maintaining a consistent case minimum across all acute inpatient medical condition episode-based measures would accurately and reliably assess cost measure performance for a large number of clinicians and clinician groups. Also, the mean reliability of the Simple Pneumonia with Hospitalization measure at 20 episodes exceeds CMS’ 0.4 reliability threshold (indicating moderate reliability) for TINs and meets that threshold for TIN/NPIs.

Attribution

CMS finalized these policies as proposed ([p. 1083](#)). For both types of measures, 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.

Submission Criteria: ***CMS finalized these policies as proposed*** ([p. 1087](#))

CMS also proposes to update §414.1360(a)(1) to further specify: “submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.”

Improvement Activities Inventory

Criteria for Nominating New Improvement Activities

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. CMS believes it is important to place attention on public health emergencies, such as the opioid epidemic, when considering improvement activities. 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 since it is also proposing a new approach for scoring the Promoting Interoperability category.

Weighting of Improvement Activities

CMS provides the following clarifications here:

- a) High-Weighting Due to Activity Intensity: CMS believes that an activity that requires significant investment of time and resources should be high-weighted (e.g., the CAHPS for MIPS survey). In contrast, medium-weighted improvement activities are simpler to complete and require less time and resources as compared to high-weighted improvement activities (e.g., Cost Display for Laboratory and Radiographic Orders because the information required to be used is readily available at no cost through the [Medicare clinical laboratory fee schedule](#) and can be distributed in a variety of manners with very little investment).
- b) High-Versus Medium Weighting: CMS clarifies that an improvement activity is by default medium-weight unless it meets considerations for high-weighting as discussed previously

Modifications to the Annual Call for Activities Timeframe

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

Improvement Activities Inventory

Criteria for Nominating New Improvement Activities

CMS finalized this new criterion as proposed ([p. 1094](#)).

CMS also finalized the removal of the Advancing Care Information criterion ([p. 1096](#)).

The updated list of criteria is available on [p. 1095](#).

Weighting of Improvement Activities

CMS reiterates these clarifications.

Modifications to the Annual Call for Activities Timeframe

CMS finalized these changes as proposed ([p. 1104](#)). Several commenters opposed these proposals, noting that the benefit of being able to modify or add measures each year outweighs the need for additional submission time. CMS countered that sufficient time is needed to thoroughly review all submissions to

next year's rulemaking cycle for possible implementation in a future year (e.g., 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.

Modifications to the Existing Improvement Activity Inventory

CMS proposes to:

- Add six 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 in [Appendix 2, Table B](#)).

CMS Study on Factors Associated with Reporting Quality Measures:

Successful participation in this previously finalized study results in full credit for the improvement activities performance category of 40 points. For the CY 2019 performance period and future years, CMS proposes 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
- Require that at least one of the minimum of three required measures be a high priority measure

ensure a meaningful and robust inventory of activities. CMS recognizes that the extended timeframe does not align with the submission, review, and implementation of quality measures as part of the Annual Call for Measures; however, it does parallel the Promoting Interoperability Annual Call for EHR Measures timeframe. CMS will continue to monitor the timeline to assess if there are any future improvements that can be made to more quickly incorporate new improvement activities into the program when feasibly possible.

Modifications to the Existing Improvement Activity Inventory

CMS finalized these updates to the Improvement Activity Inventory as proposed.

A summary of the public comments received on specific improvement activities proposals and CMS' responses may be found in [Appendix 2: Table A](#), which lists new Improvement Activities for 2019, and [Appendix 2: Table B](#), which summarizes changes to previously approved Improvement Activities.

CMS Study on Factors Associated with Reporting Quality Measure :

CMS finalized these changes as proposed (p. 1108 - 1115).

Promoting Interoperability (PI)

Renaming the Advancing Care Information Performance Category: 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.

Renaming the Advancing Care Information Performance Category: *CMS finalized revisions to the regulation text under 42 CFR part 414, subpart O, to reflect the new name (p. 1116).*

Certification Requirements: As previously finalized, beginning with the 2019 performance period, MIPS eligible clinicians must use EHR technology certified to the 2015 Edition criteria since it has improved interoperability features and up-to-date standards to collect and exchange relevant patient health information.

Scoring Methodology:

Scoring Methodology for 2017 and 2018 Performance Periods: 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.

Proposed Scoring Methodology Beginning with the MIPS Performance Period in 2019

Based on concerns expressed by stakeholders and to align with the requirements of the Medicare Promoting Interoperability program for eligible hospitals, CMS proposes a new scoring methodology that moves away from the base, performance and bonus score methodology currently in use. 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.
- The numerator and denominator for each performance measure would translate to a performance rate for that measure and will be applied to the total possible points for that measure.
- 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

Certification Requirements: Because this requirement was previously finalized and not a subject of this rulemaking, CMS did not respond to comments on this topic, but may consider them to inform future policy making ([p. 1116](#)).

Scoring Methodology:

Scoring Methodology for 2017 and 2018 Performance Periods
CMS finalized this decision ([p. 1120](#)).

A general summary overview of the scoring methodology for 2018 is provided in the [Table 38](#).

Proposed Scoring Methodology Beginning with the MIPS Performance Period in 2019

CMS finalized its proposed performance-based scoring methodology for the Promoting Interoperability performance category beginning with the performance period in CY 2019, with modifications ([p. 1147](#)). The modifications pertain to specific measures, which are described below.

Electronic Prescribing objective:

The e-Prescribing measure is worth up to 10 points in CYs 2019 and 2020. CMS modified the points for CY 2020 to reflect the following modifications in CY 2020.

- **The Query of PDMP measure is optional in CY 2019 and worth 5 bonus points. CMS is not establishing a policy for the Query of PDMP measure for CY 2020 in this final rule and intends to address this measure in future rulemaking.**
- **The Verify Opioid Treatment Agreement measure will be optional in CY 2019 and 2020, and worth five bonus points. CMS intends to reevaluate the status of the Verify Opioid Treatment Agreement measure for subsequent years in future rulemaking.**

An exclusion will be available for the e-Prescribing measure. If claimed for the e-Prescribing measure for CY 2019, the 10 points for the e-Prescribing measure will be redistributed equally among the measures associated with the Health Information Exchange objective. Since the Query of PDMP and Verify Opioid Treatment Agreement measures are optional and eligible for bonus points in CY 2019, no exclusions are available ([p. 1148](#)).

Provider to Patient Exchange objective

category score of up to 100 possible points for each MIPS eligible clinician. The total sum cannot exceed the total possible points. [TABLE 38](#) includes an example of how this proposed scoring methodology would be applied during the 2019 performance period.

- For a MIPS eligible clinician to earn a score greater than zero for the Promoting Interoperability performance category, in addition to completing the actions included in the [Security Risk Analysis](#) measure, the MIPS eligible clinician must submit their complete numerator and denominator or yes/no data for all required measures. 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.

CMS also seeks comment on 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.

Promoting Interoperability Objectives and Measures Specifications for the 2019 Performance Period:

- 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](#) and [Clinical Information Reconciliation](#)– 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.
- 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.
 - CMS proposes to add three new measures:
 - [Query of PDMP](#)
 - [Verify Opioid Treatment Agreement](#)

The [Provide Patients Electronic Access to Their Health Information](#) measure will be worth up to 40 points beginning in CY 2019. CMS had proposed that it be worth up to 35 points beginning in CY 2020, but is not finalizing that proposal because it is not requiring the [Verify Opioid Treatment Agreement](#) measure beginning in CY 2020 as proposed, which would have been worth up to 5 points. No exclusions are available for this measure ([p. 1150](#))

Public Health and Clinical Data Exchange objective

MIPS eligible clinicians must submit a yes/no response for two different public health agencies or clinical data registries for any of the measures (including the same measure) to earn 10 points for the objective: [Syndromic Surveillance Reporting](#), [Immunization Registry Reporting](#), [Electronic Case Reporting](#), [Public Health Registry Reporting](#), and [Clinical Data Registry Reporting](#). Failure to report on two different public health agencies or clinical data registries or submitting a “no” response for a measure will earn a score of zero. If an exclusion is claimed for one measure, but the MIPS eligible clinicians submits a “yes” response for another measure, they would earn the 10 points for the objective. If a MIPS eligible clinician claims exclusions for both measures they select to report on, the 10 points would be redistributed to the [Provide Patients Electronic Access to Their Health Information](#) measure under the [Provider to Patient Exchange](#) objective ([p. 1150](#))

All other scoring methodology policies and measures were finalized as proposed.

[Table 39](#) summarizes the proposed scoring methodology for the MIPS 2019 performance period.

[Table 40](#) summarizes the proposed scoring methodology beginning with the 2020 MIPS performance period.

[Table 41](#) reflects the final measures and scoring methodology for 2019

[Table 42](#) reflects the final measures and scoring methodology for CY 2020.

**Note that the maximum points available do not include points that would be redistributed in the event an exclusion is claimed.*

Some comments/concerns discussed in this section include:

- CMS disagreed with commenters that CMS only require that MIPS eligible clinicians attest to satisfying each measure for a least 1 patient instead of using a performance rate. CMS believes that a performance-based scoring mechanism will enable MIPS eligible clinicians who perform well on measures to differentiate themselves from other MIPS eligible clinicians who submitted data with lower results for the PI performance category.

- These two new measures would be optional for 2019 (each worth 5 bonus points for those who report them).
 - Support Electronic Referral Loops by Receiving and Incorporating Health Information
 - This measure combines the functionality of the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures into a new measure.
- The Security Risk Analysis measure 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.
- 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
 - 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.
 - 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. CMS also proposes exclusion criteria for each of these measures. CMS intends to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than 2022.

[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.

- CMS also disagreed with suggestions that it allow MIPS eligible clinicians to “pick and choose” measures from a “menu” of objectives and measures. CMS noted that it allowed considerable choice for years one and two and received significant feedback about how complicated it was for clinicians to understand the requirements for the base and performance scores. CMS continues to believe that a reduced set of measures will reduce burden for clinicians and will enable them to focus more on patient care. CMS declines to retain measures so that MIPS eligible clinicians have flexibility in selecting measures.
- CMS also disagreed with comments that a full calendar year's notice is necessary to ensure clinicians can update their EHR systems to accommodate these new measures. CMS believes it provides sufficient exclusions and optional measures and that the remaining measures remain the same and are supported by 2015 Edition CEHRT.

Promoting Interoperability/Advancing Care Information Objectives and Measures Specifications for the 2018:

In this section, CMS provides a detailed description of the numerator, denominator, and applicable exclusions for each measure included in 2018 ([p. 1152](#)).

Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians for 2019:

In this section, CMS summarizes feedback received on each measure proposed for 2019 and its final decision:

- ***CMS finalized the Query of PDMP measure, with modification***, to read: 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 ([p. 1178](#)).
 - A discussion about the proposal and comments received begins on [p. 1165](#).
 - Since this measure is optional for 2019, there are no exclusions.
- ***CMS finalized the Verify Opioid Treatment Agreement Measure, with modification***, to read: 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 ([p. 1189](#))
- A discussion about the proposal and comments received begins on [p. 1179](#).
- This measure will be optional in the CY 2019 and 2020 performance periods, so CMS is not finalizing the proposed exclusion for CY 2020.
- ***CMS finalized the proposal to change the name of the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information measure. It also finalized the proposal that MIPS eligible clinicians may use any document template within the C-CDA standard for purposes of the measures under the Health Information Exchange objective*** ([p. 1198](#))
 - A discussion about the proposal and comments received begins on [p. 1192](#)
- ***Request/Accept Summary of Care Measure: CMS finalized removal of this measure as proposed*** ([p. 1201](#))
 - A discussion about the proposal and comments received begins on [p. 1198](#)
- ***Clinical Information Reconciliation measure: CMS finalized removal of this measure as proposed*** ([p. 1202](#))
 - A discussion about the proposal and comments received begins on [p. 1201](#)
- ***Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure: CMS finalized this measure as proposed.*** It also finalized the proposal to apply the 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. MIPS eligible clinician must use the capabilities and standards as defined for CEHRT at §170.315(b)(1) and (b)(2) ([p. 1209](#), includes more in depth measure description)
 - A discussion about the proposal and comments received begins on [p. 1202](#)
- ***Provide Patient Access measure: CMS finalized the new name, Provide Patients Electronic Access to Their Health Information, as proposed*** ([p. 1214](#)).
 - A discussion about the proposal and comments received begins on [p. 1211](#)
- ***Patient-Generated Health Data measure: CMS finalized its decision to remove this measure*** ([p. 1216](#)).

- A discussion about the proposal and comments received begins on [p. 1214](#)
- **Patient-Specific Education Measure: CMS finalized its decision to remove this measure** ([p. 1218](#)).
 - A discussion about the proposal and comments received begins on [p. 1216](#)
- **Secure Messaging measure: CMS finalized its decision to remove this measure** ([p. 1220](#)).
 - A discussion about the proposal and comments received begins on [p. 1218](#)
- **View, Download or Transmit measure: CMS finalized its decision to remove this measure** ([p. 1221](#)).
 - A discussion about the proposal and comments received begins on [p. 1220](#)
- **Modifications to the Public Health and Clinical Data Registry Reporting Objective and Measures: CMS finalized these proposals with modification.** It is changing the name of the objective to Public Health and Clinical Data Exchange and adopting exclusions for each of the associated measures. It also is adopting a final policy to allow MIPS eligible clinicians to earn full credit for this objective by reporting to two different public health agencies or clinical data registries for any of the measures associated with the objective ([p. 1230](#)).
 - A discussion about the proposal and comments received begins on [p. 1222](#). In response to concerns about CMS' intention to remove these measures in the future, CMS noted it would continue to monitor the data it compiles specific to the public health reporting requirements and take commenter concerns into consideration in future rulemaking.

[Table 43](#) lists the **PI objectives and measures and associated certification criteria for the 2015 Edition**

Potential New Measures Health Information Exchange Across the Care Continuum:

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):

- Support Electronic Referral Loops by Sending Health Information Across the Care Continuum
- Support Electronic Referral Loops By Receiving and Incorporating Health Information Across the Care Continuum

Potential New Measures Health Information Exchange Across the Care Continuum: CMS received many comments in response to this request, and will consider them as it develops future policy regarding the potential new measures that focus on health information exchange across the care continuum ([p. 1232](#)).

Improvement Activities Bonus Score under the Promoting Interoperability Performance Category and Future Reporting Considerations: CMS proposes to not continue the bonus for completing certain improvement activities using CEHRT for the performance period in 2019, and subsequent performance periods.

Creating a More Cohesive Reporting Experience to Reduce Burden:

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

- Linking Performance Categories: e.g., 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
- Public Health Priority Sets: CMS intends to propose these for future rulemaking. The public health priority sets, which would initially focus on opioids, blood pressure, diabetes, and general health (healthy habits), would be built across performance categories and intended to decrease burden.

Additional Considerations: 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. These MIPS eligible clinicians may choose to submit PI performance category measures if they determine that these measures are applicable and available to them; however, if they choose to report, they would be scored on the PI performance category like all other MIPS eligible clinicians.

Overview: CMS proposes to amend §414.1370(f)(2) to state that if the APM Entity group is excluded from MIPS, all eligible clinicians within that APM Entity group are also excluded from MIPS.

MIPS APM Criteria: CMS previously 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

Improvement Activities Bonus Score under the Promoting Interoperability Performance Category

CMS finalized this policy as proposed ([p. 1234](#))

Creating a More Cohesive Reporting Experience to Reduce Burden:

CMS thanks commenters for their feedback, which it will consider as it develops future policy proposals ([p. 1234](#)).

Additional Considerations: *CMS is adopting its proposal with modification.*

Earlier in this rule, CMS finalized a final policy to add the following types of clinicians to the definition of MIPS eligible clinician: physical therapist, occupational therapist, qualified speech-language pathologist, qualified audiologist, clinical psychologist, and registered dietitian or nutritional professional. CMS will apply the same policy it adopted for NPs, PAs, CNSs, and CRNAs for the performance periods in 2017 and 2018 to each of these new types of MIPS eligible clinicians for the performance period in 2019 ([p. 1239](#))

MIPS APM Criteria: *CMS finalized these clarifications as proposed* ([p. 1244](#), [p. 1245](#), [1246](#)).

Based on the MIPS APM criteria, CMS expects that the following 10 APMs will satisfy the requirements to be MIPS APMs for the 2019 performance year:

- Comprehensive ESRD Care Model (all Tracks)
- Comprehensive Primary Care Plus Model (all Tracks)
- Next Generation ACO Model
- Oncology Care Model (all Tracks)

[APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs](#)

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.

CMS clarifies multiple issues related to the MIPS APM criteria:

- CMS has received questions as to whether the criterion requires MIPS APMs to base payment incentives on performance on cost/utilization “measures”, or whether it requires more generally that MIPS APMs base payment incentives on “cost/utilization.” Since CMS intended the word “measures” to modify only “quality” and not “cost/utilization,” CMS proposes to revise §414.1370(b)(3) to specify that a MIPS APM must be designed in a way that participating APM Entities are incentivized to reduce costs of care or utilization of services, or both to 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.
- CMS also proposes to clarify that it will consider each distinct track of an APM and whether it meets the criteria to be a MIPS APM, and that it is possible for an APM to have tracks that are MIPS APMs and tracks that are not MIPS APMs. However, CMS will not further consider whether the individual APM Entities or MIPS eligible clinicians participating within a given track each satisfy all of the MIPS APM criteria.
- CMS also makes clarifications for APMs that begin after the first day of the MIPS performance period for the year (currently January 1), where quality measures tied to payment must be reported for purposes of the APM from the first day of the MIPS performance period. Under these circumstances, 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.

Calculating MIPS APM Performance Category Scores: 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: Complete Reporting Requirements

In the event a MSSP ACO does not report quality measures as required by the MSSP (i.e. using the Web Interface and CAHPS surveys), an exception will

- Medicare Shared Savings Program (all Tracks)
- Medicare ACO Track 1+ Model
- Bundled Payments for Care Improvement Advanced
- Independence at Home Demonstration
- Maryland Total Cost of Care Model (Maryland Primary Care Program)
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative)

Final CMS determinations of MIPS APMs for the 2019 MIPS performance year will be announced via the QPP website at <https://qpp.cms.gov/>

Calculating MIPS APM Performance Category Scores:

Web Interface Reporters: Complete Reporting Requirements

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

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 specifically 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.

However, beginning with the 2019 performance period, 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.

Other MIPS APMs: Promoting Interoperability Category

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. 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.

MIPS APM Performance Feedback: Regarding access to performance feedback, CMS notes 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.

1. Medicare Shared Savings Program (MSSP)
2. Medicare ACO Track 1+ Model
3. Next Generation ACO Model
4. Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative)

CMS reiterates its clarification that beginning in 2019, in the case of a MSSP ACO's failure to completely report all Web Interface measures as required by the MSSP, CMS will allow a solo practitioner to report on any available MIPS measures, including individual measures (p. 1249).

After taking all comments into account, CMS did not finalize its proposal to modify the complete reporting requirement for Web Interface reporters to apply the CAHPS for ACOs survey score toward an APM Entity's quality performance category score if an ACO fails to complete reporting for Web Interface measures, but successfully reports the CAHPS for ACOs survey (p. 1250).

Other MIPS APMs: Promoting Interoperability Category

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)

CMS finalized its proposal to allow MIPS eligible clinicians participating in the MSSP to report on the Promoting Interoperability performance category at either the individual or group level (p. 1253).

MIPS APM Performance Feedback: CMS reiterates this clarification (p. 1253).

MIPS APM Measure Lists: At the end of this section, CMS includes tables listing the most current MIPS APM Measure sets:

- [Table 44](#): Comprehensive ESRD Care Model
- [Table 45](#): Comprehensive Primary Care Plus (CPC+) Model

- [Table 46](#): Oncology Care Model
- [Table 47](#): Bundled Payments for Care Improvement Advanced Model
- [Table 48](#): Maryland Total Cost of Care Model
- [Table 49](#): Independence at Home Demonstration
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[MIPS Final Score Methodology](#)

Converting Measures and Activities into Performance Category Scores:

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.

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.

Converting Measures and Activities into Performance Category Scores ([p. 1270](#)):

No changes from the proposed rule.

[MIPS Final Score Methodology: 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](#)

Scoring Terminology: 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: CMS proposes 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

Scoring Terminology ([p. 1273](#)): No changes from the proposed rule.

Quality Measure Benchmarks ([p. 1273](#)): *CMS finalized this policy as proposed for the 2019 MIPS performance year ([p. 1276](#)), to establish separate benchmarks based on collection type and to remove the mention of each individual benchmark and 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))

separate benchmarks for QCDR measures and MIPS CQMs since these measures do not have comparable specifications. 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:

- *Floor for Scored Quality Measures:* 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)).
- *Additional Policies for the CAHPS for MIPS Measure Score:* CMS proposes to reduce the denominator (i.e., 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. 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: CMS seeks 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.

Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmarks Requirements: CMS invites public comment on ways CMS can improve its case-minimum policy. A summary of the current and proposed policies is provided in Table 47.

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.

Assigning Points Based on Achievement (p. 1277)

- *Floor for Scored Quality Measures (p. 1277):* **CMS finalized its policy as proposed (p. 1278).** (§414.1380(b)(1)(i))
- *Additional Policies for the CAHPS for MIPS Measure Score (p. 1278):* **CMS finalized its policy with a minor clarification (p. 1281).** Newly added 414.1380(b)(1)(vii)(B) will state that CMS will reduce the total available measure achievement points for the quality performance category by 10 points for groups that submit 5 or fewer quality measures and register for the CAHPS for MIPS survey, but do not meet the minimum beneficiary sampling requirements. CMS may consider suggestions submitted by commenters regarding groups who might register for the CAHPS for MIPS survey if they know in advance that they are unlikely to be able to meet the sampling requirement.

Assigning Measure Achievement Points for Topped Out Measures (p. 1282): CMS thanks commenters for their suggestions and may consider them for future rulemaking (p. 1283).

Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmarks Requirements (p. 1283): CMS thanks commenters for their suggestions and may consider them for future rulemaking (p. 1285). A summary of the current and proposed policies is provided in Table 50.

CMS finalized the proposal 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 the amending of §414.1380(b)(1)(i) accordingly (p. 1287).

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.

Scoring Flexibility for Measures with Clinical Guideline Changes During the Performance Period: CMS proposes 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)).

Scoring for MIPS Eligible Clinicians that Do Not Meet Quality Performance Category Criteria: 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.

In situations where a MIPS eligible clinician may not have available and applicable quality measures and 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: 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. This differs from the current policy of adding a small practice bonus of 5 points to the final score of a clinician or group that meets the definition of small practice.

CMS finalized its proposal to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period and to amend §414.1380(b)(1)(i)(B)(1) accordingly. Measures submitted by small practices will continue to receive 3 points for all future MIPS performance periods (p. 1287).

Scoring Flexibility for Measures with Clinical Guideline Changes During the Performance Period (p.1287): ***CMS finalized the proposal with modification and adding a new paragraph at §414.1380(b)(1)(vii) stating that, beginning with the 2021 MIPS payment year, CMS will reduce the denominator of available measure achievement points for the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted by clinical guideline changes or other changes when CMS believes adherence to the guidelines in the existing measures could result in patient harm or otherwise provide misleading results as to good quality care.*** CMS regularly monitors changes to quality measures and clinical guidelines and will rely on measure stewards for notification in changes to guidelines. CMS will publish on its website suppressed measures whenever technical feasible, but by no later than the beginning of the data submission period. (p. 1293)

Scoring for MIPS Eligible Clinicians that Do Not Meet Quality Performance Category Criteria (p. 1293): CMS did not receive any comments on this proposal. As such, ***CMS finalized the policy as proposed (p. 1294).***

Small Practice Bonus (p. 1294): ***CMS finalized its proposal with modification. The small practice bonus will consist of 6 measure bonus points in the numerator of the quality performance category for MIPS eligible clinicians in small practices if the MIPS eligible clinician submits data on at least 1 quality measure.*** (§414.1380(b)(1)(v)(C)) (p. 1305).

In responding to comments on this policy, CMS noted the following:

- Analysis of 2017 MIPS performance data showed that the number of eligible clinicians whose quality performance category was reweighted to

85 percent was lower than CMS anticipated, and that for approximately three-fourths of the clinicians in small practices, quality was weighted between 45 and 60 percent of the final score under 2019 proposed policies ([p. 1298](#)).

- Analysis also continued to find that there is a gap in quality participation and performance when comparing clinicians in small practices to those in large practices ([p. 1299](#)).
- For clinicians whose quality category is weighted at 45 percent, the small practice bonus would equate to 4.5 final score points. For those with a quality category weight of 60 percent, the bonus would equate to 6 final score points. If the quality score is reweighted to 85 percent, the bonus may account “for a large part of the final score” but CMS does not believe this will affect a large proportion of practices. CMS estimates a n average of 4.4 points added to the final score for clinicians in small practices ([p. 1300](#)).
- CMS disagreed with a comment to extend the small practice bonus to rural practices ([p. 1304](#)).
- CMS noted that the 6 point total was comparable to the 10 percent cap on bonus points for the quality category ([p. 1305](#)).

Incentives to Report High-Priority Measures:

CMS proposes 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))

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. (§414.1380(b)(1)(v)(A))

Incentives to Use CEHRT to Support Quality Performance Category

Submissions: CMS proposes 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. CMS also proposes to continue to assign bonus points for end-to-end electronic reporting for the

Incentives to Report High-Priority Measures ([p. 1306](#)):

CMS finalized this policy as proposed. (§414.1380(b)(1)(v)(A)(1)(ii)) ([p. 1307](#))

CMS finalized this policy as proposed ([p. 1310](#)). CMS notes that bonus points remain available for reporting the CAHPS for MIPS survey and for end-to-end reporting. CMS also notes that Web Interface reporters are excluded from the topped out measure cap. ([p. 1309](#))

As CMS moves to fully implement 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. ([p. 1310](#))

Incentives to Use CEHRT to Support Quality Performance Category Submissions ([p. 1310](#)): ***CMS finalized its proposal to continue to assign and maintain the cap on measure bonus points for end-to-end electronic reporting for the 2019 MIPS performance period/2021 MIPS payment year and to amend regulation text***

2019 performance period, as CMS has seen that this policy encourages electronic reporting. CMS proposes to amend regulation text accordingly.

CMS proposes 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.

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:

- *Calculating Total Measure Achievement and Measure Bonus Points for Non-CMS Web Interface Reporters:* CMS previously 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. Table 48 provides examples of how CMS assigns achievement and bonus points to clinicians who submit measures across multiple collection types.
- *Calculating Total Measure Achievement and Measure Bonus Points for CMS Web Interface Reporters:* CMS does not propose any changes to these previously finalized policies.

Future Approaches to Scoring the Quality Performance Category: CMS seeks comment on the following approaches to scoring:

- 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.
- Keep its current approach of 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.

accordingly. (§414.1380(b)(1)(v)(B)) ([p. 1312](#)). CMS clarifies that the bonus is only available with 2015 Edition CEHRT.

CMS finalized these policies as proposed. ([p. 1312](#))

CMS thanks commenters for suggestions and will consider them for future rulemaking. ([p. 1313](#))

Calculating Total Measure Achievement and Measure Bonus Points ([p. 1313](#)):

- *Calculating Total Measure Achievement and Measure Bonus Points for Non-CMS Web Interface Reporters:* See [Table 51](#) for examples of how CMS assigns achievement and bonus points to clinicians who submit measures across multiple collection types.
- *Calculating Total Measure Achievement and Measure Bonus Points for CMS Web Interface Reporters:* As part of CMS' technical updates to §414.1380(b)(1), previously established policies for CMS Web Interface reporters are now referenced at §414.1380(b)(1)(i)(A)(2)(i) and (b)(1)(v)(A).

Future Approaches to Scoring the Quality Performance Category ([p. 1316](#)): CMS thanks commenters for suggestions and will consider them for future rulemaking, but does not detail comments in the rule. ([p. 1320](#))

To encourage reporting of QCDR measures, CMS also seeks comment on an approach to develop QCDR measure benchmarks based off historical measure data.

CMS also invites comment on how it can incentivize the use of electronic clinical quality measurement in the future, and other ways to encourage more efficient technology-enabled measurement approaches.

CMS seeks comment on these 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: CMS previously 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: CMS previously finalized policies on incorporating the improvement percent score into the quality performance category percent score. No policy changes on these topics are proposed.

Scoring Achievement in the Cost Performance Category: CMS previously 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: 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)). CMS also proposes to modify the performance

Improvement Scoring for the MIPS Quality Performance Category Percent Score (p. 1320): CMS finalized its proposal to continue the previously established policy for the 2019 MIPS performance period and amend regulation text accordingly. (§414.1380(b)(1)(vi)(C)(4)) (p. 1321)

Calculating the Quality Performance Category Percent Score Including Achievement and Improvement Points (p. 1322): There were no changes from the proposed rule.

Scoring Achievement in the Cost Performance Category (p. 1322): CMS finalized its proposal to codify these final policies at §414.1380(b)(2)(i). (p. 1323)

Scoring Improvement in the Cost Performance Category (p. 1323): CMS finalized these policies as proposed. (p. 1325)

In response to comments, CMS notes:

MIPS Final Score Methodology: Scoring the Cost Performance Category

MIPS Final Score Methodology: Facility-Based Measures Scoring Option for the 2019 MIPS Performance period (2021 MIPS Payment Year) for the Quality and Cost Performance Categories

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))

- CMS does not believe that it should not assess clinicians on cost if they are only assessed on a single measure since that would fail to recognize that a single measure, such as total per capita cost, could reflect care provided to a large number of patients.
- CMS does not believe that it should only incorporate the 6 highest scoring measures under the cost category since it could provide an advantage for groups with more than 6 measures.

Facility-Based Measurement Applicability: In the CY 2018 QPP final rule, CMS limited facility-based reporting to the inpatient hospital. CMS also limited measures applicable for facility-based measurement to those used in the Hospital Value-Based Purchasing (VBP) Program. 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.

Facility-Based Measurement Applicability ([p. 1326](#)):

- *Facility-Based Measurement by Individual Clinicians:* CMS proposes 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. CMS seeks comment on whether a better 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.
 - 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. 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.
 - 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 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

- *Facility-Based Measurement by Individual Clinicians ([p. 1327](#)):* **CMS finalized its policies as proposed ([p. 1338](#)).**

applicable performance period with a 30-day claims run out in determining eligibility for facility-based measurement.

- **Facility-Based Measurement by Group:** 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: 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.

No Election of Facility-Based Measurement: After considering the advantages and disadvantages of an opt-in or an opt-out process, CMS proposes 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. 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.

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. Virtual groups eligible for facility-based measurement would always be measured as a virtual group.

- **Facility-Based Measurement by Group (p. 1338):** No changes from the proposed rule.

Facility Attribution for Facility-Based Measurement (p. 1339): *CMS finalized this policy as proposed (p. 1342), with one technical wording clarification to replace the word “segment” with “period” for clarity purposes (p. 1339).*

No Election of Facility-Based Measurement (p. 1342): *CMS finalized these policies as proposed (p. 1351), with small technical modifications.* Additional detail on the technical regulation changes can be found on [p. 1351](#).

In response to comments, CMS noted that:

- CMS will consider whether there would be an opportunity for a facility-based group to elect to participate without submitting data on another performance category in the future.
- CMS intends to provide additional information to clinicians regarding their status with facility-based measurement eligibility, facility attribution, and a preview score based on data from the previous performance period. CMS anticipates that this information will be released during the first quarter of the performance period, if technically feasible, beginning with the 2019 performance period, and CMS aims to notify clinicians as soon as this information is available.
- In cases in which a clinician or group does not have a score in the cost performance category, and the weight of the cost performance category is redistributed to the quality performance category, points added to the MIPS final score will be based on how the reweighted quality category scoring compares to scoring for the quality and cost categories under facility-based measurement.

CMS also 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 proposes conforming regulation text changes to remove references to election of facility-based measurement.

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:

- *Measures in Facility-Based Scoring:* 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.

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)).

CMS proposes regulation 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.

- *Measures for MIPS 2019 Performance Period/2021 MIPS Payment Year:* For informational purposes, CMS provides a list of measures included in the FY 2020 Hospital VBP Program measures in

CMS reiterates that facility-based measurement is not applicable to any MIPS eligible clinicians scored under the APM scoring standard and further clarifies that “this includes Shared Savings Program participant TINs in ACOs that have failed to complete web interface reporting, unless these measures are specifically required under the terms of the applicable APM.”

Facility-Based Measures (p. 1352):

- *Measures in Facility-Based Scoring (p. 1353):* CMS finalized these policies as proposed (p. 1356), with small technical changes to regulation text to increase clarity. Additional details on technical changes can be found on p. 1356.

Thus, for the 2019 MIPS performance year/2021 MIPS payment year, the Hospital VBP Total Performance Score for FY 2020 will be applied.

- *Measures for MIPS 2019 Performance Period/2021 MIPS Payment Year (p. 1357):* No changes from the proposed rule. See Table 52 for the list of measures included in the FY 2020 Hospital VBP Program that will apply for the 2019 MIPS performance period/2021 MIPS payment year.

determining the quality and cost performance category scores for the 2019 MIPS performance period/2021 MIPS payment year.

Scoring Facility-Based Measurement:

- *Scoring Achievement in 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.
- *Scoring Improvement in Facility-Based Measurement:* CMS previously 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 since 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). CMS also proposes to not assess improvement for MIPS-eligible clinicians who are scored in MIPS through facility-based measurement in one year, but through another method in the following year.

Expansion of Facility-Based Measurement to Use in Other Settings: 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. CMS seeks comment on attribution methodologies and PAC QRP measures that would most appropriately measure clinician performance. CMS also 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.

Scoring Facility-Based Measurement (p. 1359):

- *Scoring Achievement in Facility-Based Measurement (p. 1359):* **CMS finalized its proposal to change the determination of the quality and cost performance category scores (p. 1360).** CMS included technical changes to regulation text for clarity.
- *Scoring Improvement in Facility-Based Measurement (p. 1360):* **CMS finalized its policies as proposed (p. 1361),** with small technical changes to regulation text to more clearly state that improvement points will not be earned.

Expansion of Facility-Based Measurement to Use in Other Settings (p. 1362):

CMS appreciates the comments received and will consider suggestions in policies that will be proposed as part of future rulemaking (p. 1363). CMS does not provide details on specific comments.

[MIPS Final Score Methodology: Scoring the Improvement Activities](#)

Regulatory Text Updates: CMS proposes updates to both §§414.1380(b)(3) and 414.1355 to more clearly and concisely capture previously established policies. Policies clarify regulation text regarding:

- Improvement Activities performance category score and total required points. Additionally, CMS is also clarifying that the

Regulatory Text Updates (p. 1363): **CMS finalized its policies as proposed (p. 1363 – p. 1366).**

Performance Category	<p>improvement activities performance category score cannot exceed 100 percent.</p> <ul style="list-style-type: none"> • Weighting of improvement activities • APM improvement activities performance category score • 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. <p>CMS also proposes one substantive change with respect to PCMH and comparable specialty practices. 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.</p> <p>CEHRT Bonus: CMS previously established that certain activities in the improvement activities performance category will qualify for a bonus under the Promoting Interoperability performance category if they are completed using CEHRT. CMS does not discuss any policy changes related to this bonus, but invites comments on its proposed new approach for scoring the Promoting Interoperability category.</p>	<p>CEHRT Bonus (p. 1366): CMS does not provide any additional information in this section. Please refer to final policies for the Promoting Interoperability performance category.</p>
MIPS Final Score Methodology: Scoring the Promoting Interoperability Performance Category	<p>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.</p>	<p>Please refer to the final policies for the Promoting Interoperability performance category.</p>
MIPS Final Score Methodology: Calculating the Final Score	<p>Accounting for Risk Factors and Considerations for Social Risk: In this section, CMS summarizes its efforts related to social risk and the relevant studies conducted under the IMPACT Act.</p> <p>Complex Patient Bonus for the 2019 MIPS Performance Period (2021 MIPS Payment Year): 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 proposes to continue for the 2019 MIPS</p>	<p>Accounting for Risk Factors and Considerations for Social Risk (p. 1367): CMS thanks commenters for their input regarding considerations for social risk and will take this input into consideration in future years.</p> <p>Complex Patient Bonus for the 2019 MIPS Performance Period (2021 MIPS Payment Year): <i>CMS finalized its policies as proposed and will continue the complex patient bonus for the 2019 MIPS performance period (p. 1373).</i></p>

performance period/2021 MIPS payment year 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)).

If CMS' proposed changes to the MIPS eligibility determination period are 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.

MIPS Final Score
Methodology:
Final Score
Performance
Category
Weights

General Weights:

- 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 proposes 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.

Flexibility for Weighting Performance Categories:

- *Scenarios Where the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories Would Be Reweighted:* CMS previously finalized policies for the first two MIPS program years under which it 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. CMS proposes 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. CMS proposes to codify established policies for assigning a scoring weight of zero percent to the Promoting Interoperability category and redistributing its weight to the other

General Weights (p. 1373): *CMS finalized the performance category weights as proposed. Table 53 summarizes the final weights specified for each performance category.*

Flexibility for Weighting Performance Categories (p. 1374):

- *Scenarios Where the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories Would Be Reweighted (p. 1374):* *CMS finalized these policies as proposed. (p. 1377)*

performance categories in the final score under §414.1380(c)(2)(i) and (iii).

- *Reweight the Quality, Cost, and Improvement Activities Performance Categories for Extreme and Uncontrollable Circumstances*: CMS proposes 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)).

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 seeks comments on the specific circumstances under which the extreme and uncontrollable circumstances policy should be made applicable to third party intermediary issues.

CMS proposes a few minor modifications to its extreme/uncontrollable circumstances policy. Beginning with the 2019 MIPS performance period/2021 MIPS payment year, CMS proposes 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. CMS discusses cases when quality data are reported via claims, potentially prior to knowledge of an extreme or uncontrollable circumstance, noting that it would score the quality category because it has received data, but if a clinician is scored on fewer than two performance categories, he will receive a final score equal to the performance threshold. CMS also notes that this proposal does not include administrative claims data that CMS receives through the claims submission process and use to

- *Reweight the Quality, Cost, and Improvement Activities Performance Categories for Extreme and Uncontrollable Circumstances (p. 1377): CMS finalized its proposals (p. 1382)*:
 - *To codify the final policy it adopted beginning with the 2018 MIPS performance period/2020 MIPS payment year to 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*
 - *That beginning with the 2019 performance period/2021 MIPS payment year, 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 in accordance with §414.1325, he or she will be scored on the submitted data like all other MIPS eligible clinicians, and the categories will not be reweighted.*
 - *That beginning with the 2018 performance period/2020 MIPS payment year, that, for groups, CMS will 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.*
 - *To update regulation text at §414.1380(c)(2)(i)(A)(6) (a correction from the citation included in the proposed rule).*

calculates the cost measures and certain quality measures; CMS would not void a reweighting application based on the availability of administrative claims data.

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. 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:* Beginning with the 2019 MIPS performance period, CMS proposes 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).
- *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. 1382](#)): **CMS finalized its policies as proposed.** ([p.1386](#))

- *Proposed Automatic Extreme and Uncontrollable Circumstances Policy Beginning with the 2020 MIPS Payment Year:* 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. CMS proposes 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 proposes 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.

CMS did not previously include an automatic extreme and uncontrollable circumstances policy for groups or virtual groups, and CMS continues to believe such a policy is not necessary.

- *Extreme and Uncontrollable Circumstance Policy for the 2017 Performance Period/2019 MIPS Payment Year:* 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 locales. CMS proposes to codify this automatic exemption policy for the quality and improvement activities performance categories for clinicians affected by extreme/uncontrollable circumstances affecting entire regions 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).

Redistributing Performance Category Weights: CMS previously established policies for redistributing the weights of performance categories for the 2017 and 2018 MIPS performance periods in the event that a scoring weight

- *Automatic Extreme and Uncontrollable Circumstances Policy Beginning with the 2020 MIPS Payment Year (p. 1386):* **CMS finalized its policies as proposed (p. 1391).** Regulation text changes are finalized at §414.1380(c)(2)(i)(A)(8) (corrected from the proposed rule) and (c)(2)(i)(C)(3).

- *Extreme and Uncontrollable Circumstance Policy for the 2017 Performance Period/2019 MIPS Payment Year (p. 1391):* **CMS adopted the IFC as a final rule without any modifications. CMS finalized the regulation text §414.1380(c)(2)(i)(A)(7) (corrected from the proposed rule) and §414.1380(c)(2)(i)(C)(3) as proposed. (p. 1395)**

Redistributing Performance Category Weights (p. 1395): **CMS finalized its policies and regulation text at §414.1380(c)(2)(ii)(A) through (C) as proposed (p.**

different from the generally applicable weight is assigned to a category or categories. CMS proposes to codify these policies under §414.1380(c)(2)(ii).

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. Reweighting scenarios under this proposal are presented in Table 51.

[1400](#)). Reweighting scenarios are presented in regulation text ([p. 2119](#)) and below.

Reweighting Scenario	Quality	Cost	IA	PI
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%

MIPS Final Score Methodology: Final Score Calculation

CMS proposes to revise the formula at §414.1380(c) for calculating the final score to omit the small practice bonus from the final score calculation beginning with the 2019 MIPS performance period.

CMS finalized its proposed revisions to §414.1380(c) as proposed ([p. 1401](#)).

CMS also seeks comments on approaches to simplify calculation of the final score that take into consideration these limitations described in the proposed rule.

CMS thanks commenters for their input and will take this input into consideration in future years.

MIPS Payment Adjustments

Final Score Used in Payment Adjustment Calculation: CMS proposes a 15-month window that starts with the second 12-month determination period (October 1 prior to the MIPS performance period through September of the MIPS performance period) and also includes the final 3 months of the performance period year (October 1 through December 31 of the performance period year). 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.

Final Score Used in Payment Adjustment Calculation ([p. 1401](#)): ***CMS finalized its policies as proposed ([p. 1404](#)).***

Establishing the Performance Threshold ([p. 1405](#)): ***CMS finalized a performance threshold of 30 points for the 2019 MIPS performance period (2021 MIPS***

Establishing the Performance Threshold: CMS proposes a performance threshold of 30 points for the 2019 MIPS performance period (2021 MIPS payment year).

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. CMS also seeks comment on whether establishing a path forward to a performance threshold for the 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.

Additional Performance Threshold for Exceptional Performance: For the 2021 MIPS payment year, CMS proposes to again de-couple the additional performance threshold from the performance threshold. 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).

Application of the MIPS Payment Adjustment Factors:

- *Application to the Medicare Paid Amount for Covered Professional Services:* As a result of changes in this rule, 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.

payment year) as proposed. CMS is codifying the performance threshold for this year and finalizing the regulation text at §414.1405(b)(6) as proposed (p. 1419).

CMS notes that final scores for the 2019 MIPS performance period/2019 MIPS payment year show a mean final score of 74.01 points and a median final score of 88.97 points. CMS also estimates mean final score of 69.53 points and a median final score of 78.72 points for the 2019 MIPS performance period/2021 MIPS payment year. CMS also notes that, based on estimated mean final and median scores based on final requirements for the 2019 MIPS performance period, CMS estimates that the performance threshold that it would establish for the 2022 MIPS performance period/2024 MIPS payment year would likely be over 65 points. Given these data points, CMS believes that a lower performance threshold for 2020 would lead to a steep increase in the performance threshold for each of the next two years. (p. 1411)

While several commenters requested scoring accommodations for newly eligible MIPS clinician types (e.g. a lower threshold or a “pick your pace” option), CMS declined to offer such an option, noting that these new clinicians would still have 4 years of transition to ramp up to year 6, when the cost weight and mean/median performance threshold would be required. (p. 1413)

Additional Performance Threshold for Exceptional Performance (p. 1420): finalized its proposal with modification. CMS finalized the additional performance threshold at 75 points for the 2019 MIPS performance period/2021 MIPS payment year. CMS codified the additional performance threshold and the proposed regulation text at §414.1405(d)(5) (p. 1430). This is based on a belief that raising the additional performance threshold will incentivize continued improved performance, but also a concern that policy changes may make it challenging for clinicians to reach an additional performance threshold of 80 points.

Application of the MIPS Payment Adjustment Factors (p. 1430):

- *Application to the Medicare Paid Amount for Covered Professional Services (p. 1430): CMS finalized its policies as proposed, including changes to regulation text at §414.1405(e) (p. 1432).* CMS refers readers its earlier discussion of the covered professional services to which the MIPS payment adjustment could be applied, as well as to the discussion of other conforming edits to the regulation text at §§414.1310(a), 414.1310(b), and 414.1310(d) that specify the circumstances when the MIPS payment adjustment would not apply to

- *Application for Non-Assigned Claims for Non-Participating Clinicians:* 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. 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: CMS proposes to amend its regulations to specify that the MIPS payment adjustment factors would not apply to certain model-specific payments for the duration of a section 1115A model's testing, beginning in the 2019 MIPS payment year (§414.1405). CMS proposes to use the authority under section 1115A(d)(1) of the Act to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and §414.1405(e) specifically for these types of payments because the waiver is necessary solely for purposes of testing models that involve such payments.

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 by updating the QPP website when new model-specific payments subject to the waiver are announced and by providing a notice in the Federal Register.

CY 2018 Exclusion of MIPS Eligible Clinicians Participating in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration: The MAQI Demonstration is designed to test whether excluding MIPS eligible clinicians who participate to a sufficient degree in

payments for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019.

- *Application for Non-Assigned Claims for Non-Participating Clinicians (p. 1432):* CMS finalized its proposal 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. (p. 1434)

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. 1434): CMS finalized its proposal to use the authority under section 1115A(d)(1) of the Act to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and §414.1405(e) specifically for payments specified at §414.1405(f). CMS includes edits to the regulation text at §414.1405(f) to clarify the requirements for payments to subject to the waiver and to increase readability and clarity. (p. 1437)

One model-specific payment to which this finalized waiver will apply is the Monthly Enhanced Oncology Services (MEOS) payment in the Oncology Care Model (OCM). The duration of this waiver will begin with the 2019 MIPS payment year and continue for the duration of the OCM. (p. 1437)

CMS finalized this policy on public notification as proposed. (p. 1438)

CY 2018 Exclusion of MIPS Eligible Clinicians Participating in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration (p. 1438):

CMS finalized its proposals (p. 1445) to:

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 proposes 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. Under the MAQI Demonstration, aggregate participation in Advanced APMs and Qualifying Payment Arrangements will be used, without applying a specific minimum threshold to participation in either type of payment arrangement. The Demonstration would start with CY 2018 and run for five years.

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.

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 voluntary 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.

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.

- **Implement the MAQI Demonstration in CY 2018**
- **Use waiver authority to waive certain requirements of section 1848(q)(6)(E) of the Act, including**
 - **the payment consequences (positive, negative or neutral adjustments) of the MIPS**
 - **the associated MIPS reporting requirements**
- **Waive the provision that requires the Secretary to allow any eligible clinician to voluntarily report on applicable measures and activities**
 - **This applies to eligible clinicians who participate in the Demonstration and meet the thresholds that will trigger application of the waivers.**
 - **As a result of this waiver, MAQI Participants who are not subject to the MIPS reporting requirements and payment adjustments will therefore not receive MIPS performance feedback under section 1848(q)(12) of the Act.**

Under the waivers identified previously:

- **Eligibility for exclusion from the MIPS reporting requirements and payment adjustment under the MAQI Demonstration will be determined using thresholds of combined participation in Qualifying Payment Arrangements and Advanced APMs that are the same as the QP thresholds under the Medicare Option of the QPP;**
- **Qualifying Payment Arrangements under the MAQI Demonstration will be identified using criteria consistent with those used to identify Other Payer Advanced APMs.**
- **A MAQI participating clinician must meet combined thresholds for Medicare payments or patients through Qualifying Payment Arrangements with MAOs and Advanced APMs, using Demonstration thresholds that match the thresholds for participation in Advanced APMs under the Medicare Option of the QPP, and based on aggregate participation in Advanced APMs and Qualifying Payment Arrangements with MAOs, without applying a specific minimum threshold to participation in either type of payment arrangement.**

CMS notes that by starting the Demonstration in CY 2018, clinicians that meet threshold levels of participation in Qualifying Payment Arrangements with MAOs in 2018 can be considered for exclusion from the MIPS reporting requirements and payment adjustment under the Demonstration a year before participation in such Qualifying Payment Arrangements could be considered under the All-Payer Combination Option. CMS anticipates collecting Qualifying Payment Arrangement

Example of Adjustment Factors: 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.

and threshold information for eligible clinicians participating in the Demonstration starting in late fall of 2018, and making final CMS determinations on whether eligible clinicians meet the criteria to be excluded from the MIPS reporting requirements and payment adjustment, based on this submitted information, by December 2018 or (January 2019 at the latest), to determine whether they meet criteria to be excluded from MIPS reporting requirements for the 2018 MIPS performance year/2020 MIPS payment year.

Example of Adjustment Factors (p. 1447): [Figure 3](#) provides an example 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 the policies adopted in this final rule for the 2021 MIPS payment year. In [Figure 3](#), the performance threshold is 30 points and the additional performance threshold is 75 points. The applicable percentage is 7 percent for the 2021 MIPS payment year.

[Table 56](#) illustrates the changes in payment adjustments based on the final policies from the 2019 MIPS payment year and the 2020 MIPS payment year, and on final policies for the 2021 MIPS payment year adopted in this final rule, as well as the statutorily required increase in the applicable percent to 7 percent.

We note that:

- scoring algorithms have not changed from the CY 2019 PFS proposed rule to final rule, with the exception of the increase in the small practice bonus from 3 to 6 measure bonus points
- the only policy change from the CY 2019 PFS proposed rule reflected in [Figure 3](#) and [Table 56](#) is the change in the exceptional performance threshold.

CMS refers readers to the CY 2019 PFS proposed rule for examples of scenarios for reaching the performance threshold of 30 points for the 2019 MIPS performance year/2021 MIPS payment year.

[Third Party Intermediaries](#)

Third Party Intermediaries Definition: CMS proposes at §414.1305 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

Third Party Intermediaries Definition: *CMS finalized these policies as proposed (p. 1456).* CMS clarifies here 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,

intermediaries” to elucidate the definition and function of a third-party intermediary.

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 also proposes to amend §414.1400(a)(4)(iv) to state that if a Low-Volume clinician chooses to opt-in to MIPS, the third party intermediary must be able to transmit that decision to CMS.

Certification Requirements for Data Submission: CMS previously finalized that all data submitted by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the intermediary to the best of its knowledge as true, accurate, and complete; and that this certification must occur at the time of the submission and accompany the submission. However, CMS has discovered this is not operationally feasible. It 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.

Qualified Clinical Data Registries (QCDRs):

Proposed Update to the Definition of a QCDR

Beginning with the 2020 performance year/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.

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.

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 Requirements for Data Submission: *CMS finalized these policies as proposed* ([p. 1457](#)).

Qualified Clinical Data Registries (QCDRs):

Proposed Update to the Definition of a QCDR

CMS finalized these changes as proposed ([p. 1465](#)).

Many commenters supported these proposals. Some requested that CMS provide more clarification or more specific criteria of what constitutes “clinical expertise in medicine and quality measure development.” While not exhaustive, CMS provided some aspects that may be considered during its evaluation of a QCDR: previous measure development experience (serving on an NQF TEP, for example); experience with the [measure development Blueprint](#) process; ability to create and use multi-strata and composite measures where appropriate; ability to risk adjust its own QCDR outcomes measures; technical expertise to run a registry; and ability to reliably collect, retain, aggregate, disseminate, and analyze data from their clinicians.

One commenter expressed concern regarding how CMS will allow technical entities to partner with an external organization to gain clinical expertise, voicing concern that this could enable technical entities to bypass this requirement too easily. CMS disagreed with these concerns, noting that the policy is intended to

Establishment of an Entity Seeking to Qualify as a QCDR

CMS proposes to re-designate §414.1400 (c)(2) as §414.1400(b)(2)(i) to state that beginning with the 2020 Performance Year/2022 MIPS Payment Year, the QCDR must have at least 25 participants by January 1 of the year prior to the performance period.

Revised QCDR Self-Nomination Period

CMS proposes that, beginning with the 2020 performance year/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). Currently, the self-nomination period is from September 1 until November 1. QCDRs also 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.

Information Required at the Time of Self-Nomination

CMS also proposes to update §414.1400(b)(3)(iii) to state that QCDRs must include their CMS-assigned QCDR measure ID number when posting their

include entities that are able to meet the definition, whether that be by a partnership with a clinical entity, or on their own.

CMS clarifies here that if an entity does not meet these QCDR standards, they may still seek to qualify as another type of third party intermediary, such as a qualified registry, since becoming a qualified registry does not require the level of measure development expertise that is needed to be a QCDR that develops measures.

Establishment of an Entity Seeking to Qualify as a QCDR

CMS finalized this policy as proposed (p. 1467). Many commenters disagreed with this proposal and felt it could place undue burden on QCDRs serving small specialties and inhibit the ability of new registries to qualify as QCDRs. CMS disagreed with commenters and believes this threshold is reasonable given increasing stakeholder interest in the use of third party intermediaries to report for MIPS. CMS notes that over the past two performance periods there have been instances of new QCDRs that were not ready to accept data from eligible clinicians from the start of the performance period due to operational issues within the QCDR, including instances of QCDRs withdrawing during the performance period because of reporting inexperience. This requirement is intended to ensure that organizations have this experience prior to self-nomination. CMS also clarifies here that this requirement would not require that the entity's prior registry experience be under MIPS or any other CMS program or that the participants include MIPS eligible clinicians.

Revised QCDR Self-Nomination Period

CMS finalized this revised timeline as proposed (p. 1476). Despite public concerns, CMS believes this timeline is beneficial for both QCDRs and CMS. The earlier self-nomination will also allow QCDRs who submit clinically similar measures to another QCDR and whose measure(s) are rejected to reach out to the QCDR whose measures are approved to attempt to enter into a licensing use agreement with the QCDR with the approved measures if desired. CMS intends on giving QCDRs the utmost resources and support as they prepare to self-nominate prior to the closing of the self-nomination period and plans to post self-nomination material prior to the start of the self-nomination period in July. As CMS develops QCDR and qualified registry related policies for future rulemaking, it will factor in how the proposals impact an entity's ability to self-nominate and participate in the program prior to deciding what year to implement the policies for.

Information Required at the Time of Self-Nomination

CMS finalized this update as proposed (p. 1476).

approved QCDR measure specifications, and also when submitting data on the QCDR measures to us.

QCDR Measure Requirements

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 2019 performance year/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.

QCDR Measure Requirements

CMS finalized these updated criteria as proposed (p. 1485).

In response to CMS' interest in elevating the standards for which QCDR measures are selected and approved so that the criteria more closely align with those used for the Call for Quality Measures, some commenters expressed concern, stating that the Call for Measures process is cumbersome and would increase burden. Other commenters expressed the belief that the Call for Measures process does not recognize the uniqueness of QCDRs, and is not agile. Despite these concerns, CMS believes that as it gains additional experience with QCDRs in MIPS, it would be appropriate to further align the criteria for QCDR measures with those of MIPS quality measures in future program years. CMS understands that some of the criteria under the Call for Measures process may be difficult for QCDRs to meet prior to submitting a particular measure for approval; however, it believes that the criteria under the Call for Measures process helps ensure that any new measures are reliable and valid for use in the program. In general, its intention with any future alignment is to work towards consistent standards and evaluation criteria that would be applicable to all MIPS quality measures, including QCDR measures.

CMS disagreed with commenters that offering multi-year approval or rolling reviews of QCDR measures would minimize redundancy. Instead, CMS believes this may actually lead to duplicative measures since it would not account for the possibility of there being more robust QCDR measures of similar concepts being submitted for CMS consideration.

In response to a suggestion that CMS adopt a common national framework for endorsement of measures by a national consensus body, CMS agreed this would be valuable and encouraged QCDRs to have their measures NQF endorsed. However, it is not a necessary requirement at this time because of its potential increase in burden and potential unintended impacts on the ability of QCDRs to adapt their measures.

CMS also noted here that it is imperative to raise the bar with QCDR measures in order to ensure they move away from standard of care, low-bar, process, and/or duplicative measures. ***Specifically, CMS is considering proposing to require reliability and feasibility testing as an added criteria in order for a QCDR measure to be considered for MIPS in future rulemaking.*** At the same time, CMS clarified that there are process measures in MIPS that are considered high priority,

QCDRs Seeking Permission from Another QCDR To Use an Existing, Approved QCDR Measure

CMS proposes at §414.1400 (b)(3)(ii)(C) that beginning with the 2019 performance year/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 at §414.1400(b)(3)(iii) that other QCDRs would be required to use the same CMS assigned QCDR measure ID.

and that CMS believes it is important to retain those so long as they demonstrate room for improvement and lead to meaningful outcomes.

QCDRs Seeking Permission from Another QCDR To Use an Existing, Approved QCDR Measure

Based on the feedback and concerns raised by stakeholders, in the interim, CMS did not finalize this proposal. Rather, it is retaining its existing policy that QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR (82 FR 53813).

CMS did finalize its proposal that other QCDRs would be required to use the same CMS-assigned QCDR measure ID ([p. 1498](#)).

CMS remains very concerned about duplicative measures and their impact on the meaningful measures initiative. The agency is eager to work with the stakeholder community to determine solutions for this issue and will continue to look for policy resolutions to address this issue.

In this section, CMS acknowledges and responds to multiple concerns about the license agreement proposal, including the following:

- CMS believes its proposal is consistent with the Administrative Procedure Act;
- CMS does not believe the proposal would have violated intellectual property rights or law, as QCDRs would not have been required to submit QCDR measures for approval, and if a QCDR had refused to enter into such a license agreement, the QCDR measure would have been rejected and another QCDR measure of similar clinical concept or topic may have been approved in its place;
- With the finalization of the updated QCDR definition, we believe CMS believes it will be able to negate any concerns of inappropriate use of QCDR measures by QCDRs who do not have the clinical expertise needed to understand the measure at hand.
- In response to feedback, CMS will look to provide listening sessions to better understand and explore the feasibility of adopting a market-based solution to create safeguards to protect the proper implementation of QCDR measures and enforce the intellectual property rights of QCDR measure developers, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development.
- One commenter recommended that a cost-based algorithm be used to determine a specific QCDR measure fee which would protect organizations that could not afford to develop a quality measure or that

were not able to develop a measure because a similar measure exists, as well as prevent QCDR measure developers from assigning unreasonable fees to their measures. **CMS requests clarification on how a cost-based algorithm can be developed.**

- CMS clarifies that CMS does not regulate the minimum or maximum amounts that a QCDR may charge as a licensing fee.
- In response to concerns that harmonization can lead to inconsistencies in implementation, yielding incomparable results and inaccurate benchmarking due to lack of accountability and standardization across registries, CMS clarified that the QCDRs would be required to use the QCDR measure without any modification.
- CMS also clarified that it is only allowing other QCDRs to report on the QCDR measures. Other submitter types would not have the QCDR measures available for reporting.
- CMS notes that MIPS quality measures provide a detailed measure specification to allow consistency in implementation, but that data abstraction may include multiple methods. CMS could require QCDRs to follow a similar approach, where QCDRs would need to provide a detailed specification to the QCDRs approved to submit the QCDR measure. This would include any applicable ICD-10-CM codes, CPT codes, required clinical data elements, etc., to allow implementation with minimal variance. **CMS would like to hear from QCDRs on whether or not they would find this useful; and if this effort will increase burden on their end regarding measure specification development.**
- CMS also clarified that the QCDR measure approval process is not intended to act as a test bed for measure concepts. CMS expect QCDRs to have measures that are analytically sound, are reliable, and feasible.
- Once the QCDR measures have been finalized for the performance period, and the specification has been finalized, CMS intends to post the list of QCDR measure specifications for QCDRs to review and consider prior to deciding whether or not they wish to support additional QCDR measures.
- In response to other public comments, CMS is not looking to set limitations, such as, one clinical domain being assigned to one entity. CMS has multiple instances where there are a few QCDRs covering similar areas (that is, surgery, anesthesia, rheumatology). **However, CMS seeks thoughts on how it can reduce benchmarking issues to incentivize QCDR measure reporting.** QCDRs are required to meet CMS data aggregation and reporting requirements and agree that it is important that QCDRs are able to meet data integrity standards in using data elements for purposes of measurement.

- CMS agrees that a QCDR must use another QCDR's measure in its original state (i.e., how it was approved for the given performance period). CMS' systems are programmed on an annual basis to only accept those QCDR measures and correlated specifications as approved for the upcoming performance period.

Qualified Registries:

Establishment of an Entity Seeking to Qualify as a Qualified Registry

CMS proposes to re-designate §414.1400(h)(2) as §414.1400(c)(2) to state that beginning with the 2020 performance year/2022 payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

Revised Self-Nomination Period

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).

Health IT Vendors or Other Authorized Third Parties That Obtain Data from MIPS Eligible Clinicians' Certified EHR Technology (CEHRT):

- 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)

Updates to CMS-Approved Survey Vendor Criteria: CMS proposes at §414.1400(e) to codify previously finalized criteria and requirements for a CMS-approved survey vendor to participate in MIPS.

Remedial Action and Termination of Third Party Intermediaries

CMS proposes multiple technical changes to amend, clarify, and streamline its policies related to remedial action and termination of third party intermediaries, including:

- In the CY 2017 QPP final rule, CMS finalized its policy regarding data inaccuracies at §414.1400(k)(4). In this rule, CMS proposes at

Qualified Registries:

Establishment of an Entity Seeking to Qualify as a Qualified Registry

CMS finalized this change as proposed ([p. 1499](#)).

Revised Self-Nomination Period

CMS finalized this change as proposed ([p. 1501](#))

Health IT Vendors or Other Authorized Third Parties That Obtain Data from MIPS Eligible Clinicians' Certified EHR Technology (CEHRT): **CMS finalized its proposal to codify these previously established policies** ([p. 1502](#)).

Updates to CMS-Approved Survey Vendor Criteria: **CMS finalized its proposal to codify these previously established criteria** ([p. 1505](#)).

Remedial Action and Termination of Third Party Intermediaries
CMS finalized these changes as proposed ([p. 1513](#)).

§414.1400(f)(3) to state that, for purposes of paragraph (f), CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if it: includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and affects more than 3 percent of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary.

- Amending §414.1400(f)(1) to state that CMS may take one or more of the following remedial actions if it determines that a third party intermediary has ceased to meet one or more of the applicable third party intermediary criteria for approval or has submitted data that is inaccurate, unusable, or otherwise compromised. CMS will require the third party intermediary to submit by a deadline specified by CMS a Corrective Action Plan (CAP) that addresses the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring; or CMS will publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.
- Proposing at §414.1400(f)(2) to state that CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician group, or virtual group for one or more of the following reasons: CMS has grounds to impose remedial action; CMS has not received a CAP within the specified time period or the CAP is not accepted by CMS; or, the third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.

CMS clarifies that data errors affecting in excess of 3 percent of the MIPS eligible clinicians or group submitted by a third party intermediary would result in remedial action or disqualification (termination) of the third party intermediary.

CMS appreciated public concerns that these proposals would allow CMS to immediately or with advance notice terminate a third party intermediary's ability to submit MIPS data without first placing the third party intermediary on probation. CMS expects that in most circumstances, it would take remedial action, including imposition of a CAP, prior to terminating the ability of a third party intermediary to submit MIPS data. Before deciding whether to terminate a third party intermediary's ability to submit MIPS data, CMS would take into account a third party intermediary's actions, the severity of the non-compliance or errors at issue, and the potential for undue hardship or negative impact on affected eligible clinicians. CMS would expect to provide advance notice of most terminations; it would likely impose immediate termination on a third party intermediary's ability to submit MIPS data only in circumstances where egregious non-compliance or data errors have occurred. However, if CMS has not received a CAP within the specified time period or the CAP is not accepted by CMS, or the third party intermediary fails to correct the deficiencies or data errors by the date specified by us, CMS may terminate the third party intermediary, immediately or with advance notice.

CMS also recognized concerns that termination of a third party intermediary's ability to submit MIPS data during a performance period may result in undue hardship on eligible clinicians who are supported by the third party intermediary. CMS clarified that it would consider whether a third party intermediary is supporting eligible clinicians in deciding when to terminate the ability of the third party intermediary to submit MIPS data. In addition, it will consider for future rulemaking whether a third party intermediary should be required to submit to CMS a transition plan that addresses how submission of data would be handled in the event that termination occurs during a performance period.

Finally, in response to requests for clarification from QCDRs, CMS clarified that the "data error rate" measures the amount of data submitted by a third party intermediary that was "inaccurate, unusable, or otherwise compromised." CMS does not believe there is a need to create a report that describes inaccuracies and data error issues since this information is already available through the 2019 Fact Sheets in the 2019 Self- Nomination Toolkits for QCDRs & Registries, located in the [QPP Resource Library](#).

A summary of previously finalized policies related to the public reporting of data for each performance category of MIPS, as well as previously finalized policies for year 3 and future years, begins on [p. 1517](#).

CMS clarifies that just because performance information is 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 to ensure that it does not include too much information on public-facing profile pages in an effort not to overwhelm website users. Although all information submitted under MIPS is technically available for public reporting, CMS will continue its phased approach to making this information public.

Regarding general comments suggesting that public reporting be delayed until the QPP is fully implemented, CMS clarified that it is required under section 1848(q)(9)(A) and (D) of the Act to publicly report certain MIPS eligible clinician and group performance information on Physician Compare. However, CMS recognizes that it is in early stages of MIPS, which is why it is continuing to publicly report this information under a phased approach.

Quality: CMS proposes to modify §414.1395(b) to reference “collection types” instead of “submission mechanisms” to accurately update the terminology so it is consistent with other proposals in this rule.

Quality: *CMS finalized these changes as proposed* ([p. 1520](#)).

CMS also 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: 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.

Cost: *CMS finalized these changes as proposed* ([p. 1522](#)).

Improvement Activities: 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

Improvement Activities: CMS reiterates these previously finalized policies on [p. 1523](#).

publicly report first year activities if all other public reporting criteria are satisfied. No other changes to this category are being proposed.

Promoting Interoperability: In response to user testing and in an effort to simplify this category, CMS proposes not to include an 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™): 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 Quality Payment Program final rule (82 FR 53827 through 53829). Additional information, including the Benchmark and Star Rating Fact Sheet, is available on the [Physician Compare Initiative website](#).

Historical Benchmarks

Promoting Interoperability: *CMS finalized this change as proposed (p. 1525).* In light of the changes to the Promoting Interoperability performance category finalized in this rule and the removal of the “base score,” *CMS also finalized a modified definition of “successful” performance to mean a Promoting Interoperability performance category score above zero beginning with year 3.* CMS will include the modified indicator (above zero) for years 1, 2, and 3 to avoid confusion and preserve year-to-year comparability, and the previously finalized indicator (base score) for years 1 and 2 for transparency and consistency with its previously finalized policy, as technically feasible.

In the CY 2017 QPP final rule (81 FR 77397), CMS finalized a policy to include, as technically feasible, additional indicators, including but not limited to indicators such as, identifying if the eligible clinician or group scores high performance in patient access, care coordination and patient engagement, or health information exchange. CMS has since determined that it is not technically feasible to include an indicator of “high” performance that meets its public reporting standards. The scoring variability in the Promoting Interoperability performance category creates challenges that CMS is still uncovering for making the data useful to Physician Compare’s primary patient and caregiver audience. Additionally, in reviewing the year 1 data (which was not available at the time the CY 2019 proposed rule was released), CMS has learned through user testing that patients and caregivers find clinician and group usage of EHR technology to generally be a meaningful indicator of quality, regardless of whether “successful” or “high” was noted. Therefore, the high performing indicator will not be reported in year 1, 2, 3 or future years of the Quality Payment Program on Physician Compare

CMS did not receive any comments on the type of EHR utilization performance information stakeholders would like CMS to consider adding to Physician Compare.

Achievable Benchmark of Care (ABC™):

Historical Benchmarks

CMS finalized this policy as proposed (p. 1531).

CMS previously finalized a policy to determine the benchmark using the most recently available data. 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. CMS proposes here to instead 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). 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. If data from a baseline period is not available, CMS would use performance data from the performance period. This approach would be consistent with how benchmarks are calculated for purposes of scoring the quality performance category, but also would give clinicians 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

Currently, only MIPS measures are star rated on Physician Compare. 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).

Voluntary Reporting: CMS previously finalized a policy to make available for public reporting all data submitted voluntarily across all MIPS performance

Regarding concerns that historical benchmarks would be based on data from a small number of clinicians from various legacy programs such as the PQRS, CMS clarified that only historical MIPS data will be used to create benchmarks (e.g., year 3, which is 2019 data available for public reporting in late 2020, would use year 1 (CY 2017) MIPS data). Still, CMS appreciates concerns raised about historical benchmarks and will continuously evaluate the data against its public reporting standards for year-to-year stability. CMS will also monitor whether the historical benchmarking approach inadvertently creates negative incentives, though early testing has not shown this to be the case.

QCDR Benchmarks

CMS finalized these policies as proposed ([p. 1533](#)).

Several commenters expressed concern about QCDR benchmarks, noting that measure scores could be misinterpreted on Physician Compare, particularly if the ABC™ methodology is used, since it may differ from the QCDR's own rating methodology and further confuse patients.

Because the QCDRs do not uniformly measure performance and each uses their own methodology, CMS believes it makes it more difficult for patients to use this information to make informed healthcare decisions.

Regarding concerns about differences in MIPS scoring benchmarks and public reporting benchmarks, CMS notes that it will continue to evaluate approaches to alignment, but reiterates that it is not always necessary or ideal to use the same methodology for scoring and public reporting given the unique goals of each. QCDR measures will undergo the same statistical testing as other measures do to ensure they meet our public reporting standards before they are publicly reported, and this testing will account for sample size concerns raised by commenters.

Voluntary Reporting: CMS reiterates these previously finalized policies [p. 1534](#).

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. 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: CMS previously 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.

APM Data: CMS reiterates these previously finalized policies ([p. 1534](#)).

Overview of the APM Incentive

General Comments on Availability of Advanced APMs: CMS received comments that it should accelerate the availability of models and that there continues to be a lack of opportunities for specialists and non-physician professionals ([p. 1536](#)). CMS replied that it agrees that it is important to make progress on the move to value-based care. CMS also cited increasing opportunities to participate in Advanced APMs, including in the BPCI Advanced model, the Maryland Total Cost of Care program, and stated that they are also “in the process of developing several new APMs and Advanced APMs, and continue to work with stakeholders on new models” ([p. 1537](#)). Stakeholders also expressed concern at the lack of uptake at CMMI of models recommended by PTAC ([p. 1538](#)). CMS stated that it understands the value of PTAC, noted that “while it seems unlikely that all of the features of any PTAC-reviewed proposed model will be tested exactly as presented in the proposal, certain features of proposed models may be incorporated into new or existing models.” ([p. 1539](#)). **The agency declined to accept a recommendation that the Secretary must reply to PTAC recommendations within 60-days (or any deadline)** ([p. 1540](#)).

Definitions and Regulatory Text Changes

CMS proposes to make a minor alteration to the list of definitions it uses for implementation of the APM Incentive Payment:

Qualifying APM Participant: modified 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

CMS finalized this proposal ([p. 1541](#)).

APM. The definition previously referred to an “Advanced APM Entity” which was a term eliminated in a previous rule.

**Advanced APM
Criteria**

Use Of CEHRT: CMS proposed 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.

CMS finalized its proposal ([p. 1550](#)).

MIPS Comparable Quality Measures:

CMS acknowledges ambiguity in its previously finalized language regarding quality measure criteria for Advanced APMs (§414.1415(b)(2)). CMS did not intend to imply that any measure that was merely submitted in response to the annual call for quality measures or developed using QPP funding would automatically qualify as MIPS-comparable even if the measure was never endorsed by a consensus-based entities, adopted under MIPS, or otherwise determined to be evidence-based, reliable, and valid. For 2019, CMS will continue to use its more permissive interpretation of the regulation text so that measures developed under the Quality Measure Development plan (§1481(s)) and submitted in response to the MIPS Call for Quality Measures will meet the criterion.

“Consensus-based Entities”. CMS notes that measures endorsed via the Core Quality Measure Collaborative are not considered “endorsed by a consensus-based entity.” CMS states that “only measures on the list of consensus-endorsed measures maintained by the NQF will currently meet the criterion as being endorsed by a consensus-based entity because NQF is the consensus-based entity that endorses standardized healthcare performance measures for CMS as defined under [1890\(b\)\(2\) and \(3\) of the Act](#)”⁵ ([p. 1554](#)).

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. In other words, CMS will treat any measure that is either included in the MIPS final list of measures or has been endorsed by a consensus-based entity as presumptively evidence-based, reliable, and valid. All other measures would need to be independently determined by CMS to be evidence-based, reliable, and valid, in order to be considered MIPS-comparable quality measures. (The same principles apply to QCDR measures. If QCDR measures are endorsed by a consensus-based entity they are presumptively

CMS finalized this proposal ([p. 1555](#)).

⁵ Social Security Act §1890(b)(2) and (3) state:

- (2) *Endorsement of measures.*—The entity shall provide for the endorsement of standardized health care performance measures. The endorsement process under the preceding sentence shall consider whether a measure—
 - (A) *is evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level; and*
 - (B) *is consistent across types of health care providers, including hospitals and physicians.*
- (3) *Maintenance of measures.*—The entity shall establish and implement a process to ensure that measures endorsed under paragraph (2) are updated (or retired if obsolete) as new evidence is developed.

considered MIPS-comparable quality measures for purposes of §414.1415(b)(2); otherwise CMS would need independent verification, or to make its own assessment and determination, that the measures are evidence-based, reliable, and valid before considering them to be MIPS-comparable quality measures.)

Outcome Measure Requirement: Effective January 1, 2020, CMS proposed to modify regulation to explicitly state that the outcome measure, on which an Advanced APM must base payment, must be evidence-based, reliable, and valid unless there is no available or applicable outcome measure.

Bearing Financial Risk for Monetary Losses:

Revenue-Based Standard: CMS proposed 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. CMS seeks comment on whether it should consider raising the nominal amount standard to 10 percent.

Benchmark-Based (Expenditure-based) Standard: CMS seeks comment on whether it should increase the Expenditure-based Standard to 4 percent (from 3 percent) for QP performance period 2025 and later.

QP Determination Claim Run Out: CMS proposed 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) before calculating the Threshold Scores so that the 3 QP determinations will be completed approximately 3 months after the end of that determination period.

Partial QP Election Report to MIPS: CMS previously finalized that in cases where the Partial QP determination is made at the individual level, the eligible clinician will make the election whether to participate in MIPS. In the absence of an affirmative election, CMS previously finalized that it would use the clinician's actual MIPS reporting to determine whether to exclude the Partial QP from MIPS. CMS proposed 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.

CMS finalized its proposal ([p. 1558](#)).

CMS finalized this proposal through the CY 2024 performance year ([p. 1562](#)). In response to stakeholder comment, CMS stated that it might consider "revisiting establishing a lower revenue-based nominal amount standard for small practices and those in rural areas in future rulemaking" ([p. 1561](#)). CMS again stated that it disagrees that the revenue-based standard should apply only to Part B revenues, stating that "many APM entities participating in Advanced APMs often include hospitals and other types of institutional providers or suppliers that may receive both Part A and Part B revenues" ([p. 1560](#)).

CMS received some support for increasing the benchmark-based standard to 4 percent. CMS stated that it will take the comments into consideration for future years ([p. 1563](#)).

CMS finalized its proposal ([p. 1567](#)).

CMS finalized its proposal ([p. 1572](#)).

[Qualifying APM Participant \(QP\) and Partial QP Determinations](#)

**All-Payer
Combination
Option**

Other Payer Advanced APM Criteria:

Investment Payments: CMS is not proposing to modify its Other Payer Advanced APM Financial Risk Standard.

Use of CEHRT: 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.

CMS proposed 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. CMS states that in order to determine whether the CEHRT use criterion was met, it will consider data from a payer or eligible clinician.

MIPS Comparable Quality Measures: CMS made proposals to align with those made earlier under the Advanced APM section for the “MIPS Comparable Quality Measures” criterion.

Financial Risk for Monetary Losses: 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.

Other Payer Advanced APM Determinations:

Multi-Year Payment Arrangements: In past rulemaking, CMS considered creating a multi-year determination process (as opposed to the annual process as finalized) to encourage the creation of more multi-year payment arrangements. However, CMS proposed to maintain the annual submission process with modification (for both the Payer Initiated and Eligible Clinician Initiated Processes):

CMS proposed that beginning with 2019 and 2020 submission periods, after the first year that a payer, APM Entity, or eligible clinician (“requester”)

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](#)

While CMS continues to receive comments of concern that CMS does not include investment payments in its calculation of risk, CMS did not change its policies ([p. 1583](#)).

CMS finalized its proposal ([p. 1585](#)).

CMS finalized its proposal ([p. 1587](#)).

CMS finalized its proposal ([p. 1591](#)). See discussion under [Advanced APM Criteria](#) section.

CMS finalized its proposal ([p. 1595](#)).

CMS finalized its proposal ([p. 1597](#)).

CMS finalized its proposal ([p. 1598](#)).

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.

CMS proposed 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.

CMS finalized its proposal ([p. 1599](#)).

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. 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.

CMS finalized its proposals beginning on [p. 1601](#). CMS summarizes the timeline for Remaining Other Payers in [Table 59](#).

Payer Initiated Process- CMS Multi-Payer Models: CMS proposed to eliminate the Payer Initiated Process and submission form that were specifically used for CMS Multi-Payer Models. These submissions would still be required, but CMS believes these models can utilize the submission forms already in existence for other payers.

CMS finalized its proposal ([p. 1605](#)).

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 and the eligible clinician could become a QP on either determination. CMS proposes to add a 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.

CMS finalized its proposal ([p. 1607](#)).

CMS proposes that it would assess QP status based on the most advantageous result for each individual eligible clinician.

CMS finalized its proposal ([p. 1607](#)).

All-Payer Combination Payment Amount and Patient Count Thresholds: CMS clarifies its policy that the minimum Medicare threshold needed to qualify

CMS finalized its proposal (and made a corresponding regulatory text correction to implement it) ([p. 1610](#)).

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.

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. CMS proposed 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.

CMS finalized its proposal (p. 1612).

Requests for Information

Topic	Proposed Rule	Final Rule
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		
	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. More information about this request is available here .	CMS received approximately 79 timely pieces of correspondence on this RFI and appreciated the input provided by commenters.
Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information		
	This RFI is a follow-up to similar provisions included in the FY 2019 Inpatient Prospective Payment System (IPPS) proposed rule , where 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 encourages all providers and suppliers “to engage in consumer-friendly communication of their charges to help patients understand what	CMS simply stated that it received 94 comments on the topic and thanks commenters for their input (p. 1621).

their potential financial liability might be” and “to update this information at least annually, or more often as appropriate to reflect current charges.

Regulatory Impact Analysis

Topic	Final Rule
PFS Impacts	
<u>Changes in RVU Impacts, Conversion Factor, and Overall Impact</u>	<p>The final CY 2019 PFS conversion factor is 36.0391, 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.</p> <p>The final CY 2019 anesthesia conversion factor is 22.2730, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments. <u>Table 92</u> and <u>Table 93</u> present how CMS calculated the final PFS and Anesthesia conversion factors for 2019.</p> <p><u>Table 94</u> shows the payment impact on PFS services of the policies contained in this final rule by specialty. The most widespread specialty impacts of the RVU changes are generally related to the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties reflect increases that are largely attributable to finalized increases in RVUs for particular services as well as updates to supply and equipment pricing and implementation of new payment policies associated with communication technology-based services. The estimated impacts for several specialties reflect decreases that are largely attributable to revaluation of individual procedures, updates to supply and equipment pricing, and continued implementation of previously finalized code-level reductions that are being phased-in over several years.</p>
<u>Estimated Impacts of Implementing the Payment and Coding Changes for Office/Outpatient E/M Services for CY 2021</u>	<p><u>Table 95</u> provides specialty-level impact estimates associated with changes to E/M coding and payment finalized for CY 2021 for illustrative purposes, showing impacts assuming the policies were implemented in 2019. CMS notes that implementation of the E/M policies would require off-setting reductions in overall PFS payments, which would be applied through a budget neutrality adjustment in the conversion factor. As a result of such an adjustment, while overall changes for most specialties are generally offsetting given increased payments for office/outpatient E/M services, specialties that do not furnish office/outpatient visits generally would see overall reductions in payment of approximately 2.0 percent.</p> <p>CMS notes that commenters have committed to considering revisions to office/outpatient codes through the CPT process. CMS plans to consider any possible changes in coding and valuation through its annual notice and comment rulemaking process, and notes that any potential changes could have significant impact on the actual change in overall RVUs that CMS cannot estimate with any degree of certainty.</p>
<u>Effect of Changes Related to Telehealth</u>	<p>CMS estimates that its policies to add two new codes to the list of Medicare telehealth services for prolonged preventive services would only have a negligible impact on PFS expenditures</p>
Other Provisions of the Regulation	
<u>Part B Drugs: Application of an Add-on Percentage for</u>	<p>CMS cannot estimate the magnitude of savings over time attributable to its final policies 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</p>

Certain
Wholesale
Acquisition Cost
(WAC)-based
Payments

cannot estimate the overall savings to the Medicare Program or to beneficiaries, CMS points 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 final policies will impair providers' or patients' access to Part B drugs.

Clinical
Laboratory Fee
Schedule:
Change to the
Majority of
Medicare
Revenues
Threshold
in Definition of
Applicable
Laboratory

CMS estimates that final policies to exclude MA plan payments from total Medicare revenues could increase the number of laboratories required to report applicable information by an additional 951 laboratories. Presuming all 835 laboratories met all of the criteria necessary to receive applicable laboratory status, CMS estimates that an additional 285,300 records would be reported for the next data reporting period, or an increase in records reported of about 5 percent.

CMS estimates that inclusion of 14X type of bills would increase the number of laboratories by 757. This translates to an additional 221,100 records that would be reported, or an increase of about 5 percent.

CMS does not expect the additional reported data resulting from its change will have a predictable, direct impact on CLFS rates.

Appropriate Use
Criteria for
Advanced
Diagnostic
Imaging Services

Impact of Required AUC Consultations by Ordering Professionals (p. 1939):

CMS finalized that the AUC consultation task may be delegated by the ordering professional to clinical staff under the direction of the ordering professional. Assuming 90 percent of practices employ the use of auxiliary personnel to interact with the CDSM for AUC consultation for advanced diagnostic imaging orders, CMS estimates a net burden reduction of \$205,137,300. CMS also provides a detailed estimate of the burden of an ordering professional voluntarily choosing to consult a second, free CDSM. If 90 percent of those consultations are performed by a medical assistant, then the annual burden estimate of the second consultation would be \$487,491.58. CMS also estimates a one-time burden of education and training to be \$116,250,431 as an upper bound.

Impact of Significant Hardship Exceptions for Ordering Professionals (p. 1947):

CMS finalized its proposal 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. 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.

Impact of Consultations beyond the Impact to Ordering Professionals (p. 1950):

- *Transfers from Ordering Professionals to Qualified CDSMs and EHR Systems:* 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.
- *Impact to Medicare Beneficiaries:* CMS believes that the 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 (2 minutes), 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.

Considering the Impact of Claims-Based Reporting ([p. 1959](#))

- *Impact on Transmitting Order for Advanced Diagnostic Imaging Services:* CMS believes final policy 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. 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:* While CMS did not include a policy 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. 1961](#).

Impact on Furnishing Professionals and Facilities ([p. 1964](#))

CMS estimates that advanced diagnostic imaging services are provided as follows across settings: 70 percent outpatient; 28 percent physician's office; 1 percent ambulatory surgical centers, and 1 percent independent diagnostic testing facilities. CMS estimates 174.064 furnishing professionals.

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. 1970](#))

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. CMS also notes that it has provided estimates, but that the estimates are based on multiple assumptions and may be an overestimate of burden as a free qualified CDSM is available and required by law.

Medicare Shared Savings Program

CMS notes that the finalized reduction in the number of ACO measures is expected to reduce ACO reporting burden and improve quality outcomes for beneficiaries.

Physician Self-Referral Law

CMS finalized policies 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 expects that the policy regarding temporary non-compliance with signature arrangements will reduce burden by giving parties additional time to obtain all required signatures.

Changes Due to Updates to the Quality Payment Program

Estimated Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

CMS estimates that approximately 8,100 additional eligible clinicians in 8 APM Entities representing approximately 225 TINs will become QPs due to finalized policies 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. However, CMS notes that the majority, if not all, of the 8,100 eligible clinicians that would become QPs if these policies are finalized, had already attained QP status in the 2018 QP performance period. Therefore, the associated APM incentive payments for these 8,100 would not be additional impacts in comparison to previous performance years, only additional impacts in the absence of finalizing these policies.

Overall, CMS estimates that between 165,000 and 220,000 eligible clinicians will 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. (This number is slightly higher than in the proposed rule due to updated data on participation.) CMS estimates that the aggregate total of the APM incentive payment of 5 percent of Part B allowed charges for QPs will 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.

CMS lists the expected Advanced APMs for performance year 2019 on [p. 1984](#).

Updates to MIPS Estimates Using QPP Year 1 Data

CMS has updated its analyses from the proposed rule to consider data submitted for the 2017 MIPS performance period (which CMS refers to in this section as QPP Year 1 data). However, impacts presented reflect final policies, not actual CY 2017 results. A few key changes from the original analysis and the revised analysis include:

- Higher group reporting than previously estimated, leading to a 42 percent increase in group reporters who otherwise would not have been MIPS eligible clinicians
- Higher participation among clinicians in small practices than estimated (89.9 percent versus 79.7 percent)
- Direct observation of performance across performance categories (particularly around the Promoting Interoperability performance category)
- Improved ability to estimate excluded clinicians, leading to fewer excluded clinicians

CMS discusses some implications of these changes as well as caveats to their analysis on [p. 1987](#).

Estimated Number of Clinicians Eligible for MIPS Eligibility

[Table 97](#) compares the MIPS eligibility status and the associated PFS allowed charges from the CY 2019 PFS proposed rule with the estimates of MIPS eligibility and the associated PFS allowed charges after using QPP Year 1 data and applying the finalized policies for the CY 2019 MIPS performance period.

In [Table 98](#), CMS provides estimates on how each finalized policy affects the estimated number of MIPS eligible clinicians. In total, CMS includes 751,498 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 797,990 MIPS eligible clinicians for the 2019 MIPS performance period.

Estimated Impacts on Payments to MIPS Eligible Clinicians

CMS' impact analysis looks at the total effect of the finalized 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 rule reflect averages by practice size based on Medicare utilization. CMS does not provide estimates by specialty. CMS notes that it did not model virtual groups due to limited data (though notes that 2 virtual groups participated for 2018, including one where all clinicians participated in a MIPS APM).

Using the assumptions in its model, CMS estimates that \$310 million would be redistributed through budget neutrality and that the maximum positive payment adjustments are 4.7 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. [Table](#)

[99](#) shows the impact of the payments by practice size and whether the clinicians are expected to submit data to MIPS. [Table 99](#) also shows that 91.2 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, 90 percent are in small practices (15,680 out of 17,376 clinicians).

However, due to many limitations, CMS notes that there is considerable uncertainty around its estimates that is difficult to quantify in detail.

Potential Costs of Compliance with the Promoting Interoperability and Improvement Activities Performance Categories for Eligible Clinicians

Potential Costs of Compliance with Promoting Interoperability Performance Category

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 the final rule 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

Given the lack of comprehensive historical data for improvement activities, and the need for further analysis of MIPS CY 2017 performance period data, CMS cannot report on the costs and benefits of implementing improvement activities. CMS believes the overall potential cost of compliance would not increase because of this 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 rule. With respect to 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.

Medicare Shared Savings Program: Accountable Care Organizations – Pathways to Success

CMS estimates that up to 200 ACOs would elect to voluntarily extend their contracts for the first 6 months of 2019, and therefore, would continue to improve care coordination and efficiency, and have the opportunity to receive shared savings for such period estimated to total approximately \$170 million. However, CMS estimates that residual savings on claims attributable to the 6-month extension period over the 12 months following the end of the extension would fully offset the \$170 million in shared savings payments for the extension period. CMS does not believe that the methodology for determining the financial performance of ACOs in a 6-month performance year from January 1, 2019, through June 30, 2019, would result in an increase in spending beyond the expenditures that would otherwise occur.

Alternatives Considered

E/M Coding and Payment

[Table 100](#) shows the specialties that would experience the greatest increase or decrease by establishing single payment rates for E/M visit levels 2 through 4, while maintaining the value of the level 1 and the level 5 E/M visits (without inherent visit complexity add-on codes).

Other alternatives explored include:

- Finalizing all elements of the proposal except for the MPPR and the single PE/hr value across the office/outpatient E/M code set (see [Table 101](#) for specialty level impacts)
- Finalizing all elements of the proposal except for separate coding for podiatric E/M visits and the application of a single PE/hr across the office/outpatient E/M codes (see [Table 102](#) for specialty level impacts)
- Finalizing all elements of the proposal except for the PE/hr change and separate coding for podiatric E/M visits, and establishing a single payment rate for levels 2 through 4, rather than levels 2 through 5 (see [Table 103](#) for specialty level impacts)
- Finalizing all elements of the proposal with the exception of the PE/hr adjustment and the MPPR, but establishing a single payment rate for levels 2 through 4 (see [Table 104](#) for specialty level impacts)

E/M Documentation

CMS considered several alternatives that would have finalized the documentation proposals not associated with coding and payment changes (i.e. regarding home visits and avoiding redundant data recording), along with additional policies, such as:

- Maintaining all five E/M visit levels (e.g. choice in documentation of current framework, MDM, or time)
- Finalizing all policies as proposed

Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

CMS considered not finalizing its proposals for the remote evaluation of patient-recorded information and for the virtual check-in, and estimates that there would have been a 0.2 percent increase to the conversion factor under such an alternative.

AUC Program

Consultation with More than One Qualified CDSM

CMS considered an alternative that would result in ordering professionals or auxiliary staff consulting more than one qualified CDSM prior to ordering advanced diagnostic imaging in order to decrease the frequency that a “not applicable” consultation result would be reported. For illustrative purposes, CMS estimates total burden associated with a second consultation for abdominal pain to be almost 10,000 hours and \$487,492. CMS did not propose this alternative.

Significant Hardship Application Process

CMS considered an alternative of requiring a significant hardship exception application process, with an estimated total annual burden of \$298,708.

Quality Payment Program

CMS considered alternatives that varied the performance threshold and the additional performance threshold (p. 2043).

CMS also ran estimates on the potential change in population if CMS established different low volume thresholds (p. 2045).

Burden Reduction Estimates

Evaluation and Management Documentation

CMS revised its burden reduction estimates from the proposed rule, given changes in policy and comments on continued burden.

For 2019 and 2020, changes reducing documentation burden are estimated to save approximately \$84 million. CMS also estimates that savings of \$513 million accrue per year after the final payment and coding-related changes are implemented and fully phased in starting in 2023; these savings are partially offset in 2021 and 2022 due to ongoing documentation burden, ramp-up costs, and training and education.

Outpatient Therapy Services

CMS finalized a policy 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 under the final policy. 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

CMS believes that the finalized changes to the physician supervision requirements for RAs furnishing diagnostic imaging procedures 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 policy to now require direct supervision of diagnostic imaging procedures done by RAs in cases where personal supervision would ordinarily be required.

Appendices

APPENDIX A: [Medicare Shared Savings Program; Accountable Care Organizations – Pathways to Success](#)

Topic	Final Rule
Background	<p>On August 17, 2018 a proposed rule, titled "Medicare Shared Savings Program (MSSP); Accountable Care Organizations--Pathways to Success" (hereinafter referred to as the "August 2018 proposed rule"), appeared in the Federal Register (83 FR 41786). This proposed rule would provide a new direction for the MSSP by establishing pathways to success through redesigning the participation options available under the program to encourage ACOs to transition to two-sided models (in which they may share in savings and are also accountable for repaying any shared losses). As part of the proposed redesign of the program, CMS proposed to establish two tracks under the program – the BASIC track and the ENHANCED track. These new participation options were designed to increase savings for the Trust Funds and mitigate losses, reduce gaming opportunities, and promote regulatory flexibility and free-market principles. The August 2018 proposed rule would also provide new tools to support coordination of care across settings and strengthen beneficiary engagement; ensure rigorous benchmarking; and promote the use of interoperable electronic health record technology among ACO providers/suppliers. In this final rule, CMS addresses a subset of the proposals described in the August 2018 proposed rule. The changes will be effective on December 31, 2018, although applicability or implementation dates may vary, depending on the policy, and the timing specified in this final rule. CMS will summarize and respond to public comments on other proposed policies in a forthcoming final rule. A fact sheet of the proposed rule is available here.</p>
Participation Options for Agreement Periods Beginning in 2019	<p>Voluntary Extension for a 6-Month Performance Year from January 1, 2019 through June 30, 2019, for ACOs whose Current Agreement Period Expires on December 31, 2018:</p> <p>In the August 2018 proposed rule (83 FR 41847), CMS indicated that it was forgoing the application cycle that otherwise would take place during CY 2018 for a January 1, 2019 start date for new MSSP participation agreements, initial use of the Skilled Nursing Facility (SNF) 3-day rule waiver, and entry into the Track 1+ Model. CMS proposed to offer a July 1, 2019 start date as the initial opportunity for ACOs to enter an agreement period under the proposed BASIC track or ENHANCED track, which would be offered under the proposed redesign of the program's participation options. CMS proposed the July 1, 2019 start date as a one-time opportunity, and thereafter would resume its typical process of offering an annual application cycle that allows for review and approval of applications in advance of a January 1 agreement start date.</p> <p>ACOs that entered a first or second agreement period with a start date of January 1, 2016 could elect to extend their agreement period for an optional fourth performance year, defined as the 6-month period from</p> <p>Voluntary Extension for a 6-Month Performance Year from January 1, 2019 through June 30, 2019, for ACOs whose Current Agreement Period Expires on December 31, 2018:</p> <p><i>CMS finalized its proposal to allow ACOs that entered a first or second agreement period beginning on January 1, 2016, to voluntarily elect a 6-month extension of their current agreement period for a fourth performance year from January 1, 2019 through June 30, 2019. CMS believes this extension is necessary in order to avoid an involuntary gap in participation as a result of CMS' decision to forgo an application cycle in 2018 for a January 1, 2019 agreement start date and to provide ACOs with an opportunity to prepare for a more rapid transition to the proposed new participation options, if finalized, including new Advanced APMs that would allow eligible clinicians participating in these ACOs to qualify for incentive payments under the QPP (p. 1642). While CMS does not actually address in this final rule the implementation of the redesigned MSSP participation options proposed for July 1, 2019 (i.e., BASIC and ENHANCED), it believes it is important to allow for continuity in participation for ACOs whose participation agreements expire December 31, 2018.</i></p>

January 1, 2019 through June 30, 2019. This election would be voluntary and an ACO could choose not to extend its agreement period, in which case it would conclude its participation in the program with the expiration of its current agreement period on December 31, 2018. This optional 6-month agreement period extension would be a one-time exception for ACOs with agreements expiring on December 31, 2018, and would not be available to other ACOs that are currently participating in a 3-year agreement in the program, or to future program entrants.

Methodology for Determining Financial and Quality Performance for the 6-Month Performance Year from January 1, 2019 through June 30, 2019:

CMS proposes an approach for determining financial and quality performance for two 6-month performance years during 2019, with the first from January 1, 2019 through June 30, 2019, for ACOs with participation agreements expiring on December 31, 2018, that elect a voluntary 6-month extension, and the second from July 1, 2019 through December 31, 2019, for ACOs entering a new agreement period beginning July 1, 2019. CMS also proposes an approach for determining financial and quality performance for the performance period from January 1, 2019 through June 30, 2019 for an ACO starting a 12-month performance year on January 1, 2019, that terminates its participation agreement with an effective date of termination of June 30, 2019, and enters a new agreement period beginning on July 1, 2019, referred to as “early renewals.”

Under CMS’ proposed approach to determining performance for the 6-month performance year from January 1, 2019 through June 30, 2019, after the conclusion of CY 2019, CMS would reconcile the financial and quality performance of ACOs that participated in the MSSP during 2019. For ACOs that extended their agreement period for the 6-month performance year from January 1, 2019 through June 30, 2019, CMS would first reconcile the ACO based on its performance during the entire 12-month calendar year, and then pro-rate the calendar year shared savings or shared losses to reflect the ACO’s participation for only half of the calendar year. The proposed approach would allow payment reconciliation to remain on a calendar year basis, which would be most consistent with the calendar year-based methodology for calculating benchmark expenditures, trend and update factors, risk adjustment, county expenditures and regional adjustments. As is the case with typical calendar year reconciliations in the MSSP, CMS anticipates results with respect to participation during CY 2019 would be made available to ACOs in summer 2020.

In this section, CMS makes other technical and conforming changes to the regulations to comply with this new policy.

Methodology for Determining Financial and Quality Performance for the 6-Month Performance Year from January 1, 2019 through June 30, 2019:

In this final rule, CMS only addresses final actions specific to its proposals regarding the 6-month extension and the methodology for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019. The other scenarios discussed in the proposed rule will be addressed in the forthcoming final rule.

After consideration of public comments, CMS finalized with modifications the proposed approach to determine financial and quality performance for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019, as specified in paragraphs (a) and (b) of a new section of the regulations at §425.609 (p. 1660). In general, CMS will continue to apply the current (i.e., proposed) benchmarking methodology during the optional fourth performance year in order to maintain ACOs’ existing historical benchmarks, allowing them to continue to build on their experience within their current agreement period and providing a more predictable and stable benchmark during the 6-month extension period. The finalized modifications simply account for the fact that this rule only addresses the 6-month extension period and not the proposal to establish a July 1, 2019 agreement start date.

CMS will do the following to determine an ACO’s financial and quality performance during the 6-month performance year from January 1, 2019 through June 30, 2019:

- CMS will compare the ACO’s historical benchmark updated to CY 2019 to the expenditures during CY 2019 for the ACO’s performance year assigned beneficiaries. If the difference is positive and is greater than or equal to the Minimum Savings Rates (MSR) and the ACO has met the quality performance standard, the ACO will be eligible for shared savings. If the ACO is in a two-sided model and the difference between the updated benchmark and assigned beneficiary expenditures is negative

CMS describes in detail its proposed approach for determining financial and quality performance for the 6-month performance period from January 1, 2019 through June 30, 2019 (83 FR 41851 through 41853).

and is greater than or equal to the Minimum Loss Rate (MLR) (in absolute value terms), the ACO will be liable for shared losses.

- ACOs will share in first dollar savings and losses.
- The amount of any shared savings will be determined using the applicable final sharing rate, which is determined based on the ACO's track for the applicable agreement period, and taking into account the ACO's quality performance for 2019. CMS will adjust the amount of shared savings for sequestration, and then cap the amount of shared savings at the applicable performance payment limit for the ACO's track. Similarly, the amount of any shared losses will be determined using the loss sharing rate for the ACO's track and, as applicable, for ACOs in tracks with a loss sharing rate that depends upon quality performance, the ACO's quality performance for 2019. CMS will then cap the amount of shared losses at the applicable loss sharing limit for the ACO's track. CMS will then pro-rate any shared savings or shared losses by multiplying by one-half, which represents the fraction of the calendar year covered by the 6-month performance year. This pro-rated amount will be the final amount of shared savings earned or shared losses owed by the ACO for the 6-month performance year ([p. 1660](#)).

Under this approach to determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, CMS would continue to determine beneficiary assignment, quality performance, and expenditures on a 12-month basis, as described in the sections below. CMS continues to believe it's important to maintain alignment with the program's existing methodology by using 12 months of data (for CY 2019) for these determinations. CMS acknowledges that this approach will add complexity to program policies and certain operational processes, but plans to assist ACOs with understanding these operational details of through education and outreach.

Because CMS is not addressing the July 1, 2019 agreement period start date for the proposed new BASIC track and ENHANCED track at this time (these policies will be addressed in the forthcoming final rule), it outlines differences between its proposed approach (which contemplated that ACOs may be participating in both a 6-month performance year from January 1, 2019 through June 30, 2019, and a 6-month performance year from July 1, 2019 through December 31, 2019) and its final policies (which are limited to the 6-month performance year from January 1, 2019 through June 30, 2019, for eligible ACOs that elect to extend their agreement period, which would otherwise expire on December 31, 2018) starting on [p. 1661](#).

ACO Participant List Used to Determine Beneficiary Assignment
CMS proposes to use the ACO participant list for the performance year beginning January 1, 2019, to determine beneficiary assignment as

ACO Participant List Used to Determine Beneficiary Assignment

specified in §§425.402 and 425.404, and according to the ACO's track as specified in §425.400. It proposes to allow all ACOs, including ACOs entering a 6-month performance year, to make changes to their ACO participant list in advance of the performance year beginning January 1, 2019.

Approach to Assigning Beneficiaries

CMS proposes to consider the allowed charges for primary care services furnished to the beneficiary during a 12-month assignment window, allowing for a 3 month claims run out. For the 6-month performance year from January 1, 2019 through June 30, 2019, CMS proposes to determine the assigned population using the following assignment windows:

- For ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window would be CY 2019.
- For ACOs under prospective assignment, Medicare FFS beneficiaries would be prospectively assigned to the ACO based on the beneficiary's use of primary care services in the most recent 12 months for which data are available. Beneficiaries would remain prospectively assigned to the ACO at the end of CY 2019 unless they meet any of the exclusion criteria.

Benchmark Year Assignment Methodology and Methodology for Calculating and Adjusting an ACO's Historical Benchmark

For the 6-month performance year from January 1, 2019 through June 30, 2019, CMS proposes to determine the benchmark and calculate performance year expenditures for assigned beneficiaries as though the performance year were the entire calendar year. The ACO's historical benchmark would be determined according to the methodology applicable to the ACO based on its agreement period in the program (i.e., §425.602 for ACOs in a first agreement period or §425.603 for ACOs in a second agreement period), except that data from CY 2019 would be used in place of data for the 6-month performance year in certain calculations (i.e., accounting for changes in severity and case mix and growth in national Medicare FFS expenditures for assignable beneficiaries).

Methodology for Determining Shared Savings and Shared Losses

For determining financial performance during the 6-month performance year from January 1, 2019 through June 30, 2019, CMS would apply the methodology for determining shared savings and shared losses according to the approach specified for the ACO's track under the terms of the participation agreement that was in effect on January 1, 2019. However,

In this rule, CMS discuss the participant list in the context of quality measure reporting and sampling, discussed below.

Approach to Assigning Beneficiaries

CMS finalized this proposed approach to assigning beneficiaries for the 6-month performance year ([p. 1653](#)).

Benchmark Year Assignment Methodology and Methodology for Calculating and Adjusting an ACO's Historical Benchmark

CMS would maintain the calendar year-based methodology for calculating benchmark expenditures, trend and update factors, and risk adjustment ([p. 1654](#)).

Methodology for Determining Shared Savings and Shared Losses

To determine shared savings and shared losses, CMS would calculate average per capita Medicare expenditures for Parts A and B services for the full CY 2019 for the

some exceptions to the otherwise applicable methodology are needed because CMS proposes to calculate the expenditures for assigned beneficiaries over the full CY 2019 for purposes of determining shared savings and shared losses for the 6-month performance year from January 1, 2019 through June 30, 2019. The steps that CMS would follow to calculate shared savings and shared losses are described in the proposed rule.

Applicability of Program Policies to ACOs Participating in a 6-Month Performance Year:

CMS proposes that program requirements under 42 CFR part 425 that are applicable to the ACO under the ACO's chosen participation track and based on the ACO's agreement start date would be applicable to an ACO participating in a 6-month performance year, unless otherwise stated. In this section, CMS describes program participation options affected by its decision to forgo an application cycle in CY 2018 for a January 1, 2019 start date, and to offer a voluntary extension to allow ACOs whose agreement periods expire on December 31, 2018, to continue their participation in the program for a 6-month performance year from January 1, 2019 through June 30, 2019. CMS discusses the following modifications to program policies to allow for the 6-month performance year and related revisions to the program's regulations:

Unavailability of an Application Cycle for Use of a SNF 3-Day Rule Waiver Beginning January 1, 2019

CMS proposes to allow eligible ACOs in performance-based risk within the BASCI track's glide path and the ENHANCED track to use the existing SNF 3-day rule waiver, regardless of their choice of prospective assignment or preliminary prospective assignment with retrospective reconciliation.

Annual Certifications and ACO Participant List Modifications

Each ACO is required to certify its list of ACO participant TINs before the start of its agreement period, before every performance year thereafter,

ACO's performance year assigned beneficiary population and compare this amount to the updated historical benchmark. CMS would then pro-rate any shared savings or shared losses by multiplying the amounts by one-half, which represents the fraction of the calendar year covered by the 6-month performance year ([p. 1654](#)).

Applicability of Program Policies to ACOs Participating in a 6-Month Performance Year ([p. 1662](#)):

In this final rule, CMS does not address the considerations related to the proposed July 1, 2019 agreement period start date because it is not addressing the proposal to offer that start date at this time.

Unavailability of an Application Cycle for Use of a SNF 3-Day Rule Waiver Beginning January 1, 2019

In light of its decision to forgo an application cycle in CY 2018 for a January 1, 2019 agreement period start date, CMS will not offer an opportunity for ACOs to apply for a start date of January 1, 2019, for initial use of a SNF 3-day rule waiver. The next available application cycle for a SNF 3-day rule waiver would occur in advance of a July 1, 2019 start date (if finalized). ACOs within existing agreement periods in Track 3 or the Track 1+ Model would not have the opportunity to apply to begin use of the waiver until January 1, 2020. CMS notes that its proposals to extend the availability of a SNF 3-day rule waiver and to give ACOs the opportunity to offer beneficiary incentive programs were developed in conjunction with its proposed changes to the participation options for ACOs participating in the MSSP and will be considered as part of the forthcoming final rule ([p. 1638](#), [1664](#)).

Annual Certifications and ACO Participant List Modifications

and at such other times as specified by CMS in accordance with §425.118(a). A request to add ACO participants must be submitted prior to the start of the performance year. An ACO must notify CMS no later than 30 days after termination of an ACO participant agreement, and the entity is deleted from the ACO participant list effective as of the termination date of the ACO participant agreement. Absent unusual circumstances, the ACO participant list that was certified prior to the start of the performance year is used to determine beneficiary assignment for the performance year and therefore also the ACO's quality reporting samples and financial performance. CMS proposes that these policies would apply for ACOs participating in a 6-month performance year consistent with the terms of the existing regulations.

Repayment Mechanism Requirements

In general, ACOs that started a first or second agreement period on January 1, 2016, in a two-sided model would have in place under current program policies a repayment mechanism arrangement that would cover the 3 years between January 1, 2016 and December 31, 2018, plus a 24-month tail period until December 31, 2020. CMS would expect an ACO with an agreement period ending December 31, 2018, that extends its agreement for the 6-month performance year from January 1, 2019 through June 30, 2019, to extend the term of its repayment mechanism in accordance with current policies so that it will be in effect for the duration of the ACO's participation in a two-sided model plus 24 months following the conclusion of the agreement period (i.e., until June 30, 2021).

Quality Reporting Period and Quality Measure Sampling

To determine an ACO's quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, CMS proposes to use the ACO's quality performance for the 2019 reporting period (i.e., using quality measure data reported for the 12-month CY 2019).

CMS also proposes to use a different quality measure sampling methodology depending on whether an ACO participates in both a 6-month performance year beginning on January 1, 2019, and a 6-month performance year beginning on July 1, 2019, or only participates in a 6-month performance year from January 1, 2019 through June 30, 2019.

For purposes of determining the quality reporting samples for the 2019 reporting period, CMS proposes to use the ACO's most recent certified ACO participant list available at the time the quality reporting samples are

ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement period for a 6-month performance year beginning on January 1, 2019, were given the opportunity during 2018 to make changes to their ACO participant list to be effective for the 6-month performance year from January 1, 2019, to June 30, 2019 (p. 1665). To prepare for the possible implementation of this 6-month performance year, CMS has allowed these ACOs to submit change requests during 2018 in accordance with usual program procedures to indicate additions, updates, and deletions to their existing ACO participant lists, and if applicable, SNF affiliate lists (contingent upon issuance of these final rule policies). CMS notes here that it is operationally feasible to extend the date for ACOs to submit change requests after September 28, 2018, the date it communicated to ACOs as being the deadline to add ACO participants to be effective for performance years beginning on January 1, 2019.

Repayment Mechanism Requirements

In the forthcoming final rule, CMS expects to summarize and respond to comments on its proposed changes to §425.204(f) regarding repayment mechanism requirements for ACOs that are in a two-sided model. (p. 1669) In the interim, CMS has notified ACOs participating under a two-sided model that if they elect the 6-month extension from January 1, 2019 through June 30, 2019 then CMS expects that they will extend their repayment mechanisms in accordance with §425.204(f)(4) (i.e., until June 30, 2021).

Quality Reporting and Quality Measure Sampling

For ACOs electing the voluntary 6-month extension, CMS finalized without modification its proposal to determine the ACO's quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, using the ACO's quality performance for the 12-month CY 2019 (2019 reporting period) (p. 1676). This aligns with the program's existing quality reporting methodology and measure specifications, which require 12-months of data, and the APM scoring standard under MIPS.

Given the limited scope of this final rule, at this time, CMS finalized only its proposal to use the ACO's latest certified participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period for ACOs that extend their prior participation agreement for the 6-month performance year from January 1, 2019 to June 30, 2019 (p.

generated, and the assignment methodology most recently applicable to the ACO for a 2019 performance year.

CMS proposes two approaches to determine the certified ACO participant list, assignment methodology, and assignment window that would be used to generate the quality reporting samples for measuring quality performance of ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019:

- For ACOs that enter a new agreement period under the proposed July 1, 2019 agreement start date, including ACOs that extended their prior participation agreement for the 6-month performance year from January 1, 2019, to June 30, 2019: CMS proposes to use the certified ACO participant list for the performance year starting on July 1, 2019, to determine the quality reporting samples for the 2019 reporting period.
- For ACOs that extend their participation for the first 6 months of 2019, but do not enter a new agreement period beginning on the proposed July 1, 2019 agreement start date: CMS proposes to use the ACO's latest certified participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period.

Beneficiary assignment for purposes of generating the quality reporting samples would be based on the assignment methodology applicable to the ACO during its 6-month performance year from January 1, 2019 through June 30, 2019, either preliminary prospective assignment or prospective assignment, with excluded beneficiaries removed as applicable.

CMS clarifies that ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019, and the 6-month performance year from July 1, 2019 through December 31, 2019 (if finalized as proposed), would only have to report quality once for CY 2019 (i.e., report quality for one beneficiary sample for CY 2019).

Payment and Recoupment for 6-Month Performance Years

CMS proposes to apply the same policies regarding notification of shared savings and shared losses and the timing of repayment of shared losses to ACOs in a 6-month performance year that apply under its current regulations to ACOs in 12-month performance years (i.e., §425.604(f) for Track 1; §425.606(h) for Track 2, and §425.610(h) for Track 3).

[1676](#)). CMS will address proposals related to the proposed July 1, 2019 agreement start date in the forthcoming final rule.

CMS clarifies that for the 2019 reporting period, ACOs would be required to report quality data through the CMS Web Interface, according to the method and timing of submission established by CMS. The period for reporting quality data through the CMS Web Interface typically occurs for a 12-week period between January and March, following the conclusion of the calendar year. Thus, ACOs that participate in a 6-month performance year from January 1, 2019 through June 30, 2019, along with all other MSSP ACOs would be required to report for the 2019 reporting period, and would report quality data through the CMS Web Interface during the designated reporting period in early 2020.

ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019, also would be required to contract with a CMS-approved vendor to administer the CAHPS for ACOs survey for the 2019 reporting period, consistent with program-wide policies applicable to all other ACOs.

Payment and Recoupment for 6-Month Performance Years
CMS finalized these changes as proposed ([p. 1680](#)).

CMS anticipates determining financial and quality performance for ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019, according to the typical annual projected timeline for making these determinations, and for issuing performance reports to ACOs (i.e., the summer following the conclusion of the 12-month performance year). CMS also plans to provide ACOs that participate in the 6-month performance year quarterly reports for the third and fourth quarter of CY 2019.

Interactions With the Quality Payment Program

Under §414.1425(c)(7)(i), for Advanced APMs that start during the QP Performance Period and are actively tested for at least 60 continuous days during a QP Performance Period, CMS will make QP determinations and Partial QP determinations for eligible clinicians in the Advanced APM using claims data for services furnished during those dates on which the Advanced APM is actively tested. CMS performs QP determinations for eligible clinicians in an APM entity three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31. This means that an APM (such as a two-sided model of the Shared Savings Program) would need to begin operations by July 1 of a given performance year in order to be actively tested for at least 60 continuous days before August 31 – the last date on which QP determinations are made during a QP Performance Period. Therefore, CMS believes that its proposed July 1, 2019 start date for the proposed new participation options under the MSSP would align with QPP rules and requirements for participation in Advanced APMs.

In the proposed rule, CMS does not address QP determinations for eligible clinicians participating in an ACO whose agreement period expires on December 31, 2018, that elects a voluntary extension for the 6-month performance year from January 1, 2019 through June 30, 2019, and does not continue in the program past June 30, 2019.

Interactions With the Quality Payment Program

CMS makes the following clarifications regarding ACOs that elect to extend for the 6-month performance year January 1, 2019 through June 30, 2019:

- For ACO that is in a track that meets the Advanced APM criteria and elects to extend for the 6-month performance year, the agreement period would end during the QP performance period. However, because the ACO would have been active for more than 60 days, it would continue to be an APM entity in an Advanced APM in 2019 (§414.1425(c)(7)). Therefore, clinicians who obtain QP status based on the March 31, 2019, or June 30, 2019 snapshot through participation in an ACO with a 6-month extension of its agreement period will: maintain QP status, be exempt from MIPS, and receive the APM incentive payment, as long as their ACO completes its agreement period by remaining in the program through June 30, 2019.
- CMS also clarifies what would happen to an eligible clinician's QP status if they are participating in an ACO that is in a track that meets the Advanced APM criteria and elects to extend for the 6-month performance year from January 1, 2019 through June 30, 2019, and either voluntarily terminates or is involuntarily terminated prior to June 30, 2019. If their ACO terminates or is involuntarily terminated any time after March 31, 2019, and before August 31, 2019, then eligible clinicians previously determined to have had QP status would lose their status as a result of the termination, and would instead be scored under MIPS using the APM Scoring Standard. If their ACO terminates before March 31, 2019, then the eligible clinicians would not be scored under the APM Scoring Standard and will be assessed under regular MIPS scoring rules.
- ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) participating in an ACO that completes a 6-month performance year from January 1, 2019 through June 30, 2019, would continue to be scored under MIPS using the APM Scoring Standard, based on quality data submitted **for all of 2019** during the regular submission period in early 2020. Thus, for a Track 1 ACO in a 6-month performance year from January 1, 2019 through June 30, 2019, whose agreement period expires

and the ACO does not renew to continue program participation, the ACO would be scored under the MIPS APM scoring rules for quality reporting based on the entire CY 2019.

Sharing CY 2019 Aggregate Data With ACOs in 6-Month Performance Year From January 1, 2019 Through June 30, 2019

Under the program's current regulations, CMS shares aggregate data with ACOs during the agreement period, including data at the beginning of each performance year, during each quarter, and in conjunction with the annual reconciliation. For ACOs that extend their agreement for the additional 6-month performance year, CMS proposes to continue to deliver aggregate reports for all four quarters of CY 2019 based on the ACO participant list in effect for the 6-month performance year.

Technical or Conforming Changes to Allow for 6-Month Performance Years
CMS proposes to make certain technical, conforming changes to certain provisions of the regulations to govern the calculation of the financial and quality results for the proposed 6-month performance years within CY 2019.

Payment Consequences of Early Termination

CMS proposes to impose payment consequences for early termination by holding ACOs in two-sided models liable for pro-rated shared losses. This approach would apply to ACOs that voluntarily terminate their participation more than midway through a 12-month performance year and all ACOs that are involuntarily terminated by CMS. ACOs would be ineligible to share in savings for a performance year if the effective date of their termination from the program is prior to the last calendar day of the performance year. However, CMS would allow an exception for ACOs that are participating in a 12-month performance year under the program as of January 1, 2019, that terminate their agreement with an effective date of June 30, 2019, and enter a new agreement period under the proposed BASIC track or ENHANCED track beginning July 1, 2019. In these cases, CMS would perform separate reconciliations to determine shared savings and shared losses for the ACO's first 6 month period of participation in 2019 and for the ACO's 6-month performance year from July 1, 2019, to December 31, 2019, under the subsequent participation agreement.

Sharing CY 2019 Aggregate Data With ACOs in 6-Month Performance Year From January 1, 2019 Through June 30, 2019

CMS finalized this policy as proposed ([p. 1686](#)).

Technical or Conforming Changes to Allow for 6-Month Performance Years

CMS addresses only the proposals specific to the 6-month performance year from January 1, 2019 through June 30, 2019, starting on [p. 1686](#).

Payment Consequences of Early Termination

CMS finalized its proposed policies for determining payment consequences of early termination to account for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. These policies are described starting on [p. 1692](#).

CMS will address policies related to the payment consequences of early termination from 12-month performance years and from 6-month performance years beginning on July 1, 2019, in the forthcoming final rule.

In the August 2018 proposed rule (83 FR 41894 through 41911), CMS proposes various revisions that are designed to update policies under the MSSP.

Revisions to Policies on Voluntary Alignment: Section 1899(c) of the Act requires that beneficiaries be assigned to an ACO based on their use of primary care services furnished by a physician as defined in section 1861(r)(1) of the Act, and beginning January 1, 2019, services provided in RHCs/FQHCs. CMS currently requires that a beneficiary receive at least one primary care service during the beneficiary assignment window from an ACO professional in the ACO who is a physician with a specialty used in assignment in order to be assigned to the ACO (see §425.402(b)(1)). For performance year 2019 and subsequent performance years, for purposes of the assignment methodology, CMS treats a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician. After identifying the beneficiaries who have received a primary care service from a physician in the ACO, CMS uses a two-step, claims-based methodology to assign beneficiaries to a particular ACO for a calendar year (see §425.402(b)(2) through (4)).

As finalized in the CY 2017 PFS final rule (81 FR 80501 through 80510), CMS also now provides an option in which a beneficiary may select any practitioner who has a record on the Physician Compare website as their primary clinician. However, CMS will only assign the beneficiary to an ACO if they have chosen a practitioner who is a primary care physician (as defined at §425.20), a physician with one of the primary specialty designations included in §425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist.

Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary, for performance year 2018 and beyond, to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO. Therefore, CMS proposes to modify its current voluntary alignment policies at §425.402(e)(2)(iii) to provide that it will assign a beneficiary to an ACO based upon their selection of any ACO professional, regardless of specialty, as their primary clinician. Under this proposal, a beneficiary may select a practitioner with any specialty designation (e.g., a specialty of allergy/immunology or surgery), as their primary care provider and be eligible for assignment to the ACO in which the practitioner is an ACO professional. A voluntary identification by a

Revisions to Policies on Voluntary Alignment: *CMS finalized its proposed revisions to the voluntary alignment methodology at §425.402(e)(2) without modification. Specifically, it finalized the following policies:*

- *To assign a beneficiary to an ACO based upon their selection of any ACO professional, regardless of specialty, as their primary clinician.*
- *To remove the requirement that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in §425.402(c) within the 12-month assignment window in order to be assigned to the ACO.*
- *Not to voluntarily align a beneficiary to an ACO when the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services* ([p. 1710](#)).

CMS disagreed with concerns about allowing beneficiaries to select specialists as their primary provider and whether specialists would be willing to take on the role of a primary care physician and manage the overall care of the beneficiary. CMS believes that all practitioners, regardless of specialty, play an important role in coordinating care for beneficiaries.

CMS understands concerns about an ACO's potential inability to maintain an assigned population of 5,000 beneficiaries if beneficiaries are able to voluntarily align with another ACO, but notes that experience to date shows that the majority of beneficiaries who voluntarily align to an ACO would have been assigned to the same ACO via CMS' two-step claims-based assignment methodology under §425.402(b).

CMS also believes requiring beneficiaries to renew their primary clinician selection would create additional unnecessary burden on beneficiaries.

Other commenters expressed concern that physicians with a specialty designation not used in assignment would become subject to the exclusivity requirements (i.e., would be required to be exclusive to a single MSSP ACO) in the event that a beneficiary voluntarily aligns to a practitioner billing under the TIN of that ACO participant. CMS agrees with these concerns and clarifies the operational process it will implement if a beneficiary designates a clinician billing under the

Medicare FFS beneficiary under this provision supersedes any claims-based assignment otherwise determined by the Secretary.

The current policy at §425.402(e)(2)(iv) also provides that a beneficiary will not be assigned to an ACO for a performance year if the beneficiary has designated a required provider or supplier type outside the ACO as their primary clinician responsible for coordinating their overall care. Consistent with the changes discussed above, CMS proposes to revise §425.402(e)(2)(iv) to indicate that if a beneficiary designates any provider or supplier outside the ACO as their primary clinician responsible for coordinating their overall care, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year.

Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, also requires the Secretary to allow a beneficiary to voluntarily align with an ACO, and does not impose any restriction with respect to whether the beneficiary has received any services from an ACO professional. As such, CMS proposes to remove the requirement at §425.402(e)(2)(i) that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in §425.402(c) within the 12-month assignment window in order to be assigned to the ACO. Under this proposal, a beneficiary who selects a primary clinician who is an ACO professional, but who does not receive any services from an ACO participant during the assignment window, will remain eligible for assignment to the ACO.

Because a beneficiary who has voluntarily identified a MSSP ACO professional as their primary care provider will remain assigned to the ACO regardless of where they seek care, this proposed change could also impact assignment under certain Innovation Center models in which overlapping beneficiary assignment is not permitted. CMS believes it would be appropriate, in limited circumstances, to align a beneficiary to an entity participating in certain specialty and disease-specific Innovation Center models, such as the Comprehensive ESRD Care (CEC) Model, since the beneficiary could benefit from the focused attention and increased care coordination. Thus, CMS proposes to create an exception to the general policy that a beneficiary who has voluntarily identified a MSSP ACO professional as their primary care provider will remain assigned to the ACO regardless of where they seek care. Specifically, CMS would not assign such a beneficiary to the ACO when the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded

TIN of an ACO participant that participates in more than MSSP ACO (as permitted under certain circumstances under §425.306(b)) as their primary clinician. ACO participants that do not bill for services that are considered in assignment will not be required to be exclusive to a single MSSP ACO as a result of the changes to the voluntary alignment methodology. In the circumstance where a beneficiary aligns with a clinician billing under an ACO participant TIN that is participating in more than one MSSP ACO, CMS will determine where the beneficiary received the plurality of their primary care services under its claims-based assignment methodology under §425.402(b). If the beneficiary did not receive the plurality of their primary care services from ACO professionals in either ACO, CMS will not assign the beneficiary to either of the ACOs. However, consistent with §425.402(c)(2)(iv), CMS will honor the beneficiary's selection of a primary clinician and will not align the beneficiary to another ACO in which their primary clinician is not participating.

under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by the Secretary that a waiver under section 1115A(d)(1) of the Act of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model. In these instances, the Innovation Center would notify the beneficiary of their alignment to an entity participating in the model. Although such a beneficiary may still voluntarily identify his or her primary clinician and may seek care from any clinician, the beneficiary would not be assigned to a MSSP ACO even if the designated primary clinician is an ACO professional in a MSSP ACO.

CMS proposes to apply these modifications to its policies under the MSSP regarding voluntary alignment beginning for performance years starting on January 1, 2019, and subsequent performance years.

Revisions to the Definition of Primary Care Services used in Beneficiary Assignment: Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician and all services furnished by RHCs and FQHCs. However, the statute does not specify which kinds of services may be considered primary care services for purposes of beneficiary assignment. CMS established the initial list of services that it considered to be primary care services in the November 2011 final rule (76 FR 67853). CMS updated the list of primary care service codes in subsequent rulemaking to reflect additions or modifications to the codes that have been recognized for payment under the Medicare PFS, as summarized in the CY 2018 PFS proposed rule (82 FR 34109 and 34110). These additions are effective for purposes of performing beneficiary assignment under §425.402 for performance year 2019 and subsequent performance years.

General Revisions

Based on feedback from ACOs and further review of the HCPCS and CPT codes currently recognized for payment under the PFS, CMS proposes to revise the definition of primary care services in §425.400(c) used in assigning beneficiaries to ACOs to reflect the following recent code changes:

1. Advance care planning service codes: CPT codes 99497 and 99498;

Revisions to the Definition of Primary Care Services used in Beneficiary Assignment:

General Revisions

CMS finalized its proposed revisions to the definition of primary care services, with the exception of the proposal to include the three add-on HCPCS codes GPC1X, GCG0X, and GPRO1 since the proposal to create these three new codes was part of the broader proposal to simplify documentation requirements and more accurately pay for office or other outpatient E/M services, which was not finalized in this rule. Specifically, CMS is revising the definition of primary care services in §425.400(c) to add CPT codes 99497, 99498, 96160, 96161, 99354, and 99355, and HCPCS codes G0444, G0442, and G0443 (p. 1725).

2. Administration of health risk assessment service codes: CPT codes 96160 and 96161;
3. Prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure: CPT codes 99354 and 99355;
4. Annual depression screening service code: HCPCS code G0444;
5. Alcohol misuse screening service code: HCPCS code G0442; and
6. Alcohol misuse counseling service code: HCPCS code G0443.

In addition, in the CY 2019 PFS proposed rule (see 83 FR 35841 through 35844), CMS proposes to create three new HCPCS codes to reflect the additional resources involved in furnishing certain evaluation and management services:

1. GPC1X add-on code, for the visit complexity inherent to evaluation and management associated with certain primary care service;
2. GCG0X add-on code, for visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care; and
3. GPRO1, an additional add-on code for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure.

Revisions to Services Furnished in a SNF

CMS also proposes to revise how it determines whether services identified by CPT codes 99304 through 99318 were furnished in a SNF (83 FR 41897 through 41899). CMS currently identifies services billed under CPT codes 99304 through 99318 furnished in a SNF by using the POS modifier 31. CMS continues to believe it is appropriate to exclude from assignment services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF. However, to increase the accuracy of beneficiary assignment for these vulnerable and generally high cost beneficiaries, CMS proposes to revise its method for determining whether services identified by CPT codes 99304 through 99318 were furnished in a SNF to focus on whether the beneficiary also received SNF facility services on the same day. CMS believes it would be feasible to directly and more precisely determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF by analyzing its facility claims data files rather than by using the POS modifier 31 in its professional claims data files. Thus, CMS would exclude professional services claims billed under CPT

Additional information about the HCPCS and CPT codes that CMS proposed to add to the definition of primary care services starts on [p. 1715](#).

A discussion of comments received on the new codes CMS proposed to add to the definition of primary care services for purposes of MSSP ACO beneficiary assignment begins on [p. 1721](#).

Revisions to Services Furnished in a SNF

CMS finalized, as proposed, the revisions to its method for excluding services identified by CPT codes 99304 through 99318 when furnished in a SNF and the proposed technical changes to §425.400(c)(1)(iv) ([p. 1725](#)).

codes 99304 through 99318 from use in the ACO assignment methodology when there is a SNF facility claim in the claims files with dates of service that overlap with the date of service for the professional service. To reflect this, CMS proposes to revise the regulation at §425.400(c)(1)(iv)(A)(2), effective for performance years starting on January 1, 2019 and subsequent performance years, to remove the exclusion of claims including the POS code 31 and in its place to indicate more generally that it will exclude services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF.

Behavioral Health Integration Code Updates

Effective for CY 2018, the HCPCS codes for behavioral health integration G0502, G0503, G0504 and G0507 have been replaced by CPT codes 99492, 99493, 99494 and 99484. Therefore, CMS proposes to revise the primary care service codes in §425.400(c)(1)(iv) to reflect these updates for performance years starting on January 1, 2019, and subsequent performance years.

Extreme and Uncontrollable Circumstances Policies for the Shared Savings Program:

Modification of Quality Performance Scores for all ACOs in Affected Areas
CMS proposes to extend policies recently adopted for ACOs impacted by extreme and uncontrollable circumstances during 2017 to 2018 and subsequent performance years.

Behavioral Health Integration Code Updates

CMS finalized these changes as proposed ([p. 2149](#)).

Extreme and Uncontrollable Circumstances Policies for the Shared Savings Program:

Modification of Quality Performance Scores for all ACOs in Affected Areas

CMS finalized its proposals to extend the policies for determining the quality scores for ACOs affected by extreme and uncontrollable circumstances established for performance year 2017 to performance year 2018 and subsequent performance years ([p. 1746](#)).

Specifically, CMS is revising §§425.502(e) and 425.502(f) to state that for performance year 2018 and subsequent performance years, including the applicable quality data reporting period for the performance year if the reporting period is not extended, in the event that CMS determine that 20 percent or more of an ACO's assigned beneficiaries, as determined using the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the QPP, or that the ACO's legal entity is located in such an area, CMS will use the following approach to calculate the ACO's quality performance score:

- The ACO's minimum quality score will be set to equal the mean quality performance score for all MSSP ACOs for the applicable performance year.
- If the ACO is able to completely and accurately report all quality measures, CMS will use the higher of the ACO's quality performance score or the mean quality performance score for all MSSP ACOs. If the ACO's quality performance score is used, the ACO will also be eligible for quality improvement points.

- If the ACO receives the mean MSSP quality performance score, the ACO will not be eligible for bonus points awarded based on quality improvement during the applicable performance year.
- If an ACO receives the mean MSSP ACO quality performance score for a performance year, in the next performance year for which the ACO reports quality data and receives a quality performance score based on its own performance, CMS will measure quality improvement based on a comparison between the ACO's performance in that year and in the most recently available prior performance year in which the ACO reported quality.

If an ACO reports quality data in a year in which it is affected by an extreme and uncontrollable circumstance, but receives the national mean quality score, CMS will use the ACO's own quality performance score to determine quality improvement bonus points in the following year. For example, if an ACO reported quality data in years 1, 2, and 3 of an agreement period, but received the national mean quality score in year 2 as the result of an extreme or uncontrollable circumstance, CMS would determine quality improvement bonus points for year 3 by comparing the ACO's year 3 quality score with its year 2 score. If the ACO received the mean score in year 2 because it did not report quality, CMS would compare year 3 with year 1 to determine the bonus points for year 3.

In regards to the interaction between this alternative quality scoring methodology and MIPS, CMS clarifies that the MIPS quality performance category is reweighted to zero if a disaster-affected ACO receives the mean quality score under the MSSP's extreme and uncontrollable circumstance policy, because it did not or could not report quality data at the ACO (APM Entity) level, regardless of whether or not any of the ACOs participant TINs reported quality outside the ACO. This reweighting under MIPS results in MIPS performance category weighting of 75 percent for the PI performance category and 25 percent for IA performance category. If, for any reason, the PI performance category also is reweighted to zero, which could be more likely when there is a disaster, there would be only one performance category triggering the policy under which the ACO would receive a neutral (threshold) MIPS score, as per §414.1380(c) (see discussion at 83 FR 53778). If any of the ACO's participant TINs do report PI, then the TIN or TINs' PI performance category scores will be used to score the ACO under the MIPS scoring standard, the PI performance category will not be reweighted, and the policy to assign a neutral (threshold) MIPS score will not be triggered.

Mitigating Shared Losses for ACOs Participating in a Performance-based Risk Track

Mitigating Shared Losses for ACOs Participating in a Performance-based Risk Track

CMS proposes to extend its policy for mitigating shared losses owed by ACOs affected by extreme and uncontrollable circumstances established for performance year 2017 to performance year 2018 and subsequent performance years.

CMS explains that these proposals would not change the status of those payment models that meet the criteria to be Advanced APMs under the QPP. These policies would reduce the amount of shared losses owed by ACOs affected by a disaster, but the overall financial risk under the payment model would not change and participating ACOs would still remain at risk for an amount of shared losses in excess of the Advanced APM generally applicable nominal amount standard. Additionally, these policies would not prevent an eligible clinician from satisfying the requirements to become a QP for purposes of the APM Incentive Payment (available for payment years through 2024) or higher physician fee schedule updates (for payment years beginning in 2026) under the QPP.

Determination of Historical Benchmarks for ACOs in Affected Areas

In considering whether it might be necessary to make an additional adjustment to ACOs' historical benchmarks to account for expenditure variations related to extreme and uncontrollable circumstances, CMS considered an approach where it would adjust the historical benchmark by reducing the weight of expenditures for beneficiaries who resided in a disaster area during a disaster period and placing a correspondingly larger weight on expenditures for beneficiaries residing outside the disaster area during the disaster period (83 FR 41905).

Program Data and Quality Measures: CMS also solicits comment on considerations related to supporting ACOs' activities to address the national opioid crisis and the agency's meaningful measures initiative. In particular, CMS seeks suggestions for other types of aggregate data related to opioid use that could be added for informational purposes to the aggregate quarterly and annual reports CMS provides to ACOs. The aim would be for ACOs to utilize this additional information to improve population health management for assigned beneficiaries, including prevention, identifying anomalies, and coordinating care. CMS also seeks comment on measures related to various aspects of opioid use, such as prevention, pain management, or opioid use disorder treatment, and on

CMS finalized this revision as proposed. It is revising §§425.606(i) and 425.610(i) to indicate that it will reduce the amount of shared losses calculated for the performance year by an amount determined by multiplying (1) the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance; and (2) the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance. CMS also finalized its proposal to adjust shared losses for ACOs with a 6-month performance year from January 1, 2019 through June 30, 2019. In these instances, CMS will first determine shared losses for the ACO over the full calendar year, reduce the ACO's shared losses for the calendar year for extreme and uncontrollable circumstances, and then determine the portion of shared losses for the 6-month performance year ([p. 1757](#)).

Determination of Historical Benchmarks for ACOs in Affected Areas

After considering comments on the determination of historical benchmarks for ACOs in areas affected by extreme and uncontrollable circumstances, CMS is not making any changes to the benchmarking methodology to address such events at this time. CMS will continue to monitor the impact of extreme and uncontrollable circumstances on benchmark expenditures and, if applicable, the extent to which any impact is mitigated by the use of regional factors in establishing and updating the benchmark. If warranted, it will propose additional modifications to its benchmarking methodology to address the effects of extreme and uncontrollable circumstances through future notice and comment rulemaking ([p. 1765](#)).

Program Data and Quality Measures: CMS thanks the public for its feedback on this topic. As it plans for future updates and changes to the MSSP quality measure set, it will consider this feedback before making any proposals with respect to the addition of opioid use measures.

A discussion of CMS' considerations begins on [p. 1766](#).

A summary of comments received on this topic begins on [p. 1773](#).

measures related to addiction. In particular, it is considering the following NQF-endorsed measures, with emphasis on Medicare beneficiaries with Part D coverage who are 18 years or older without cancer or enrolled in hospice:

- NQF #2940 Use of Opioids at High Dosage in Persons Without Cancer
- NQF #2950 Use of Opioids from Multiple Providers in Persons Without Cancer
- NQF #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer

Promoting Interoperability: CMS proposes to discontinue use of the quality performance measure that assesses the level of adoption of CEHRT by the eligible clinicians in an ACO (ACO-11: Use of Certified EHR Technology) and proposes instead that ACOs be required to certify upon application to participate in the MSSP and annually thereafter that the percentage of eligible clinicians participating in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds certain thresholds.

In the CY 2017 Quality Payment Program final rule (81 FR 77408), CMS finalized that an Advanced APM is an APM that, among other criteria, requires its participants to use CEHRT. CMS further established that Advanced APMs meet this requirement if the APM either:

1. Requires at least 50 percent of eligible clinicians in each participating APM Entity, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or other health care providers; or
2. For the MSSP, applies a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity.

In the August 2018 MSSP proposed rule, CMS proposes to add a requirement that all ACOs demonstrate a specified level of CEHRT use in order to be eligible to participate in the MSSP.

ACOs in a MSSP Track that Does Not Meet the Financial Risk Standard to be an Advanced APM

For performance years starting on January 1, 2019, and subsequent year, these ACOs would be required to certify at the time of application to participate in the MSSP and annually thereafter that at least 50 percent of

Promoting Interoperability: *Based on comments received and CMS' desire to align with the QPP, under which eligible clinicians must certify regarding their CEHRT use by the last day of the reporting period, CMS is not finalizing its proposal to require ACOs to certify at the time of application that they meet the applicable CEHRT requirements. However, it finalized its proposal to require ACOs to certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage during the current performance year ([p. 1792](#)).*

CMS also finalized its proposal to remove ACO-11: Use of Certified EHR Technology measure from the MSSP quality measure set, effective with quality reporting for performance years starting on January 1, 2019, and subsequent performance years ([p. 1799](#)).

ACOs in a MSSP Track that Does Not Meet the Financial Risk Standard to be an Advanced APM

CMS finalized with modification its proposal. As noted above, CMS finalized the requirement that ACOs make this certification annually in the form and manner specified by CMS, but CMS is not finalizing its proposal to require ACOs to make this certification at the time of application. Accordingly, for performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track

the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers.

CMS clarifies that this policy, if finalized, would not affect the previously finalized requirements for MIPS eligible clinicians reporting on the Promoting Interoperability performance category under MIPS. MIPS eligible clinicians who are participating in ACOs under a payment track that is not an Advanced APM and/or who are not QPs would continue to report as usual on the Promoting Interoperability performance category.

ACOs in Tracks that Meet the Financial Risk Standard to be an Advanced APM

CMS proposes to align the CEHRT use threshold with the criterion on use of CEHRT established for Advanced APMs under the QPP. Specifically, for performance years starting on January 1, 2019, and subsequent performance years, CMS proposes that these ACOs would be required to certify at the time of application and annually thereafter that they meet the higher of the 50 percent threshold proposed for ACOs in a track that does not meet the financial risk to be an advanced APM or the CEHRT use criterion for Advanced APMs under the QPP at §414.1415(a)(1)(i). This proposal would ensure alignment of eligibility requirements across all MSSP ACOs, while also ensuring that if the CEHRT use criterion for Advanced APMs were higher than 50 percent, those MSSP tracks that meet the financial risk standard to be an Advanced APM would also meet the CEHRT threshold established under the QPP. CMS anticipates that for performance years starting on January 1, 2019, the tracks that would be required to meet the CEHRT threshold designated at §414.1415(a)(1)(i) would include Track 2, Track 3, and the Track 1+ Model, and for performance years starting on July 1, 2019, would include the proposed BASIC track, Level E, and the proposed ENHANCED track.

that does not meet the financial risk standard to be an Advanced APM must certify annually that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers (p. 1797).

ACOs in MSSP Tracks that Meet the Financial Risk Standard to be an Advanced APM

CMS also finalized with modification its proposal with respect to ACOs in MSSP tracks that meet the financial risk standard to be an Advanced APM.

- To minimize complexity, CMS did not finalize the requirement that ACOs certify that they meet the higher of the 50 percent threshold or the applicable threshold under the QPP. Rather, ACOs will be required to certify only that they meet the applicable threshold established under the QPP at §414.1415(a)(1)(i).
- CMS also is not finalizing its proposal that ACOs certify that they meet the CEHRT requirement at the time of application.

For performance years starting on January 1, 2019, and subsequent years, ACOs in a track that meets the financial risk standard to be an Advanced APM must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under the QPP (p. 1793, 1798).

Note that earlier in this rule, CMS finalized changes to the CEHRT use requirement for APMS to meet criteria for designation as Advanced APMs under the QPP. For QP Performance Periods beginning in 2019, 75 percent of eligible clinicians in each participating APM Entity group, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or health care providers.

CMS also finalized in this section:

- Proposed changes to the regulation at §425.302(a)(3)(iii) to establish the new annual certification requirement.
- Proposed amendments to §425.20 to incorporate a definition of “CEHRT” consistent with the definition at §414.1305, including any subsequent updates or revisions to that definition, and to incorporate the definition of “eligible clinician” at §414.1305 that applies under the QPP.

Applicability of
Final Policies to
Track 1+ Model
ACOs

In this section of the August 2018 proposed rule, CMS discusses the applicability of proposed policies to Track 1+ Model ACOs. Unless stated otherwise in the Track 1+ Model Participation Agreement, the requirements of the MSSP under 42 CFR part 425 continue to apply.

55 Shared Savings Program Track 1 ACOs entered into the Track 1+ Model beginning on January 1, 2018. Since CMS is not offering an application cycle for a January 1, 2019 start date for new agreement periods under the MSSP, it is similarly not offering a start date of January 1, 2019, for participation in the Track 1+ Model. However, existing Track 1+ Model ACOs would be able to complete the remainder of their current agreement period in the model. ACOs that entered the Track 1+ Model beginning in 2018 will complete their participation in the Track 1+ Model by no later than December 31, 2020.

In the August 2018 proposed rule (83 FR 41913 through 41914), CMS provides a comprehensive discussion of the applicability of the proposed policies to Track 1+ Model ACOs to allow these ACOs to better prepare for their future years of participation in the program and the Track 1+ Model.

- Its proposed amendment to the separate MSSP CEHRT use criterion at §414.1415(a)(1)(ii) so that it applies only for QP Performance Periods under the QPP prior to 2019.

Unless specified otherwise, the changes to the program's regulations finalized in the 2019 PFS final rule that are applicable to MSSP ACOs within a current agreement period will apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 1, so long as the applicable regulation has not been waived under the Track 1+ Model. Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or Track 3 have been incorporated for ACOs in the Track 1+ Model under the terms of the Track 1+ Model Participation Agreement, changes to the regulations as finalized in this final rule will also apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 2 or Track 3. For example, the following policies apply to Track 1+ Model ACOs:

- Revisions to voluntary alignment policies applicable for the performance year beginning on January 1, 2019, and subsequent performance years.
- Revisions to the definition of primary care services used in beneficiary assignment, applicable for the performance year beginning on January 1, 2019, and subsequent performance years.
- Discontinuation of quality measure ACO-11; requirement to attest as part of the annual certification that a specified percentage of the ACO's eligible clinicians use CEHRT, applicable for the performance year beginning on January 1, 2019, and subsequent performance years.

CMS will also apply the following policies finalized in this final rule to Track 1+ Model ACOs through an amendment to the Track 1+ Model Participation Agreement executed by CMS and the ACO:

- Annual certification that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under §414.1415(a)(1)(i). This certification is required to ensure the Track 1+ Model continues to meet the CEHRT criterion to qualify as an Advanced APM for purposes of the QPP.
- Extreme and uncontrollable circumstances policies for determining shared losses for performance years 2018 and subsequent years, consistent with the policies specified in §425.610(i).
- Other policies related to the voluntary 6-month extension, described on [p. 1804](#).