healthcare financial management association

# Medicare Physician Fee Schedule Final Rule for 2019 Summary Part II

Medicare Program: Quality Payment Program

[CMS-1693-F, CMS-1693-IFC, CMS-5522-F3, and CMS-1701-F]

On November 1, 2018, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule relating to the Medicare physician fee schedule (PFS) for CY 2019<sup>1</sup> the Quality Payment Program (QPP) and other policies. It is scheduled to be published in the November 23, 2018 issue of the *Federal Register*. Unless otherwise noted, the policies in the final rule take effect on January 1, 2019.<sup>2</sup>

**Due to the length of this final rule, HPA is providing a summary in three parts.** Part I covers sections I through III.H of the final rule, including payment policies under the PFS, Medicare Shared Savings Program requirements, the Medicaid Promoting Interoperability Program, and expanding use of telehealth services for treatment of opioid use disorder under the SUPPORT Act. Part II will primarily cover the QPP and Part III will cover the Provisions from the Medicare Shared Savings Program – Accountable Care Organizations – Pathways to Success.

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#### III. Other Provisions of the Final Rule

## I. 2019 Updates to the Quality Payment Program (QPP)

## 1. Executive Summary

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

For 2019, the third year of the QPP, CMS discusses how its finalizes proposals address stakeholder input (including MedPAC) and are designed to reduce clinician burden, revise the MIPS Promoting Interoperability (formerly known as Advancing Care Information) performance category, and continue to support small and rural practices. CMS believes the Meaningful

<sup>&</sup>lt;sup>1</sup>Henceforth in this document, a year is a calendar year unless otherwise indicated.

<sup>&</sup>lt;sup>2</sup> For items finalized with comment, the 60-day comment period ends at the close of business on December 31,2018.

Measures Initiative will produce quality measures that are more focused on meaningful outcomes.<sup>3</sup> For the 2019 MIPS performance period, CMS finalizes adding 8 new MIPS quality measures, including 4 patient reported outcome (PRO) measures, and removing 26 quality measures. CMS finalizes modified performance category weights for the 2021 payment year. Table 53, reproduced below, shows the previously weights for the transition year and 2020 payment along with the weights for the 2021 payment.

TABLE 53: Finalized Weights by MIPS Performance Category and MIPS Payment Year

<b>Performance Category</b>	Transition Year	2020 MIPS Payment Year	2021 MIPS Payment Year
Quality	60%	50%	45%
Cost	0%	10%	15%
Improvement Activities	15%	15%	15%
Promoting Interoperability	25%	25%	25%

CMS finalizes several changes to the criteria for an APM to be considered an Advanced APM and analogous changes are finalized for Other Payer Advanced APMs. The increased CEHRT usage level will also be required for clinicians in the Advanced APM tracks of the Shared Savings Program. Details are finalized for the only Other Payer Advanced APM payer category whose processes for requesting Advanced APM determinations had not yet been finalized (Remaining Other Payers – this includes commercial payers). These determinations may be renewed annually for up to 5 years through a streamlined certification process; clinician QP status determinations continue to be for one year only. CMS finalizes an option for QP status to be determined at the TIN level as well as the individual and APM Entity levels for clinicians being assessed under the All-Payer Combination Option.

## Payment Adjustments

CMS updated its analysis form the proposed rule to include data submitted for the 2017 MIPS performance period (QPP Year 1 data).

For the 2019 MIPS performance period, CMS includes approximately 1.5 million clinicians who had physician fee schedule (PFS) claims from September 1, 2016 to August 31, 2017 and included a 30-day run-out. Of this group, CMS estimates that approximately 798,000 clinicians (54%) will be MIPS eligible clinicians. For the 2021 MIPS payment year, including the statutory requirement for budget neutrality, CMS estimates that payment adjustments will be equally distributed between negative payment adjustments at \$390 million and positive payment adjustments at \$390 million. Positive payment adjustment will also include an additional \$500 million for exceptional performance to MIPS eligible clinicians who have a final score that meets or exceeds the finalizes additional performance threshold of 75 points.

CMS estimates that between 165,000 and 220,000 clinicians will be Qualifying APM Participants (QP) and the total lump sum APM incentive payment for QPs will be approximately \$600-800 million for the 2021 MIPS payment year. A QP is an eligible clinician that is exempt from the MIPS reporting requirements and payment adjustment, and qualifies for a lump sum

<sup>&</sup>lt;sup>3</sup>Meaningful Measures web page: <a href="https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo?MMF/General-info-Sub.Page.html">https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo?MMF/General-info-Sub.Page.html</a>

incentive payment based on 5 percent of their aggregate payment amounts for covered professional services for the prior year.

## 2. Program Details

## a. Definition of a MIPS Eligible Clinician

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

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

- To define a MIPS eligible clinician as a physician (as defined in section 1861(r)<sup>4</sup> of the Act), a physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS) (as such terms are defined in section 1861(aa)(5) of the Act), a certified registered nurse anesthetist (CRNA) (as defined in section 1861(bb)(2) of the Act), and a group that includes such clinicians.
- To exclude Qualifying APM Participants (QPs), Partial Qualifying APM participants (Partial QPs) who choose not to report data under MIPS, low-volume threshold eligible clinicians, and new Medicare-enrolled eligible clinicians (as defined at §414.1305) from the definition of a MIPS eligible clinician per the statutory exclusions.

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

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

Alternatively, CMS proposed to include additional eligible clinician types (specifically, qualified speech-language pathologist, qualified audiologist, certified nurse-midwives, and registered dietitians or nutritional professionals), provided each applicable eligible clinician type would have at least 6 MIPS quality measures.

Many commenters supported the proposal to expand the definition of MIPS eligible clinicians to include physical therapists, occupational therapists, clinical social workers and clinical

<sup>&</sup>lt;sup>4</sup> Physicians are defined in section 1861(r) of the Act to include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors.

psychologists. Other commenters specifically requested the addition of qualified audiologist and qualified speech-language pathologists; one commenter requested the addition of registered dietitians. A few commenters requested that clinical social workers not be included in MIPS and noted there were only four quality measures appropriate for use by social workers. CMS agrees with these requests to be included in MIPS. CMS also agrees that clinical social workers may not have six applicable quality measures and supports the request not to be included in MIPS. CMS encourages clinical social workers to create an applicable specialty measure set during the solicitation process. In response to commenters requesting nurse navigators, oncology staff nurses, and clinical pharmacists be considered as MIPS eligible clinicians, CMS notes it does not have the discretion under the statute to include clinicians other than those specified in section 1848(q)(1)(C)(II) of the Act.

In response to commenters requesting "ramp-up" policies for clinicians joining MIPS after the first year, CMS notes that the MIPS program is still ramping up and will continue to have a gradual and incremental transition until the sixth year of the QPP. Additional eligible clinicians joining with the 2019 performance year will have 4 years in the program before ramping up is completed. In response to concerns that these new clinician types would be able to participate in the Promoting Interoperability (PI), as discussed below in Section III.I.2.(5)(f), the PI measure discussion, CMS finalizes its proposal to automatically assign a zero percent weighting for the PI performance category for these new clinicians. In response to comments requesting clarification about how new clinicians billing under a hospital- or facility based TIN without their rendering NPI on the hospital claim (UB-04) would be included in MIPS, CMS notes that these additional clinicians will be defined as MIPS eligible clinicians and be subject to the same requirements as other MIPS eligible clinicians billing under a hospital- or facility-based TIN. CMS acknowledges that facility-based outpatient therapy and skilled nursing facility claims do not contain the rendering NPI and usually contain just a facility NPI and therefore, these claims will not be eligible for MIPS. Medicare B allowed charges that CMS can associate with a MIPS eligible clinician at an NPI level will be included for purposes of applying any MIPS payment adjustment. CMS notes it intends to provide clinicians with their eligibility status prior to the performance period through the QPP portal eligibility determination tool.

CMS disagrees with commenters' suggestions that there is misalignment between the proposed list of eligible clinicians for MIPS and the scope of clinician types for the Advanced APM pathway under the QPP. CMS states that the proposed expansion of clinician types actually aligns with the current scope of eligible clinicians under Advanced APMs and notes that each APM offers participation opportunities for a broad scope of eligible clinicians. CMS invites ideas on how to further engage the full scope of eligible clinicians as it works to develop more APM opportunities.

After consideration of comments, CMS finalizes a modification of its proposal to amend §414.1305 to revise the definition of a MIPS eligible clinician as identified by a unique billing TIN and NPI used to asses performance, to include beginning with the 2021 MIPS payment year the following additional clinician types:

- Physical therapist,
- Occupational therapist,
- Clinical psychologist (as defined by section 1861)(ii) of the Act, and

• A group that includes such clinicians.

#### **b.** MIPS Determination Period

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

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

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

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

CMS finalizes its proposal that the determination based on the initial segment period will continue to be used as the determination for the applicable MIPS payment year regardless of the determination based on the second segment. For example, for the 2021 MIPS payment year, the first segment will be October 1, 2017 through September 30, 2018 and the second segment will be October 1, 2018 through September 30, 2019. If a clinician meets the low-volume threshold criteria in the first segment but not the second segment, the clinician will still be considered to have met the low-volume threshold criteria. CMS believes that some eligible clinicians whose TIN or TIN/NPIs are identified as eligible during the first segment do not exist in the second segment because they are no longer utilizing the same TIN or TIN/NPI combination. In this example, CMS states that this clinician will not be eligible to participate in MIPS based on either segment of the determination period because the TIN that was assess for the first segment of the determination no longer exists. However, if a TIN or TIN/NPI did not exist in the first segment but does exist in the second segment, eligible clinicians could be eligible for MIPS.

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

Several commenters supported this proposal and stated that it was important for the clinician to know their eligibility status before the start of the performance period. CMS understands and intends to provide eligibility determinations as close to the beginning of the performance period as feasible. CMS also agrees with comments that the quarterly snaps may provide useful information and is working to provide the quarterly snapshots, if feasible.

Several commenters did not support the proposed 24-month MIPS determination period and recommended a single, 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. CMS responds that a single eligible determination period would not identify eligible clinicians who switch practices between the first and second segments of the MIPS determination period. CMS estimates that approximately 13 percent of eligible clinicians may switch practices between the first and second determination periods and the second segment accounts for the identification of additional, previously unidentified eligible clinicians who do not exceed the low-volume threshold or meet other special circumstances.

#### c. Low-Volume Threshold

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

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

As enacted in 2015, MIPS payments apply to payments for Medicare Part B "items and services" furnished on or after January 1, 2019. Effective for MIPS performance periods beginning on or after January 1, 2018, MIPS payments apply to "covered professional services" as that term was applied under the Physician Quality Reporting System (PQRS).<sup>5</sup>

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

<sup>&</sup>lt;sup>5</sup> The elimination of the term "items" from MIPS payment calculations allows the Secretary to implement this provision by eliminating Part B drugs from these calculations since Part B drugs were not included as covered professional services under PQRS.

Amendments to Comply with the BBA of 2018

For the 2018 MIPS performance year, CMS finalizes its proposal to amend (§414.1305) to modify the definition of low-volume threshold to mean:

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

#### MIPS Program Details

CMS finalizes its proposal to modify the following:

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

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

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

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

In response to commenters opposed to the low-volume threshold because the thresholds are too high and exclude too many clinicians, CMS believes the proposed low-threshold provides the right balance between including a sufficient number of clinicians, while excluding those who are not quite ready to participate, such as clinicians in small and rural practices. CMS thinks the addition of the third criterion in conjunction with the opt-in policy (discussed in the following section), will increase clinician participation in MIPS.

Many commenters thought the proposed low-volume threshold limits the number of clinicians in MIPS and because the MIPS payment adjustment is budget neutral, the threshold limits the payment adjustment that MIPS eligible clinicians with good performance can achieve. In

response, CMS provides analysis from the 2017 MIPS performance period showing that less than 1 percent of total PFS dollars that could be included in the 2021 MIPS payment year were associated with clinicians who did not meet the low-volume threshold. CMS notes that the majority of clinicians excluded from MIPS because of the low-volume threshold are clinicians in small practices with fewer than 15 clinicians. Figure 1 in the final rule shows the redistribution and maximum payment adjustment for different low-volume thresholds.

In response to a comment, CMS clarifies that allowed charges refers to the maximum amount Medicare will pay for a covered professional service under the PFS, which is the fee schedule amount reduced by the applicable beneficiary co-payment. For purposes of the MIPS low-volume threshold, allowed charges are calculated before any Multiple Procedure Payment Reduction is applied (82 FR 52578 through 53579).

#### Low-Volume Threshold Opt-in

Beginning with the 2019 MIPS performance year, CMS finalizes its proposal that if an eligible clinician or group meets or exceeds one or two, but not all of the finalized low-volume threshold determinations, then these eligible individuals or groups may choose to opt-in to MIPS.

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

CMS finalizes that applicable eligible clinicians and groups would be required to make a definitive choice to opt-in by making an election via the QPP by logging into their account and selecting either the option to opt-in (and receive a MIPS adjustment) or remain excluded from MIPS and voluntarily report (no MIPS adjustment). If the decision is not to participate, then no action would be required. The decision to opt-in to MIPS would be irrevocable and could not be changed for the applicable performance period.

The low-volume threshold opt-in option also applies to virtual groups. CMS finalizes its proposal that a virtual group election will constitute a low-volume threshold opt-in for any prospective member of the virtual group (solo practitioner or group) that exceeds at least one, but not all, of the low-volume threshold criteria. Solo practitioners and groups opting-in to participate in MIPS as part of a virtual group will not need to independently make a separate election to opt-in because being identified as a TIN in a submitted virtual group election signifies an election to participate in MIPS as part of a virtual group.

CMS also finalizes its proposal that APM Entities in MIPS APMS, which meet one or two, but not all of the low-volume threshold elements will be required to make a definitive choice at the APM Entity level to participate in MIPS. The APM entities will make an election to opt-in via a similar process that individual eligible clinicians and groups use to make an election to opt-in. CMS notes that APM Entities in MIPS APMs that do not decide to opt-in to MIPS cannot voluntarily report. CMS also finalizes for applicable eligible clinicians participating in a MIPS APM, whose APM does not decide to opt-in to MIPS, the eligible clinician is still excluded from

MIPS even though the eligible clinician is part of a TIN or virtual group. Because the low-volume threshold determinations are currently conducted at the APM Entity level for all applicable eligible clinicians in MIPS APMS, CMS believes the low-volume threshold opt-in option should similarly be determined at the APM Entity level and not at the individual eligible clinician, TIN, or virtual group level.

Many commenters supported the opt-in policy. In response to comments, CMS notes that if an eligible clinician chooses to opt-in to MIPS they will be subject to the MIPS payment adjustment (positive, negative or neutral) during the applicable MIPS payment year. If a clinician is eligible to opt-in but does not want to participate in MIPS, and not be subject to the MIPS payment adjustment, the clinician could voluntarily report.

Many commenters also opposed the opt-in policy; some expressed concerns that the additional clinicians will be high performers and reduce the MIPS payment adjustment for eligible clinicians who are required to participate. CMS discusses the analysis it did using different assumptions to model the impact of the opt-in policy, including assumptions that no clinicians opt-in, a random 33% of clinicians opt-in or only high performers opt-in. Based on this analysis, CMS found the opt-in policy would have a small impact on the budget neutral pool when it assumed a random 33% of clinicians' opt-in and a minimal impact on payment adjustment when the other assumptions were used (Figure 2 in the final rule). Given this very modest impact to the payment adjustments, CMS does not believe the opt-in policy will reduce incentives for MIPS participation. As discussed in greater detail in the Regulatory Impact Analysis in this final rule, CMS uses the 33% opt-in assumption for all 2019 performance estimates.

In response to comments about the process to opt-in, CMS plans to create a process that is least burdensome but also provides clinicians with the most flexibility. It is working to see if it can operationally allow clinicians to opt-in at any time prior to the submission period. CMS will provide subregulatory guidance if this becomes available. CMS believes the opt-in decision is irrevocable, because it is not fair to other clinicians if a clinician can alter their decision after they have reviewed their final feedback and scoring information. CMS agrees with a commenter's suggestion to change the name of the voluntary participation option to minimize confusion with the opt-in participation option. CMS will modify the participation terms on the QPP website to provide clear direction for the three MIPS options: voluntary reporting, opt-in participation, and required participation.

#### Part B Services Subject to MIPS Payment Adjustment

CMS finalizes its proposal to amend §414.1405(e) to modify the application of both the MIPS adjustment factor and, if applicable, the additional MIPS adjustment factor. Beginning with the 2019 MIPS payment year, the MIPS adjustment factors will apply to Part B payments for covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by MIPS eligible clinicians during the year. CMS will make this change with the first MIPS payment year and payment 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.

## d. Partial QPs Elections within Virtual Groups

CMS notes that in the 2019 PFS proposed rule (83 FR 35890 through 35891), it incorrectly stated that that affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period would constitute an explicit election to report under MIPS. CMS also incorrectly stated that all eligible clinicians who participate in a virtual group and achieve Partial QP status would remain subject to the MIPS payment adjustment due to their virtual group election to report under MIPS, regardless of their Partial QP status.

In this final rule, CMS restates that affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period <u>does not</u> constitute an explicit election to report under MIPS as it pertains to making an explicit election to either report to or be excluded from MIPS for individual eligible clinicians or APM Entities that have Partial QP status.

CMS also clarifies that beginning with the 2021 MIPS payment year, for eligible individuals who are determined to be Partial QPs individually, CMS will not use the eligible clinician's actual reporting MIPS activity to determine whether to exclude the Partial QP from MIPS in the absence of an explicit election (discussed below in section III.I.4.e). This eliminates the scenario in which affirmatively agreeing to participate in MIPS as part of a virtual group prior to the start of the applicable performance period would constitute an explicit election to report under MIPS for eligible clinicians who are determined to be Partial QPs and make no explicit election to either report to MIPS or be excluded from MIPS.

## e. Group Reporting

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

In the 2019 PFS proposed rule, CMS specifically requested comments on the following:

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

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

#### f. Virtual Groups

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

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

Beginning with the 2020 MIPS performance year and future years, CMS finalizes its proposed policy modifications at §413.1315:

- The virtual group eligibility determination period will align with the first segment of the MIPS determination period, which includes an analysis of claims during the 12-month assessment period (fiscal year) that begins on October 1 of the calendar year 2 years prior to the applicable period and end on September 30 of the calendar year preceding the applicable performance period and includes a 30-day claims run out. As part of the virtual group eligibility determination period, TINs will be able to inquire about their TIN size prior to making an election during a 5-month timeframe, which begins on August 1 and ends on December 31 of a calendar year prior to the applicable performance period.
- MIPS eligible clinicians will be able to contact their designated technical assistance (TA) representative or beginning with the 2020 MIPS performance year, the QPP Service Center to inquire about their TIN size. This information will be for informational purposes in order to assist MIPS eligible clinicians in determining whether or not to participate in a virtual group.
- A virtual group representative will make an election on behalf of a virtual group by registering to participate in MIPS as a virtual group in a form and manner specified by CMS. CMS anticipates that a virtual group representative will make the election via a web-based system developed by CMS.

CMS also finalizes updates to §413.1315 to more clearly and concisely capture previously established policies.

## g. MIPS Performance Period

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

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

CMS disagrees with commenters' suggestion to decrease the quality and cost performance period to 90-days. CMS reiterates its discussion in the 2018 QPP final rule (82FR53618) about sample size and how statistically, larger sample sizes provide more accurate information. In addition, a full calendar year performance period is consistent with how many of the measures were designed to be reported and some measures do not allow for a 90-day performance period. CMS also disagrees with commenter's statements that a 90-day performance period would allow CMS to set benchmarks based on more current data. CMS believes that benchmarks based on a 90-day performance period would be less reliable because there would be fewer reported instances to meet the case minimum needed to be included in the benchmarks. In addition, CMS disagrees that reducing the performance period would provide greater flexibility to incorporate previous MIPS feedback into performance. CMS believes the 3 rounds of feedback (round 1 – at the point of submission feedback; round 2 – pre-performance feedback; and round 3 – performance feedback) provides information for a clinician to gain insight into their possible performance prior to the release of the final performance feedback (round 3).

In response to comments recommending a full calendar year for the Promoting Interoperability (PI) performance period, CMS notes that MIPS eligible clinicians are required to report for a minimum of 90 days and have the flexibility to report for a longer performance if they choose,

## h. MIPS Performance Category Measures and Activities

#### (1) Data Submission Requirements

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

To ensure clarity, CMS finalizes its proposals to define the following terms:

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

## (b) Performance Category Measures and Reporting

Tables 32 and 33 (reproduced below) summarize CMS finalized proposals for data submission for MIPS eligible clinicians reporting as individuals and as groups. CMS also finalizes its proposal 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 scoring methodology (described in §413.1380(e)).

Table 32: Data Submission Types for MIPS Eligible Clinicians Reporting as Individuals				
Performance Category/Submission Combinations Accepted	Submission Type	Submitter Type	Collection Type	
Quality	Direct	Individual or Third Party	eCQMs	
	Log in and upload	Intermediary <sup>2</sup>	MIPS CQMs	
			QCDR measures	
	Medicare Part B claims	Individual	Medicare Part B claims	
	(small practices) <sup>1</sup>		measures (small practices	
Cost	No data submission required <sup>2</sup>	Individual	-	
Promoting Interoperability	Direct	Individual or Third Party	-	
	Log in and upload	Intermediary		
	Log in and attest			
Improvement Activities	Direct	Individual or Third Party	-	
	Log in and upload	Intermediary		
long to the state of the state	Log in and attest			

<sup>&</sup>lt;sup>1</sup>Third part intermediary does not apply to Medicare Part B claims submission type

<sup>&</sup>lt;sup>2</sup>Requires no separate data submission to CMS: measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare claims. NOTE: As used in this proposed rule, the term "Medicare Part B claims' differs from "administrative claims" in that "Medicare Part B claims' require MIPS eligible clinicians to append certain billing codes to denominator-eligible claims to indicate the required quality action or exclusion occurred.

Table 33: Data Submission Types for MIPS Eligible Clinicians Reporting as Groups				
Performance Category/Submission Combinations Accepted	<b>Submission Type</b>	Submitter Type	Collection Type	

Table 33: Data Submission Types for MIPS Eligible Clinicians Reporting as Groups					
Performance Category/Submission Combinations Accepted	Submission Type	Submitter Type	Collection Type		
Quality	Direct Log in and upload CMS Web Interface (groups of 25 or more eligible clinicians) Medicare Part B claims (small practices) <sup>1</sup>	Group or Third Party Intermediary	eCQMs MIPS CQMs QCDR measures CMS Web Interface measures Medicare Part B claims measures (small practices CMS approved survey vendor measures Administrative claims measures		
Cost	No data submission required <sup>1,2</sup>	Group	-		
Promoting Interoperability	Direct Log in and upload Log in and attest	Group or Third Party Intermediary	-		
Improvement Activities	Direct Log in and upload Log in and attest	Group or Third Party Intermediary	-		

<sup>&</sup>lt;sup>1</sup>Third part intermediary does not apply to Medicare Part B claims submission type

#### Medicare Part B Claims

Beginning with the 2019 MIPS performance year, CMS finalizes its proposal to make the Medicare Part B claims collection type available only to MIPS eligible clinicians in small practices. CMS also finalizes its proposal that data must be submitted on claims with dates of service during the performance period that must be processed no later than 60 days following the close of the performance period.

Several commenters opposed limiting the Medicare Part B claims reporting to only clinicians in small practices. CMS reiterates its desire to move away from claims reporting, since approximately 69 percent of the Medicare Part B claims measures are topped out and it believes there are a sufficient number of other collection types and submitter types available for non-small practices.

#### CMS Web Interface

CMS previously finalized that groups (consisting of 25 or more eligible clinicians) may submit their MIPS data using the CMS Web Interface for the quality, improvement activities and promoting interoperability performance categories. For the 2019 performance year, CMS finalizes its proposal that the CMS Web Interface submission type will no longer be available for groups to submit data for the improvement activities and promoting interoperability performance categories. CMS recognizes the benefit of having data submitted by a third party intermediary

<sup>&</sup>lt;sup>2</sup>Requires no separate data submission to CMS: measures are calculated based on data available from MIPSeligible clinicians' billings on Medicare claims. NOTE: As used in this proposed rule, the term "Medicare Part B claims' differs from "administrative claims" in that "Medicare Part B claims' require MIPS eligible clinicians to append certain billing codes to denominator-eligible claims to indicate the required quality action or exclusion occurred.

and finalizes its proposal to allow third party intermediaries to submit data using the CMS Web Interface on behalf of groups.

CMS acknowledges the comments it received on its consideration of expanding the CMS Web Interface submission type to groups consisting of 15 or more eligible clinicians. It will take these in consideration for future rulemaking.

#### c. Submission Deadlines

As discussed in the previous section, the terms submission mechanism does not align with the existing process of data submission to the QPP. CMS finalizes its proposal to redesignate §414.1325(f)) as 414.1325(e), to outline data submission deadlines for all submission types for individual and eligible clinicians and groups for all performance categories. CMS also finalizes its proposal to revise §414.1325(e)(1) to allow flexibility for CMS to alter submission deadlines for the direct, login and upload, the CMS Web Interface, and login and attest submission types. This allows CMS to extend the submission period when the March 31st deadline falls on a weekend or holiday to the next business day and also allows extension of the submission period due to unforeseen technical issues. In addition, CMS finalizes its proposal to align the deadline for the CMS Web Interface submission type with all other submission type deadlines at §414.1325(e)(1) and to remove the previously finalized policy at §414.1325(e)(3) because it is no longer necessary to mandate a different submission deadline for the CMS Web Interface submission type.

# (2) **Ouality Performance Category**

#### (a) Background

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

## Contribution to Final Score

Section 1848(q)(5)(E)(i)(I) if the Act, as amended by section 5003(a)(1)(C)(i) of the BBA of 2018, provides that 30 percent of the final score shall be based on performance with respect to the quality performance category, but for each of the first through fifth years for which MIPS applies to payments, the quality performance category percentage shall be increased so that the total percentage points of the increase equals the total number of percentage points by which the cost performance category percentage is less than 30 percent for the respective year.

For the 2021 payment year, CMS finalizes its proposal to weight the cost performance category at 15 percent. Thus, for the 2021 payment year, CMS finalizes to weight the quality performance category at 45 percent of a MIPS eligible clinician's final score. In response to commenters' recommendation that it reduce the weight of the improvement activities performance category to preserve the weight of the quality performance category, CMS notes it does not have the

discretion to reduce the weight of the improvement activities performance category except when measures and activities are not available and applicable.

#### Quality Data Submission Criteria

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

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

In response to comments, CMS clarifies that if a MIPS eligible clinician chooses to report on a specialty or subspecialty measure set, and if the set contains at least 6 measures, if the clinician reports on fewer than 6 measures through the MIPS CQM or Medicare B claims collection type, the clinician will be subjected to the measure validation process. If the measure validation process determines that at least 6 measures were available and applicable to the clinician's practice, they will receive zero points for each unreported measure. CMS refers readers to Appendix 1, Table Group B for finalized specialty sets.

Submission Criteria for Group Reporting CMS Web Interface Measures. For 2019, CMS did not propose any changes to the established submission criteria for CMS Web Interface measures. CMS acknowledges responses received to its request for comments on expanding the CMS Web Interface option to groups with 16 or more eligible clinicians. These comments may be considered in the future.

The CMS Web Interface measures for MIPS are applicable to ACO quality reporting under the Shared Savings Program. For the 2019 MIPS performance year, CMS refers readers to Appendix 1 – Final MIPS Quality Measures for additional details on CMS Web Interface measures.

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

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

<u>Summary of Data Submission Criteria.</u> CMS did not propose any changes to the quality data submission criteria for the 2019 MIPS performance year. As previously discussed, CMS finalized changes to existing and additional submission related terminology. Tables 34 and 35, reproduced below, summarize the data completeness requirements and submission criteria by collection type for individual clinicians and groups

Table 34: Summary of Data Completeness Requirements and Performance Period by Collection					
Type for 2020 and 2021 MIPS Payment Year					
Collection Type	Performance Period	Data Completeness			
Medicare Part B claims measures	Jan 1- Dec 31	60 percent of individual MIPS eligible clinician's or group's Medicare Part B patients for the performance period			
Administrative claims measures	Jan 1- Dec 31	100 percent of individual MIPS eligible clinician's Medicare Part B patients for the performance period			
QCDR measures, MIPS CQMs, and eCQMs	Jan 1- Dec 31	60 percent of individual MIPS eligible clinician's or group's patients across all payers for the performance period.			
CMS Web Interface measures	Jan 1- Dec 31	Sampling requirements for the group's Medicare Part B patients: populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries			
CAHPS for MIPS survey	Jan 1- Dec 31	Sampling requirement for the group's Medicare Part B patients			

Table 35: Summary of Quality Data Submission Criteria for MIPS Payment Year 2021 for Individual Clinicians and Groups					
Clinician Type	Submission Criteria	Measure Collection Types (or Measure Sets) Available			
Individual Clinicians	Report at least 6 measures including one outcome measure or if an outcome measure is not available report another high priority measures. If less than 6 measures apply then report on each measure that is applicable. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	Individual MIPS eligible clinicians select their measures from the following collection types: Medicare Part B claims measures (individuals in small practice only), MIPS CQMs, QCDR measures, eCQMs, or reports on one of the specialty measure sets if applicable.			
Groups (non-CMS Web Interface)	Report at least 6 measures including one outcome measure or if an outcome measure is not available report another high priority measures. If less than 6 measures apply then report on each measure that is applicable. Clinicians would need to meet the applicable data	Groups select their measures from the following collection types: Medicare Part B claims measures (individuals in small practice only), MIPS CQMs, QCDR measures, eCQMs, or the CAHPS for MIPS survey – or reports on one of the specialty measure sets if applicable.			

Table 35: Summary of Quality Data Submission Criteria for MIPS Payment Year 2021 for Individual Clinicians and Groups				
Clinician Type Submission Criteria		Measure Collection Types (or Measure Sets) Available		
	completeness standard for the applicable performance period for each collection type.	Groups of 16 or more clinicians who meet the case minimum of 200 will also be automatically scored on the administrative claims based all-cause hospital readmission measure.		
Groups (CMS Web Interface for group of at least 25 clinicians)	Report on all measures included in the CMS Web Interface collection type and optionally the CAHPS for MIPS survey. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	Groups report on all measures included in the CMS Web Interface collection type and optionally the CAHPS for MIPS survey.  Groups of 16 or more clinicians who meet the case minimum of 200 will also be automatically scored on the administrative claims based all-cause hospital readmission measure.		

In response to a comment, CMS clarifies that the reference in Table 31 in the proposed rule to a 90-day performance period for certain measures was an inadvertent error and clarifies there is no 90-day performance period for any MIPS quality measure.

In response to a comment, CMS clarifies that MIPS eligible clinicians are required to submit data on at least 60 percent of applicable Medicare Part B patients seen during the performance period (Table 34). CMS agrees with commenters' recommending increases in the data completeness threshold, but it believes it should be done in a gradual manner. CMS states that any increase in the data completeness threshold needs to take into consideration the ability of MIPS eligible clinicians ability to participate and perform well in MIPS.

Application of Facility-Based Measures. Section 1848(q)(2)(C)(ii) of the Act allows the Secretary to use measures used for payment systems other than for physicians, such as inpatient hospitals, for purposes of the quality and cost performance categories. Except for services furnished by emergency physicians, radiologists, and anesthesiologists, the Secretary may not use measures used for hospital outpatient departments. Facility-based measures and scoring for the 2021 payment year are discussed below in section III.I.3.i. of this summary.

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

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

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<sup>&</sup>lt;sup>6</sup> A link to the Meaningful Measures will page will be provided at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.

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

Beginning with the 2019 performance period, CMS finalizes its proposal to define a high priority measure to mean an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures include intermediate-outcome and patient reported outcome (PRO) measures.

In response to commenters expressing concerns about the unintended consequences of including opioid related quality measures, CMS clarifies it does not intend to create barriers for seriously ill patients to receive appropriate pain management but to encourage proposer monitoring, management, follow-up, and education of patients. CMS will discuss with measure stewards the need for exceptions for patients receiving hospice and palliative care. CMS clarifies that the finalized definition of a high priority measure is broad enough to include all aspects of opioid-related measurement and does not focus on a specific aspect of opioid measurement. CMS notes it will consider opioid-related quality measures submitted through the call for measure processor as QCDR measures, and also encourages the development of fully tested eCQMs.

For eCQMs, CMS encourages MIPS eligible clinicians to work with their EHR vendors to ensure they have the most recent version of the eCQM. CMS will not accept an older version of an eCQM as a submission for the quality performance category or the end-to-end electronic reporting bonus. The annual updates to the eCQM specifications are available on the electronic quality improvement (eCQI) Resource Center at <a href="https://ecqi.healthit.gov">https://ecqi.healthit.gov</a>. A few commenters did not support the timeline for removing eCQMs from the measure set because of the time required for EHR vendors to modify systems. One commenter recommended supporting the last two versions of eCQMs to allow sufficient time. CMS responds that it updates specifications annually but will take this recommendation into further consideration.

CMS understand the comments related to the burden associated with the current release of measure specifications in December but notes that it is not technically feasible to release the MIPS quality measure specifications until the final rule is published. It will consider the operational feasibility of releasing the specifications earlier than December on the QPP Explore Measures Tool on the QPP website at <a href="https://qpp.cms.gov">https://qpp.cms.gov</a>. CMS notes that it receives over a thousand QCDR measure submissions and that these specifications are available on the QPP resource library.

#### *Topped Out Measures*

In the 2018 QPP final rule, CMS finalized a 4-year timeline to identify topped out measures, after which it may propose to remove the measure through future rulemaking. In the 4<sup>th</sup> year, if finalized through rulemaking, the measure would be removed. The 2018 MIPS Quality

Benchmarks' file on the QPP resource library lists which measures are topped out for 2018 and will be subject to the cap if they are also topped out in the 2019 MIPS Quality Benchmarks' file which will be released in late 2018.<sup>7</sup>

CMS finalizes its proposal that once a measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98<sup>th</sup> to 100<sup>th</sup> percentile range), CMS may propose the measure for removal in the next rulemaking cycle, regardless of the measure's status in the measure lifecycle. CMS will consider retaining the measure if there are compelling reasons why it should not be removed (for example, if the removal would impact the number of measures available to a specialist type of addressed an area of importance to the Agency).

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

Many commenters did not support the proposal for removal of extremely topped out measures for a variety of reasons including potential impact on quality measure options for small practices and specialists. Many commenters stated that all measures should all have the same 4-year timeline and a few recommended a 2-year timeline. CMS does not believe it should retain extremely topped out measures for 4 years and believes there are sufficient quality measures in the MIPS quality set and QCDR measures. CMS will take commenters' suggestion to defer the definition of topped out measures to measure developers and national organizations into future consideration. In response to commenters opposed to the QCDR proposal, CMS states that QCDRs are expected to develop QCDR measures that are robust in their quality action and demonstrate a performance gap. CMS notes it is a well-established process that QCDR measures are reviewed for approval on an annual basis and stakeholders should be working on appropriate quality measures.

#### Removal of Quality Measures

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

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

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the measure addresses a priority area highlighted in the Measure Development Plan <sup>8</sup>

<sup>&</sup>lt;sup>7</sup> This information is available at e MIPS Quality Benchmarks' files are located at <a href="https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html">https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html</a>.

- 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 98<sup>th</sup> to 100<sup>th</sup> percentile range, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made.

The list and additional information about the finalized measures removed for the 2019 performance period is provided in Appendix 1, Table C.

In response to comments not supporting the proposal because of concerns about having insufficient measures, CMS notes that prior to proposing to remove a quality measure it considers the impact the removal would have on the number of measures available to clinicians. CMS acknowledges that important quality of care aspects may only be captured by some topped out process measures and it encourages clinicians to measure their performance in these areas but it does not believe that these measures should be tied to a pay for performance program such as MIPS. CMS understands that some of these measures may be required to be reported to other payers, but notes that this difference may reflect different goals of their programs.

### Categorizing Measures by Value

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

CMS solicited comment on implementing a system where measures are classified at a particular value (gold, silver, or bronze) and points are awarded based on the value of a measure. For example, higher value measures that are considered "gold", could include outcome measures, composite measures, or measures that address agency priorities. The CAHPS for MIPS survey could also be considered a high measure. Second tier or "silver" measures could be process measures that are directly related to outcomes and have a good gap in performance. Lower value measures or "bronze" measures could be standard of care process measures or topped out measure. CMS does not discuss the comments it received but acknowledges they may take this input into consideration in future years.

# (3) <u>Cost Performance Category</u>

# (a) Weighting in the Final Score.

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

 $<sup>{\</sup>small ^8\,Available\,at\,\underline{https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-\underline{development.html}.}$ 

For the 2021 MIPS payment year, CMS finalizes its proposal that the cost performance category will be 15% of a MIPS eligible clinician's final score. CMS finalizes only a modest increase in the weight of the cost performance category because it recognizes that cost measures are still relatively early in development and clinicians are not familiar with the measures. CMS anticipates that it will increase the weight of the cost performance category by 5 percentage points each year until it reaches the required 30% weight for the 2024 MIPS payment year. CMS appreciates the comments it received on its approach for increasing the weight in subsequent years and will consider these for future rulemaking.

Commenters were opposed to the proposed increase in the weight of the cost performance category for several reasons including the limited clinical and risk adjustments for cost measures and the introduction of episode groups. CMS notes it continues to investigate ways to accommodate social risk adjustments and believes that the adoption of a complex patient bonus at the final score level adjusts for clinical risk. CMS disagrees that introduction of new measures should mean that the weight of the cost performance category should be maintained.

#### (b) Cost Criteria

In the 2018 QPP final rule, CMS established two cost measures: total per capita cost measure and the Medicare spending per beneficiary (MSPB) measure.

CMS expects to evaluate cost measures according to the measure revaluation and maintenance process outlined in the "Blueprint for the CMS Measures Management System". To the extent that updates would constitute a substantive change, CMS will ensure the changes are proposed through rulemaking. It will also comprehensively reevaluate measures every 3 years to ensure they meet measure priorities. CMS will continue to update measure specifications to accommodate changes in coding, risk adjustment and other factors and expects to continue to seek stakeholder input.

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

Episode-Based Measures Proposed for the 2019 and Future Performance Periods
CMS notes that episode-based measures are different from the total per capita cost measure and the MSPB measure because episode-based measure specifications only include items and services that are related to the episode of care for a clinical condition or procedure, as opposed to including all services that are provided to a patient over a given timeframe. For the 2019 MIPS performance period, CMS finalizes the proposed 8 episode-based measures (see Table 36, reproduced below). After consideration of public comments, CMS modifies the ST-Elevation Myocardial Infarction (STEMI) with Elective Outpatient Percutaneous Coronary Intervention (PCI), and Revascularization for Lower Extremity Chronic Care Limb Ischemia episode-based measures to remove assignments of the MS-DRGs without myocardial infarction (MI) or heart

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<sup>&</sup>lt;sup>9</sup> The "Blueprint for the CMS Management System" is available at <a href="https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-130.pdf">https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-130.pdf</a>.

failure (HF) admissions (MS-DRGs 224-225; Defib with Cath without MI/HF and MS-DRGs 226-227; Defib without Cath without MI/HF).

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

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

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

Table 36: Episode-Based Measures Finalized for the 2019 MIPS Performance Period and Future Performance Periods			
Measure Topic	Measure Type		
Elective Outpatient Percutaneous Coronary Intervention (PCI)	Procedural		
Knee Arthroplasty	Procedural		
Revascularization for Lower Extremity Chronic Critical Limb Ischemia*	Procedural		
Routine Cataract Removal with Intraocular Lens (IOL) Implantation	Procedural		
Screening/Surveillance Colonoscopy	Procedural		
Intracranial Hemorrhage or Cerebral Infarction	Acute inpatient medical condition		
Simple Pneumonia with Hospitalization	Acute inpatient medical condition		
ST-Elevation Myocardial Infarction (STEMI) with PCI*	Acute inpatient medical condition		
* CMS modifies the STEMI with DCI Elective Outpotient DCI and Developing attention	n for Lower Extremity Chronic Core Limb		

<sup>\*</sup> CMS modifies the STEMI with PCI, Elective Outpatient PCI, and Revascularization for Lower Extremity Chronic Care Limb Ischemia episode-based measures to remove assignments of the MS-DRGs without MI or HF (MS-DRGs 224-225; Defib with Cath without MI/HF and MS-DRGs 226-227; Defib without Cath without MI/HF).

In response to comments requesting more detailed feedback on cost measures, CMS discusses the user research conducted on feedback provided for the first year of MIPS. It may consider providing beneficiary-level data on cost measures in the future. In response to a commenter's suggestion for an alternative metric, CMS will continue to monitor the information provided and will explore ways to provide actionable information to clinicians.

In response to comments expressing concerns with the development of episode based measures, CMS provides additional details about the comprehensive framework and systematic process it uses for creating episode-based measures. CMS discusses the risk adjustment for the cost measures which includes risk adjustors from the CMS-HCC model and additional measure-specific risk adjustors recommended by the Clinical Subcommittee for the measures. Additional information about this framework and measure specifications is available at <a href="https://qpp.cms.gov">https://qpp.cms.gov</a>. CMS notes that stakeholders could review draft measure specifications for each of the 8 new episode-based measures. The episode-based measures were considered by the NQF-convened Measures Application Partnership (MAP), and were all conditionally supported by the MAP, with the recommendation of obtaining NQF endorsement. CMS intends to submit these measures to NQF for endorsement in the future.

CMS responds to comments it received about specific measure specifications. It agrees with a commenter's suggestion to exclude Implantable Cardioverter Defibrillator (ICD) implantation from the Elective Outpatient PCI and STEMI with PCI measures to ensure there are no adverse incentives to providing a service that is both covered and clinically indicated and modifies the specifications of these 2 measures.

In response to commenters concerns about the continued inclusion of the total per capita cost measure and the MSPB measure, CMS notes these measures are being refined as part of the measure maintenance and re-evaluation process. CMS is completing an outreach initiative to share performance information with clinicians as part of field testing. CMS may propose the re-evaluated measures to replace the current versions of these measures.

## Reliability

CMS examined the reliability of the proposed 8 episode-based measures at various case minimums and found that all these measures meet the reliability threshold of 0.4 for the majority of clinicians and groups at a case minimum of 10 episodes for procedural measures and 20 episodes for acute inpatient medical condition episodes. Table 37 (reproduced below) represents the percentage of TINs and TIN/NPIs with 0.4 or higher reliability as well as the mean reliability for the subset of TINs and TIN/NPIs who meet the proposed case minimums.

Table 37: Percentage of TINs and TIN/NPI with 0.4 or Higher Reliability from June 2016 to May					
31, 2017 at Proposed Case Minimums					
Measure Name	Percentage TINs with 0.4 or higher reliability	Mean Reliability for TINs	Percentage TINs with 0.4 or higher reliability	Mean Reliability for TIN/NPIs	
Elective Outpatient PCI	100.0%	0.73	84.1%	0.53	
Knee Arthroplasty	100.0%	0.87	100.0%	0.81	
Revascularization for Lower Extremity Chronic Critical Limb Ischemia	100.0%	0.74	100.0%	0.64	
Routine Cataract Removal with IOL Implantation	100.0%	0.95	100.0%	0.94	
Screening/Surveillance Colonoscopy	100.0%	0.96	100.0%	0.93	
Intracranial Hemorrhage or Cerebral Infarction	100.0%	0.70	74.9%	0.48	
Simple Pneumonia with Hospitalization	100.0%	0.64	31.8%	0.40	
STEMI with PCI	100.0%	0.59	100.0%	0.59	

CMS finalizes its proposal of a case minimum of 10 episodes for the procedural episode-based measures and 20 episodes for the acute inpatient medical condition episode-based measures. CMS also codifies 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 at §414.1350(c). The comments CMS received on expanding the performance period for measures in the cost performance category will be considered for future rulemaking.

CMS acknowledges that the percentage of TIN/NPIs with 0.4 or greater reliability for the Simple Pneumonia with Hospitalization measure, meets the reliability threshold based but is lower that all the other proposed measures. CMS considered an alternative case minimum of 30 for this measure and found that although the mean reliability would increase, the number of TINs and TIN/NPIs that would meet this case minimum would decrease. Several commenters supported CMS' alternative proposal. CMS believes, however, a consistent case minimum for acute inpatient medical condition episode-based measures would be easier for clinicians and since the mean reliability of this measure at 20 episodes still exceeds the 0.4 reliability threshold, it finalizes the case minimum at 20.

Attribution Rules for the Proposed Episode-Based Measures

CMS finalizes its proposal that the attribution methodology will be the same for all of the measures within each type of episode groups – acute inpatient medical condition episodes groups and episode-based measures.

Beginning in the 2019 performance period, for <u>acute inpatient medical condition episode groups</u>, CMS finalizes:

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

Beginning in the 2019 MIPS performance period, for <u>procedural episode groups</u>, CMS finalizes its proposal:

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

A few commenters opposed the proposed attribution methodology for acute inpatient medical episode-based measures and expressed concern that the methodology had changes after field testing. CMS notes the attribution approach differs from the approach initially established for acute inpatient medical condition episode groups. Stakeholders, however, were concerned the initial approach did not capture patients' episodes when a group collaborates to manage a patient but no individual clinician exceeds the 30 percent threshold. CMS believes the E&M threshold requirement of 30 percent reflects stakeholder input throughout the measure development process.

CMS disagrees with commenters concerns with the attribution for procedural episode groups based on a trigger service identified by HCPCS/CPT procedure codes. CMS believes that the clinician who performs the service has a significant influence on the costs of care.

#### (4) Improvement Activities Performance Category

## (a) Weighting in the Final Score

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

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

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

Public comments on specific improvement activities and CMS' responses are found in these tables.

#### (b) Submission Criteria

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

As previously discussed, CMS finalizes updates to the terminology for the data submission process. CMS revises §414.1360(a)(1) to state that data would be submitted "via direct, login and upload, and login and attest" instead of "via qualified registries; EHR submission mechanisms; QCDR; CMS Web Interface; or "attestation". CMS also finalizes its proposal to

specify, submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.

## (c) Subcategories

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

# (d) Improvement Activities Inventory

Annual Call for Activities

In the 2018 QPP final rule, CMS formalized the Annual Call for Activities process for Year 3 and future years and added additional criteria for submitting nominations for improvement activities. Applicants need to indicate that one or more of the 11 criterion were applicable to the improvement activity. CMS notes that in order to submit a request for a new activity or a modification to an existing improvement activity, the stakeholder must submit a nomination form available at <a href="https://www.qpp.cms.gov">www.qpp.cms.gov</a> during the Annual Call for Activities.

For the 2019 performance period and future years, CMS finalizes its proposal to adopt an additional criterion entitled "Include a public health emergency as determined by the Secretary" to the criteria for nominating new improvement activities. CMS agrees with commenters that there is need for adequate notice for clinicians' time to prepare for improvement activities related to public health emergencies and clarifies it is just adding a new criterion such that public health emergencies are considered for improvement activities. CMS clarifies that the criteria used in selecting improvement activities are just one factor in determining which improvement activities it proposes. CMS notes it also takes into other factors, such as whether the nominated activity uses publically available products or techniques, or whether the activity duplicates any current activity.

CMS finalizes its proposal to remove the criterion entitled "Activities that may be considered for an advancing care information bonus". This policy is being finalized with changes in the promoting interoperability (PI) performance category.

#### Weighting of Improvement Activities

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

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

- The need for additional transparency and guidance on the weighting of improvement activities.
- Applying high-weighting for any improvement activity employing CEHRT. CMS will take comments it received into consideration as it develops future policies.

# Timeframe for the Annual Call for Activities

CMS discusses how the current timeline does not provide sufficient time for processing and reviewing all the improvement activities nominations. Beginning with the 2019 performance period and future years, CMS finalizes its proposal to:

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

Several commenters did not support the proposed extension of the time line because they thought it would be a barrier to aligning improvement activities with the quality improvement cycle and not appropriately award early activities of activities. CMS acknowledges that improvement activities do not have the same testing requirements as quality measures but it believes that sufficient time is needed to thoroughly review all submissions. CMS recognizes that the timeline does not align with the annual call for quality measures but does align with the annual call for PI measures.

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

CMS did not propose any changes to the study purpose, aim, eligibility or credit. For the 2019 performance period and future years, CMS finalizes its proposed changes to the following:

- <u>Title</u>. CMS finalizes the title change to "CMS Study on Factors Associated with Reporting Quality Measures".
- <u>Sample Size</u>. CMS finalizes an increase in the sample size from a minimum of 102 to a minimum of 200 MIPS eligible clinicians. CMS believes this will enable it to more rigorously analyze the statistical difference between the burden and factors associated with individuals and groups of varying sizes.
- <u>Focus Group</u>. CMS finalizes that focus group participation is a requirement only for a selected subset of study participants, using purposive sampling and random sampling methods.

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

(5) <u>Promoting Interoperability (PI) (previously known as the Advancing Care Information Performance Category)</u>

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

(a) Certification Requirements Beginning in 2019

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

Beginning with the 2019 performance period, MIPS eligible clinicians must use EHR technology certified to the 2015 Edition certification criteria as specified in §414.1305. CMS notes that because this requirement was not a subject of this rulemaking, it is not responding to comments it received, although it may consider them in future policy making.

(b) Scoring Methodology Beginning with the MIPS Performance Period in 2019 CMS finalize its proposal for a new scoring methodology based on performance on individual measures. The goal of this scoring methodology is to provide increased flexibility to clinicians and enable them to focus more on patient care and health data exchange through interoperability. CMS notes this methodology will also align the requirements of the PI performance category with the requirements of the PI program for eligible hospitals and critical access hospitals (CAHs).

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

The score for each individual measure will be added together to calculate the PI performance score of up to 100 possible points for each MIPS eligible clinician. In general, the PI performance category score makes up 25 percent of the MIPS final score. CMS finalizes its proposal that MIPS eligible clinicians need to report on all of the required measures across all

objectives. Failure to report any required measure, or reporting a "no" response on a "yes or no" response measure, unless an exclusion applies would result in a score of zero.

Tables 39 and 40, reproduced below, summarize CMS' proposal for the scoring methodology for the MIPS performance period in 2019 (table 39) and 2020 (table 40).

Table 36: Proposed Scoring Methodology for the MIPS Performance Period in 2019				
Objectives	Maximum Points			
e- Prescribing	e-Prescribing	10 points		
	Bonus: Query of Prescription Drug Monitoring Program (PDMP)	5 points bonus		
	Bonus: Verify Opioid Treatment Agreement	5 points bonus		
Health Information	Support Electronic Referral Loops by Sending Health	20 points		
Exchange	Information			
	Support Electronic Referral Loops by Receiving and	20 points		
	Incorporating Health Information			
Provider to Patient	Provide Patients Electronic Access to Their Health Information	40 points		
Exchange				
	Choose two of the following:	10 points		
- 0.0 0 0.0 0 0 0 0 0	Public Health and  • Immunization Registry Reporting			
Clinical Data Exchange	Electronic Case Reporting			
	Public Health Registry Reporting			
	Clinical Data Registry Reporting			
	Syndromic Surveillance Reporting			

Table 37: Proposed Scoring Methodology for the MIPS Performance Period in 2020				
Objectives	ectives Measures			
e- Prescribing	e-Prescribing	5 points		
	Query of Prescription Drug Monitoring Program (PDMP)	5 points		
	Verify Opioid Treatment Agreement	5 points		
Health Information	Support Electronic Referral Loops by Sending Health	20 points		
Exchange	Information			
	Support Electronic Referral Loops by Receiving and	20 points		
	Incorporating Health Information			
Provider to Patient	Provide Patients Electronic Access to Their Health Information	35 points		
Exchange				
	Choose two of the following:			
Public Health and	Public Health and  • Immunization Registry Reporting			
Clinical Data Exchange	Electronic Case Reporting			
	Public Health Registry Reporting			
	Clinical Data Registry Reporting			
	Syndromic Surveillance Reporting			

Many commenters supported CMS' proposal to reduce the number of measures to be reported and to reduce the complexity of the scoring methodology. Many commenters recommended a threshold of 50 points to align with the Medicare PI Program for eligible hospitals and CAHs. CMS appreciates this comment and will take it into consideration for future proposals. Some commenters expressed concern that CMS has gone back to an "all or nothing" approach, which existed in the original meaningful use program. Commenters suggested that MIPS eligible clinicians who cannot attest to a measure should not receive points for that particular measure, but they should still earn points for all of the other measures they submit data for. CMS

disagrees with these comments and notes it would disadvantage clinicians if it did not redistribute points for measures when an exclusion is claimed.

CMS considered an alternative approach: scoring would occur at the objective level, instead of the individual measure level, and MIPS eligible clinicians would be required to report on only one measure from each objective to earn a score for that objective. Under this methodology, the total PI performance category score would be based on only four measures instead of six measures. Each objective would be weighted similar to the proposed methodology and bonus points would be award for reporting any additional measures beyond the required four. Many commenters supported the alternative approach because they considered it more flexible. Some commenters did not think CMS should implement the alternative proposal because it would allow MIPS eligible clinicians to report on fewer measures. CMS did not finalize the alternative approach to scoring and believes the finalized objective and measure set will enable eligible clinicians to focus on interoperability and improving patient access to health information.

Tables 41 and 42, reproduced below, summarize CMS' final policy for the scoring methodology for the MIPS performance period in 2019 (table 41) and 2020 (table 42).

Table 41: Scoring Methodology for the MIPS Performance Period in 2019				
Objectives	Measures	Maximum Points		
e- Prescribing	e-Prescribing**	10 points		
	Bonus: Query of Prescription Drug Monitoring Program (PDMP)	5 point bonus		
	Bonus: Verify Opioid Treatment Agreement	5 point bonus		
Health Information	Support Electronic Referral Loops by Sending Health	20 points		
Exchange	Information**	_		
	Support Electronic Referral Loops by Receiving and	20 points		
	Incorporating Health Information**			
Provider to Patient	Provide Patients Electronic Access to Their Health Information	40 points		
Exchange				
	Report to two different public health agencies or clinical data			
Public Health and	registries for any of the following:	10 points		
Clinical Data Exchange	<ul> <li>Immunization Registry Reporting**</li> </ul>			
	Electronic Case Reporting**			
	<ul> <li>Public Health Registry Reporting**</li> </ul>			
	Clinical Data Registry Reporting**			
	Syndromic Surveillance Reporting**			
**Exclusion available				

Table 42: Scoring Methodology for the MIPS Performance Period in 2020				
Objectives	Measures	Maximum Points		
e- Prescribing	e-Prescribing**	10 points		
	Bonus: Verify Opioid Treatment Agreement	5 point bonus		
Health Information	Support Electronic Referral Loops by Sending Health	20 points		
Exchange	Information**			
	Support Electronic Referral Loops by Receiving and	20 points		
	Incorporating Health Information**			
Provider to Patient	Provide Patients Electronic Access to Their Health Information	40 points		
Exchange				
	Report to two different public health agencies or clinical data			
Public Health and	registries for any of the following:	10 points		
Clinical Data Exchange	Immunization Registry Reporting**			

Table 42: Scoring Methodology for the MIPS Performance Period in 2020		
Objectives	Measures	Maximum Points
	Electronic Case Reporting**	
	<ul> <li>Public Health Registry Reporting**</li> </ul>	
	<ul> <li>Clinical Data Registry Reporting**</li> </ul>	
	<ul> <li>Syndromic Surveillance Reporting**</li> </ul>	
**Exclusion available		-

Security Risk Analysis Measure: CMS finalizes its proposal to require MIPS eligible clinicians to attest that they completed the actions included in the Security Risk analysis measure some time during the calendar year for the MIPS performance period. Eligible clinicians who fail to attest will not earn any score for the PI performance category, regardless of whether they report on other measures in this category. CMS disagrees with commenters recommending that the Security Risk Analysis measure should be associated with a credit. CMS does not believe points should be award because this measure includes actions already required under HIPAA and that eligible clinicians should already be performing these activities.

Electronic Prescribing Objective Scoring: CMS finalizes the e-Prescribing objective with modifications. The e-Prescribing measure will be worth up to 10 points in 2019 and 2020. CMS modifies the points for 2020 to reflect the modification to its proposal for the Query of the Prescription Drug Monitoring Program (PDPM). Thee Query of PDPM measure is optional in 2019 and worth 5 bonus points. CMS is not establishing a policy for the Query of PDPM measure for 2020 in this final rule and intends to address this in future rulemaking. The Verify Opioid Treatment Agreement is optional in 2019 and 2020, and worth five bonus points.

If an exclusion is claimed for the e-Prescribing measure for 2019, the 10 points for this measure will be redistributed equally among the measures associated with the Health Information Exchange objective.

<u>Health Information Exchange Objective Scoring</u>: CMS finalizes its proposal to require reporting for both measure, each worth 20 points. CMS notes these measures are weighted heavily to emphasize the importance of sharing health information through interoperable exchange.

For the 2019 performance period, CMS acknowledges that these measures may not be fully developed or implemented and finalizes an exclusion for the Support Electronic Referral Loops by Receiving and Incorporating Health Information. Any eligible clinician who is unable to implement this measure for the 2019 performance period will be excluded from reporting this measure; the 20 points would be redistributed to the Support Electronic Referral Loops by Sending Health Information and that measure would be worth 40 points. CMS will address in future rulemaking how the points will be redistributed if exclusions are claimed for both measures.

Provider to Patient Exchange Objective Scoring: CMS finalizes the Provider to Patient Exchange objective with modifications. Beginning with the 2019 MIPS performance period, this measure is worth up to 40 points and no exclusions are available. A few commenters stated that an allocation of 40 points to a single measure is too high. CMS disagrees because it believes it is

essential for patients to have access to their health information and the assignment of 40 points reflects the importance of this measure.

<u>Public Health and Clinical Data Exchange Objective Scoring</u>: CMS finalizes its proposal for the Public Health and Clinical Data Exchange objective with modifications. CMS agrees with a comment that a clinician in active engagement with two different public health agencies or clinical data registries for purposes of the same measure accomplishes the same policy goal as CMS' proposal to report two measures.

If an exclusion is claimed for one measure, but the MIPS eligible clinician submits a "yes" response for another measure, the clinician will earn the 10 points for the Public Health and Clinical Data Exchange objective. If a 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.

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

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

(d) Promoting IP Category Measure Proposals for MIPS Eligible Clinicians
Table 39 from the proposed rule (83 FR 35920 through 35932), reproduced below, provides a summary of the proposals for the PI category measures for the MIPS 2019 performance period.

Table 39: Summary of Proposals for the PI Performance Category Objectives and Measures for the MIPS Performance Period in 2019				
Measure Status	Measure			
Measures retained-no modifications*	e-Prescribing			
Measures retained with modifications	- Send a Summary of Care (name proposal – Support Electronic Referral Loops by Sending Health Information) - Provider Patient Access (name proposal – Provide Patients Electronic Access to Their Health Information - Immunization Registry Reporting - Syndromic Surveillance Reporting - Electronic Case Reporting - Public Health Registry Reporting - Clinical Data Registry Reporting			
Removed measures	- Request/Accept Summary of Care - Clinical Information Reconciliation - Patient-Specific Education - Secure Messaging - View, Download or Transmit - Patient-Generated Health Data			
New measures	- Query of Prescription Drug Monitoring Program (PDMP) - Verify Opioid Treatment Agreement - Support Electronic Referral Loops – Receiving and Incorporating Health Information			
- Support Electronic Referral Loops – Receiving and Incorporating HealthInformation  * Security Risk Analysis is retained, but not included as a measure under the proposed scoring methodology				

CMS finalizes its proposals for the measures for the 2019 MIPS performance period. The reader is referred to the discussion in the final rule for more specific details about each measure description, denominator and numerator.

Table 43, reproduced below, includes the 2015 Edition certification criteria required to meet the objectives and measures.

Table 43: Promoting Interoperability Objectives and Measures and Certification Criteria for the 2015 Edition				
Objective	Measure	2015 Edition		
Protect Public Health Information	Security Risk Analysis	The requirements are a part of CEHRT specific to each certification criterion (References from Title 45)		
e-Prescribing	e-Prescribing	§170.315(b)(3) (Electronic Prescribing) §170.315(a)(10) (Drug Formulary and Preferred Drug List checks)		
	Query of PDMP	§170.315(a)(10) and §170.315(b)(3)		
	Verify Opioid Treatment Agreement	§170.315(a)(10), §170.315(b)(3), and §170.315(b)(2) (Electronic Prescribing Standard)		
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	§170.315(b)(1) (Transitions of Care)		
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	§170.315(b)(1) and §170.315(b)(2) (Clinical Information Reconciliation and Incorporation)		
Provider to Patient Exchange	Provide Patient Electronic Access to Their Health Information	\$170.315(e)(1) (View, Download, and Transmit to 3 <sup>rd</sup> Party) \$170.315(g)(7) (Application Access-Patient Selection) \$170.315(g)(8) (Application Access-Data Category Request) \$170.315(g)(9) (Application Access-All Data Request) The three criteria combined are the "API" certification criteria.		
Public Health and Clinical Data Exchange	Immunization Registry Reporting	§170.315(f)(1) (Transmission to Immunization Registries)		
	Syndromic Surveillance Reporting	§170.315(f)(2) (Transmission to Public Health Agencies – Syndromic Surveillance) Urgent Care Setting Only		
	Electronic Case Reporting	§170.315(f)(5) (Transmission to Public Health Agencies – Electronic Case Reporting)		
	Public Health Registry Reporting	EPs may choose one or more of the following: §170.315(f)(4) (Transmission to Cancer Registries) §170.315(f)(7) (Transmission to Public Health Agencies – Health Care Surveys)		
	Clinical Data Registry Reporting	No 2015 Edition health IT certification criteria at this time		

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

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

Some commenters opposed discontinuation of bonus points because it provided evidence of CMS' understanding of the important role of health IT. CMS notes it continues to believe that the use of health IT is important and encourages stakeholders to submit new improvement activities through the Annual Call for Activities that encourage the use of health IT.

CMS also considers proposing in future rulemaking public health priority sets across all four MIPS performance categories. CMS believes that public health priority sets would allow clinicians to focus on activities and measures that fit within their workflow, address their patient population needs, and encourage increased participation in MIPS. CMS intends to develop the first few public health priority sets around opioids, blood pressure, diabetes, and general health (healthy habits). CMS appreciates comments it received about this issue and will consider comments as it develops future policy proposals.

## (f) Additional Considerations

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

Physical therapists, Occupational therapists, Clinical social workers, and Clinical psychologists. CMS finalizes its proposal with modifications. 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 2019 performance period. CMS will assign a weight of zero to the PI performance category if there are not sufficient measures applicable and available to these new types of MIPS eligible clinicians. CMS is not adopting a policy related to clinical social workers because they are not being added as MIPS eligible clinicians at this time.

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

MIPS eligible clinicians including those participating in MIPS APMs, are subject to MIPS reporting requirements and payments adjustments, unless excluded on another basis. CMS finalized under §414.1370(f) that, under the APM scoring standard, MIPS eligible clinicians will

be scored at the APM entity group level and each MIPS eligible clinician will receive the APM Entity's final MIPS score.

## (a) MIPS APM Criteria

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

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

CMS finalizes its proposal to revise the third criterion to specify that a MIPS APM must be designed in such a way that participating APM Entities are incented to reduce costs of care or utilization of services, or both. CMS modifies the criterion at §414.1370(b) to state that the APM bases payment incentives on performance (either at the APM entity or eligible clinician level) on quality measures and cost/utilization.

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

CMS also finalizes its clarification of its interpretation of the rule at §414.1370(b)(4)(i). 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. CMS believes it would be counter to the purpose of the APM scoring standard to report duplicative reporting of quality measures for both the APM and MIPS and to create potential conflicting incentives between the quality scoring requirements and payment incentives.

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

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

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

CMS will post the final determination of the MIPS APMs for the 2019 MIPS performance year on the QPP website at <a href="https://qpp.cms.gov">https://qpp.cms.gov</a>. In making these determinations, CMS will use the MIPS APM criteria established in §414.1370(b), taking into account the clarifications finalized in this final rule.

#### (b) Calculating MIPS APM Performance Category Scores

Quality Performance Category. 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 APMs and available for scoring as specified in §414.1370(g)(1).

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

If a Shared Savings Program ACO does not report quality measures as required, each ACO participant TIN will be treated as a unique APM entity for purposes of the APM scoring standard, and may report data for the MIPS quality performance category according to the MIPS submission and reporting requirements. CMS clarifies that any "partial" reporting through the CMS Web Interface that does not satisfy the requirements of the Shared Savings Program will be considered a failure to report. In this situation, each ACO participant TIN will also have the opportunity to report quality data to avoid a score of zero for the quality performance category.

CMS acknowledges that successfully reporting MIPS according to group reporting requirements may be difficult for solo practitioners and proposes a modification in the exception policy. Beginning with the 2019 performance period, when a Shared Savings Program ACO fails to report complete quality data for all Web Interface measures, CMS finalizes its proposal to allow a solo practitioner (a MIPS eligible clinician who has only one NPI billing though their TIN), to report on any available MIPS measures, including individual measures.

CMS does not finalize its proposal to modify the complete requirement for Web Interface reporters, so that, in the case when a Shared Savings Program ACO fails to complete reporting for Web Interface measures but successfully reports the CAHPS for ACO survey, CMS would score the CAHPS survey and apply it towards the APM Entity's quality performance category score. Some commenters supported this proposal and others expressed concerns about this proposal. CMS notes that upon further consideration, it believes the proposal would have unduly limited the ACO participant TINs' opportunity to achieve the highest possible quality performance category score.

For the 2019 performance period, CMS will continue its current policy. Thus, in the case where a Shared Savings Program ACO fails to successfully report Web Interface measures but does successfully report the CAHPS for ACOs survey, CMS will continue to treat the ACO Participant TINs as unique APM Entities under the APM scoring standard and will score each TIN only on the MIPS measures it has reported.

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

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

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

For the 2019 MIPS performance period, CMS expects there will be up to six Other MIPS APMs and lists each specific APM measure list set in Tables 44 through 49 in the final rule:

- Comprehensive ESRD Care Model (Table 44),
- Comprehensive Primary Care Plus Model (Table 45),
- Oncology Care Model (Table 46),
- Bundled Payments for Care Improvement Advanced Model (Table 47),
- Maryland Total Cost of Care Model (Maryland Primary Care Program (Table 48), and
- Independence at Home Demonstration (Table 49).

As finalized for 2018 (82 FR 53695 and 53696), the measure sets on the MIPS APM measure list for the year will represent all possible measures, which may contribute to an APM Entity's MIPS score for the MIPS quality performance category and may include measures that are the same or similar to those used by MIPS. CMS notes that a given measure might not be used for scoring, for example if the data for the measure set becomes inappropriate or unavailable for scoring.

Promoting Interoperability Performance Category. For the Shared Savings Program, CMS finalized at §414.1370(g)(4)(i) that ACO participant TINs are required to report on the PI performance category, and it will weight and aggregate the ACO participant TIN scores to determine an APM Entity group score. CMS has found that limiting reporting to the ACO participant TIN creases confusion and restricts PI reporting options for MIPS eligible clinicians participating in the Shared Savings Program.

Beginning in the 2019 MIPS performance period, CMS finalizes its proposal to no longer apply the requirements at §414.1370(g)(4)(i) and instead apply the existing policy at §414.1370(g)(4)(ii) so that MIPS eligible clinicians participating in the Shared Savings Program may report on the PI performance category at either the individual or group level under the APM scoring standard. A commenter requested that CMS maintain the current requirement because larger ACOs may encounter difficulty managing the PI reporting for all of the individual MIPS

eligible clinicians that bill through TINs of ACO participants. CMS notes the PI performance category may be reported at either the individual or group level, not the APM (ACO) level. If the participant TIN reports for the PI performance category, there would be no need for the ACO to manage reporting for individual MIPS eligible clinicians. If the TIN fails to report, the individual MIPS eligible clinician within the TIN would have an opportunity to reduce the negative impact of that failure by reporting individually.

#### (c) MIPS APM Performance Feedback

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

## i. MIPS Final Score Methodology

#### (1) Converting Measures and Activities into Performance Category Scores

#### (a) Background

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

# (b) Scoring the Quality Performance Category

While the basic structure is continued, CMS finalizes a number of changes to the scoring of the quality performance category for 2021 payment. Regulatory text at §414.1380(b) is modified accordingly.

Quality Measure Benchmarks. Regulatory text at §414.1380(b) is modified to reflect the changes in terminology discussed earlier in this summary with respect to data collection versus data submission. Separate benchmarks are established 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. For example, the eCQM benchmark will apply regardless of whether the submitter is a MIPS eligible clinician, a group or a third-party intermediary. Benchmarks will be established by collection type from all available sources including MIPS eligible clinicians and APMs, to the extent feasible.

CMS does not describe the comments it received in response to its request for comment on potential future approaches to scoring the quality performance category, specifically on

clarifying its benchmarking process and considering ways to align it with Physician Compare benchmarking. These comments may be considered in the future.

<u>3-Point Floor</u>. CMS finalizes continuation of the 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period. It plans to revisit this policy in future rulemaking.

<u>CAHPS for MIPS</u>. Beginning with the 2021 payment year, the denominator (the total available achievement points) will be reduced by 10 points for groups that submit 5 or fewer quality measures and register for the CAHPS for MIPS but do not meet the beneficiary sampling requirements. This proposal was made because CMS is concerned that some groups that expect to meet the beneficiary sampling requirements for the CAHPS for MIPS measure will find out late in the performance year that they have failed to do so, and therefore will not receive a score on this measure. This change effectively removes the impact of the group not receiving a score on this measure, and a group in that circumstance will not need to find a replacement measure.

Responding to comments CMS clarifies that the policy will not automatically be applied. Notifications are sent twice to groups that have registered for the CAHPS for MIPS survey and who have insufficient sample size; the second notification usually occurs in September. The notification encourages groups to select other measures that can be completed. For groups that submitted 6 or more quality measures and do not meet the CAHPS for MIPS sampling requirements, it will score the six measures with the highest achievement points; for these groups the denominator will not be adjusted.

CMS does not expect the notification process for minimum beneficiary sample to change. CMS communicates about sample size eligibility with the point of contact provided by each group during the registration process; providing more than one point of contact would help promote timely delivery of the information to the group.

Comments were sought on whether this policy should be limited to only one MIPS performance period for a group because CMS does not want groups to register for the CAHPS for MIPS measure if they know in advance that they are unlikely to meet the sampling requirement. The comments it received are not described but CMS will consider them for the future.

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

<u>Scoring Measures that Do Not Meet Case Minimum, Data Completeness, and Benchmarks</u>
Requirements. Table 50 in the final rule summarizes policies for measures that are submitted but

cannot be scored because they do not meet case minimum or data completeness requirements, or because they do not have a benchmark. CMS finalizes continuation of these policies for the 2019 MIPS performance period. In addition, beginning with the 2020 performance period, CMS will assign zero points to measures that do not meet data completeness requirements. This is part of its effort to move toward complete and accurate reporting. Small practices will continue to receive 3 points for all future MIPS performance periods, although CMS may revisit this policy in the future. Changes to regulatory text are made accordingly.

Scoring for Measures with Clinical Guideline Changes During the Performance Period. CMS finalizes that beginning with the 2021 MIPS payment year, for each measure that a MIPS eligible clinician submits that is significantly impacted by clinical guideline changes or other changes that CMS believes may result in patient harm or misleading results, the total available measure achievement points are reduced by 10 points. This policy is codified in a new paragraph at §414.1380(b)(1)(vii) with wording modifications from the proposed rule. In responding to comments, CMS clarifies that it monitors changes to quality measures and clinical guidelines and will rely mainly on measure stewards for notification in changes to clinical guidelines. Measure stewards often defer to the clinical organizations or other stakeholders who own and update the clinical guideline when a guideline change is warranted. CMS will publish suppressed measures on its website whenever technically feasible, but no later than the beginning of the data submission period.

In addition, CMS emphasizes that it believes this policy will be used rarely and will hold harmless any clinician submitting data on an affected measure. The policy will be used under two circumstances. The first is when there is wide consensus that newly issued or updated guidelines would result in a significant change to a quality measure. CMS anticipates that in these cases the quality measure would be reviewed and updated during the next rulemaking process. Second, the policy will be used in rare cases where there is a new or revised guideline but no broad consensus within the specialty, because in that case some clinicians will begin to adopt a new guideline that is inconsistent with the quality measures and affect performance on the measure. In that case the measure would be suppressed until the guidelines and measure are reviewed by the Measures Application Partnership (MAP) and other processes, including rulemaking. CMS does not envision using this policy when guideline revisions are anticipated but not completed, or if a guideline changes does not significantly impact measure results.

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

<u>Small Practice Bonus</u>. CMS finalizes a small practice bonus for 2021 payment that differs from what it had proposed, based on its analysis of new data as well as concerns of commenters. As previously adopted, for the 2020 payment year, CMS will add a 5 point small practice bonus to

the final score for clinicians, groups, APM entities and virtual groups who meet the definition of a small practice (§414.1305) and submit data on at least one performance category for the 2018 MIPS performance period.

For 2021 payment, CMS finalizes a small practice bonus 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 to MIPS on at least 1 quality measure. Adding 3 points to the quality performance category numerator had been proposed. Subsequent to issuing the proposed rule, CMS reviewed data for the 2017 performance period and discovered that fewer eligible clinicians had the quality performance category reweighted to 85 percent of the final score than expected. Therefore, the proposed 3 bonus points would represent a lower overall bonus than CMS had anticipated. Because it was not CMS' intent to lower the overall impact of the bonus on the final score, it is finalizing the 6-measure bonus points policy instead. The CMS analysis found that without the bonus, the average quality score for submitters in small practices was 62 percent compared to 82 percent for clinicians in large groups.

While CMS further analyzes the implications of these results (e.g., whether the discrepancy results from Web Interface reporting, to performance, or to factors related to data collection), it believes that a small practice bonus of 6 measure bonus points to the quality performance score numerator is appropriate for 2021 to ensure that participation is incentivized during the transition years without reducing the impact of the small practice bonus. The magnitude of the bonus will vary because of category reweighting; On average, CMS estimates the small practice bonus will add 4.4 points to the final score for clinicians in small practices who submit quality information to MIPS. CMS plans to monitor the final score affects in order to keep the bonus as equitable as possible in the future.

CMS reiterates that the small practice bonus was meant to be temporary and it expects that it will be reduced or removed in future rulemaking. While recognizing the unique challenges of small practices, CMS believes that the small practice bonus may not address the underlying reasons for the disparate performance between small practices and other clinicians. As a result, it intends to revisit this bonus during next year's rulemaking cycle.

Responding to many comments supporting continued application of the small practice bonus to the final score, CMS says that it is appropriate for the bonus to apply in the quality category because small practices have different reporting options there which could affect their score, and because other policies assist small practices in the improvement and promoting interoperability categories while data submission is not required for the cost category. While moving the small practice bonus to the quality category may add to scoring complexity CMS believes it is appropriate to encourage the submission of quality measures.

<u>Incentives to Report High-Priority Measures</u>. CMS will maintain for the 2021 payment year the cap on high-priority bonus points, which is set to equal 10 percent of the total possible measure achievement points the MIPS eligible clinician could receive in the quality performance category. However, measure bonus points are discontinued for CMS Web Interface reporters for reporting high-priority measures. Bonus points were intended as a transition policy, and CMS has found that practices electing to report via the CMS Web Interface generally perform better

than other practices, so the benefit of bonus points is limited and CMS believes they would create higher than normal scores. CMS says that it will consider eliminating the high priority bonus points entirely after the 2021 payment year. Responding to comments, CMS notes that Web Interface reporters are excluded from the topped-out measure cap (82 FR 53576), so they are still able to receive maximum achievement points for all measures, even though some of the CMS Web Interface measures may be considered topped out. Additionally, CMS Web Interface reporters are still able to receive measure bonus points for reporting the CAHPS for MIPS survey and for end-to-end reporting.

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

<u>Calculating Total Measure Achievement and Measure Bonus Points</u>. No changes were proposed to the policy for calculating total measure achievements and bonus points for non-CMS Web Interface reporters. Terminology changes and technical changes to the regulatory text apply with respect to the scoring policies for CMS Web Interface reporters. Table 51 in the final rule presents an example of assigning points for a clinician who submits measures collected across multiple collection types, which CMS expects will be a rare circumstance. CMS does not encourage clinicians to submit the same measure collected via multiple collection types.

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

If this approach was adopted, the scoring methodology would be changed accordingly. CMS sought comment on several possible approaches to simplifying scoring, and whether they would encourage more accurate reporting of high value measures. The approaches were: 1) restructuring requirements with a pre-determined denominator (e.g., 50 points) but no specific requirements about the number of measures that must be submitted; 2) continuing the current requirements (6 measures including one outcome measure, all worth up to 10 points) but changing the minimum number of measure points available by measure tier; 3) moving to sets of measures; and 4) developing QCDR measure benchmarks using historical measure data. CMS also invited comment on how to incorporate incentives for the use of eCQMs into the approaches described above, and welcomed comments on other approaches to simplify scoring, incentivize submission of outcome measures and develop data that can distinguish clinician performance and determine clinicians that provide high value care. The comments it received are not described in the final rule, but CMS will consider them in future rulemaking.

<u>Improvement Scoring for the MIPS Quality Performance Category</u>. CMS continues its policy for improvement scoring in the quality performance category for the 2019 MIPS performance period. Under this policy, 2019 performance will be compared to an assumed 2018 performance category achievement percent score of 30 percent for a clinician who earned a quality performance category score for 2018 that is less than or equal to 30 percent.

## (c) Scoring the Cost Performance Category

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

Responding to comments, CMS does not believe that using a scoring policy for this category like the quality category (i.e., only scoring the top 6 measures) is appropriate because unlike the quality category the cost measures do not require data submission. At the same time groups with more than 6 measures would be advantaged because this approach would disregard those measures on which performance was poorest.

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

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

In this rule, CMS adopts (without change from the proposed rule) four changes to the determination of a facility-based individual.

- Professional services provided in the on-campus outpatient hospital setting (POS code 22) will be considered in determining eligibility for facility-based measurement. CMS does not agree with comments that off-campus outpatient hospital services (POS code 19) should also be included because clinicians working in these settings may not have any impact on the hospital inpatient care as measured in the inpatient hospital VBP score that will be used in facility-based MIPS scoring. CMS notes that clinicians who work in more varied settings and therefore cannot meet the 75 percent threshold may be better measured through another MIPS participation method.
- A clinician must have at least one single service billed with the POS code used for the
  inpatient hospital or emergency room settings. This is intended to ensure that the
  clinicians eligible for facility-based measurement contribute to services that are measured
  under the Hospital VBP Program. CMS will monitor this requirement and may propose a
  change if it finds evidence of gaming, such as clinicians providing inpatient services
  primarily to qualify for facility-based scoring.
- If a facility with a Hospital VBP Program score cannot be attributed to the clinician, the clinician will not be eligible for facility-based measurement. CMS believes this situation will be rare.

• The time period for determining eligibility for facility-based measurement is aligned with changes to the dates used to determine MIPS eligibility and special status. Data (with a 30-day claims run out) from October 1<sup>st</sup> 2 years prior to the performance period through September 30 of the year preceding the performance period will be used to determine eligibility for the facility-based measurement.

In response to comments, CMS also commits to monitoring the impact of facility-based scoring to ensure that it does not offer unfair advantages, although it notes that there is a range of scores for the inpatient hospital VBP program just as there is under the MIPS.

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

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

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

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

In MIPS, clinicians are scored as individuals unless they submit data as a group; this will also be true with respect to facility-based measurement. While there are no submission requirements for the quality performance category under facility-based measurement, a group must submit data in the improvement activities or promoting interoperability categories to be measured as a group under facility-based measurement. Submitting these data signal an intent to be scored as a group. If a group does not submit these data, facility-based measurement will be applied to individual clinicians. Virtual groups must be formed prior to the MIPS performance period and those eligible for facility-based measurement are always measured as a virtual group. CMS believes this preserves the clinician's choice to be scored as a group without the burden of an election process.

CMS responds to a variety of comments it received on this proposal. While many commenters were supportive, many other commenters expressed concern about not allowing for an election of facility-based measurement. CMS notes that in all cases combined performance in the cost and quality categories will be compared and the clinician or group will be assigned the higher score whether using facility-based measurement or another submission type. Further, CMS believes that a formal opt-in or opt-out process would be unnecessarily burdensome for individual clinicians and groups, and that clinicians who wish to better control their performance in MIPS may submit measures through another method. Regarding the requirement that groups submit data for the improvement and promoting interoperability categories in order to receive a facility-based score, CMS says this is necessary to determine whether an individual clinician should be measured as part of the group. However, it points out that clinicians in a facility-based group who meet the requirements for facility-based measurement as individuals will receive individual scores in the quality and cost categories if there is no data submission from the group in the improvement or promoting interoperability categories. Other responses include an example of facility-based scoring when no cost category score is available.

Notification and as much information as possible on a clinician's eligibility for facility-based performance will be provided as early as possible to assist clinicians in making decisions. This includes eligibility for facility-based measurement, facility attribution, and a preview score based on data from the previous performance period. CMS anticipates this information will be provided during the first quarter of the performance period, if technically feasible, beginning in 2019.

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

In this rule, CMS finalizes continuation of the Hospital VBP Program measures for purposes of MIPS facility-based measurement scoring. The measures used will be for the fiscal year Hospital VBP program for which payment begins during the MIPS performance period. In addition, CMS will use the Hospital VBP Program Total Performance Score for facility-based measurement. For example, for the 2019 MIPS performance period (2021 payment), the FY 2020 Hospital VBP Program total performance score will be used. The FY 2020 VBP performance periods for the measures vary but they all end during 2018. For informational purposes, Table 52 in the final rule lists the Hospital VBP Program measures for FY 2020. Corresponding changes to and clarifications to the regulatory text are made.

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

also clarified to state that MIPS-eligible clinicians who are scored in MIPS through facility-based measurement for a year will not receive improvement points based on prior performance in the MIPS quality or cost categories.

<u>Expansion of Facility-Based Measurement to Other Settings</u>. In the proposed rule CMS sought comment on a series of questions regarding how it might expand facility-based measurement into post-acute care (PAC) and end-stage renal disease (ESRD) settings. The comments received in response are not described but CMS will consider them in future rulemaking.

#### (e) Scoring the Improvement Activities Performance Category

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

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

# (f) Scoring the Promoting Interoperability Performance Category

CMS refers readers to a previous section of the final rule (discussed in section III.I.2.h(5) of this summary) for discussion of scoring the promoting interoperability performance category.

## (2) Calculating the Final Score

CMS finalizes its proposals to continue the complex patient bonus for the 2021 MIPS payment year, modify the final score category weights and reweighting policies, and revise final score formula.

#### (a) Accounting for Risk Factors

CMS reviews work it has underway regarding the potential role of social risk factors in the MIPS scoring methodology, and references studies undertaken by the Assistant Secretary for Planning and Evaluation (ASPE) and the National Quality Forum socioeconomic status trial. It plans to continue working with ASPE, the public and key stakeholders on this issue.

Complex Patient Bonus for 2021 MIPS Payment. CMS continues for 2021 the complex patient bonus of up to 5 percent that was adopted for the 2020 payment year. The adjustment is meant to protect access to services for complex patients and avoid disadvantaging the clinicians who care for them. CMS emphasizes that this is a short-term solution and it intends to review updated data and other available to determine if a different approach would better account for social risk factors. Responding to comments, CMS says it is unaware of data sources for other possible indicators of social risk factors such as income and education that are readily available for all Medicare beneficiaries.

In addition, CMS finalizes changes to dates for the second 12-month segment of the MIPS determination period, which is used in the complex patient bonus when calculating average risk scores and proportion of dual eligible beneficiaries. Beginning with the 2021 payment year the second 12-month segment of the MIPS determination period will begin on October 1<sup>st</sup> of the calendar year preceding the performance period and end on September 30<sup>th</sup> of the year in which the performance period occurs.

#### (b) Final Score Performance Category Weights

As discussed in section III.H.2.h above, CMS finalizes modified performance category weights for the 2021 payment year. Table 53, reproduced below, shows the previously adopted weights for the transition year and 2020 payment along with the weights for 2021 payment. Specifically, the quality category weight is decreased from 50 percent to 45 percent and the cost category weight concomitantly increased from 10 percent to 15 percent.

TABLE 53: Finalized Weights by MIPS Performance Category and MIPS Payment Year

Performance Category	Transition Year	2020 MIPS Payment Year	2021 MIPS Payment Year
Quality	60%	50%	45%
Cost	0%	10%	15%
Improvement Activities	15%	15%	15%
Promoting Interoperability	25%	25%	25%

Flexibility for Weighting Performance Categories. CMS codifies previously adopted policies for determining when there are sufficient measures applicable and available for the quality and cost performance categories and continues them for subsequent payment years. Under the MIPS, CMS has the authority to assign different performance category scoring weights based on the extent to which the category is applicable to the type of clinician involved and the measure or activity is applicable and available to the type of clinician involved. Similarly, policies previously adopted for assigning a zero weight to the promoting interoperability category and redistributing that weight to other categories are continued. CMS continues to believe that all MIPS eligible clinicians have sufficient activities applicable and available, except in the case of extreme and uncontrollable circumstances.

<u>Reweighting for Extreme and Uncontrollable Circumstances</u>. A few modifications are finalized to the previously adopted policies regarding clinicians experiencing extreme and uncontrollable circumstances.

• Beginning with the 2019 performance period, an eligible clinician who submits an application for reweighting based on extreme and uncontrollable circumstances and also submits data on quality measures or improvement activities will be scored on the submitted data and the categories will not be reweighted. In the case of a clinician submitting quality codes on claims which might occur prior to the extreme circumstance, no total score will be calculated unless they also submitted data for the improvement activities or promoting interoperability categories. Administrative data used to calculate the cost category measures and some quality measures are not included in this policy, as CMS says it would be inappropriate to void a reweighting application based on receipt of administrative data.

• For groups submitting reweighting applications for extreme and uncontrollable circumstances, CMS will apply the policy previously finalized for virtual groups. That is, CMS will evaluate whether sufficient measures and activities are applicable and determine whether to reweight a performance category based on the information provided for the individual clinicians and practice locations affected by the extreme circumstances. This policy begins with the 2018 performance period (2020 payment year).

Reweighting for Clinicians Joining a Practice in the Final 3 Months of the Performance Year. CMS finalizes a new policy for cases in which an eligible clinician joins a new practice during the final three months of the MIPS performance period or joins an existing practice (TIN) that is not participating in MIPs as a group during the final 3 months of the MIPS performance period. In each scenario all four of the performance categories will be reweighted to zero and the clinician will receive a final score equal to the performance threshold and a neutral MIPS payment adjustment. CMS adopts this policy because no data on measures and activities from these clinicians are accessible from its data systems. By contrast, in the case of a clinician joining an existing practice that reports as a group, CMS can accept data for the group, and reweighting is not necessary.

Automatic Extreme and Uncontrollable Circumstances Policy. CMS codifies the policy adopted for the transition year under which it will automatically reweight the performance categories for eligible clinicians who are affected by natural disasters or other extreme and uncontrollable circumstances affecting entire regions or locales. Although the transition policy did not include the cost performance category because it then had a zero weight, this finalizes policy includes all four performance categories. Even if administrative claims data are received and a cost category score could be calculated, CMS will assign a zero weight to this category. This policy is effective beginning with the 2018 performance period/2020 payment year. CMS continues to believe that an automatic policy is not needed for groups. Any group sufficiently impacted by an event should apply for consideration for reweighting under the regular extreme and uncontrollable circumstances policy.

Redistributing Performance Category Weights. CMS codifies previously adopted policies for redistributing performance category weights under the flexibilities discussed above. In general, where possible weights will be redistributed to the quality performance category. Table 54 in the final rule shows the performance category reweighting policies finalized for the 2021 payment determination. CMS had presented an alternative for comment in the proposed rule that would also redistribute weights to the improvement activities category. However, it continues to believe that emphasis on the quality category is appropriate, and there are few cost performance measures for the 2019 performance period. CMS will review reweighting approaches in coming years, including impact on small and rural practices, and the comments it received will be considered.

Performance Category Redistribution Policies for the 2021 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	45%	15%	15%	25%
Reweight One Performance Category				
-No Cost	60%	0%	15%	25%
-No Promoting Interoperability	70%	15%	15%	0%
-No Quality	0%	15%	40%	45%
-No Improvement Activities	60%	15%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	50%	50%
-No Cost and no Improvement Activities	75%	0%	0%	25%
-No Promoting Interoperability and no Quality	0%	15%	85%	0%
-No Promoting Interoperability and no Improvement Activities	85%	15%	0%	0%
-No Quality and no Improvement Activities	0%	15%	0%	85%

#### (c) Final Score Calculation

CMS revises the formula for calculating the final score to reflect its decision (discussed above) to eliminate the to small practice bonus from the final score calculation beginning with the 2021 payment year. Under that policy, the bonus will apply instead to the quality performance category score.

#### j. MIPS Payment Adjustments

# (1) Final Score Used in Payment Adjustment Calculation

Under previously adopted policies, for groups submitting data using the TIN identifier, CMS applies the group final score to all the TIN/NPI combinations that bill under the TIN during the performance period. In this rule CMS finalizes a modification to the timeline under this policy beginning with the 2019 performance period (2021 payment). Specifically, the window is the 15-month period that starts with the second 12-month determination period (October 1 prior to the MIPS performance period through September of the MIPS performance period) and also includes the final 3 months of the performance period year (October 1 through December 31 of the performance period year). For groups submitting data using the TIN identifier, the group final score will be applied to all TIN/NPI combinations that bill under that TIN during the 15-month window. CMS believes that partially aligning with the second 12-month determination period creates consistency with its eligibility policies. (MIPS determination periods are discussed in section III.1.2.b. of this summary.)

#### (2) Establishing the Performance Threshold

The Secretary is required to annually compute a performance threshold for purposes of determining the MIPS payment adjustment factors. The threshold is either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. The statute provides for special rules for the initial 2 years of the MIPS, and as a result of the BBA of 2018, an additional special rule applies for the third year through the fifth year (payment in 2021)

through 2023). The new additional special rule requires the Secretary to increase the performance threshold for each of the three specified years to ensure a gradual and incremental transition to the performance threshold specified for year six (2024).

For 2021 payment, CMS adopts a performance threshold of 30 points, which represents a modest increase over the 15 points established for the 2020 payment year and provides for the required gradual and incremental transition to the estimated 2024 performance threshold. In this final rule, CMS looked at the actual finals scores for the 2017 performance period and found the mean final score was 74.01 points and the median was 88.97 points. CMS estimates that the performance threshold for the 2024 MIPS payment year will likely be higher than 65 points. (This level is within the range of 63.5 and 82.5 points estimated for the proposed rule, which relied on data from the 2017 QPP final rule regulatory impact analysis (81 FR 77514-77536)).

While many commenters did not support the increase in the performance threshold from 15 points in 2020 to 30 points in 2021, CMS believes that if it were to set the performance threshold for 2021 at a level below 30 points the increases required in 2022 and 2023 would be too steep a transition to the 2024 threshold to meet the statutory requirement for gradual and incremental increases. While CMS acknowledges that some policy changes in the final rule may dampen final scores<sup>10</sup>, it believes that there are many ways in which a MIPS clinician, including those newly eligible, can achieve a final score at or above 30 points.

Responding to concerns about solo practitioners and small practices, CMS reviews the special policies available including the small practice bonus, the assignment of 3 points to quality measures that do not meet data completeness criteria, the significant hardship exception for the Promoting Interoperability category and associated reweighting, and special scoring for the improvement activities category.

In the proposed rule CMS sought comment on its approach to establishing a path forward to a performance threshold for the 2024 MIPS payment year, and on estimating the 2024 threshold. The comments received are not described in the final rule but will be considered in the future.

#### (3) Additional Performance Threshold for Exceptional Performance

CMS finalizes the additional performance threshold for exceptional performance for 2021 payment year at 75 points. Clinicians with final scores at or above this threshold are eligible to share in the \$500 million available for additional payments for exceptional performance. The 75-point level is higher than the 70-point threshold previously set for 2020 payment, but below the 80 points CMS had proposed for 2021.

Many commenters had supported retaining a 70-point threshold because policy changes will make it more difficult for clinicians to achieve 80 points. However, CMS believes that based on current data a 75-point threshold is achievable for many clinicians, allows for multiple pathways to exceptional performance, and incentivizes continued improvement. Even recognizing that

<sup>&</sup>lt;sup>10</sup> Changes in the Promoting Interoperability performance category, impact of topped out quality measures, increased weighting in the cost category and the introduction of episode-based cost measures are offered as examples of changes that make it more difficult to achieve a perfect score of 100 percent in a performance category.

policy changes finalized in this rule will tend to lower total scores, CMS projects a mean final score of 69.53 for the 2019 performance period and a median of 78.72.<sup>11</sup>

#### (4) Application of the MIPS Payment Adjustment Factors

# (a) Application to the Medicare Paid Amount for Covered Professional Services

CMS finalizes changes to how the MIPS payment adjustment factor is applied in order to conform to changes enacted in the BBA of 2018. Specifically, instead of continuing to apply the adjustment factor to the to the Medicare paid amount for Part B items and services furnished by the MIPS eligible clinician during the year, beginning with the 2019 payment year the factor will be applied to Part B payments for covered professional services (defined as those services for which payment is made under or based on the Medicare Physician Fee Schedule) and which are furnished by an eligible professional. Conforming changes to the regulatory text are made. The finalized formula multiplies the amount otherwise paid under Part B for covered professional services provided by a MIPS eligible clinician for a payment year by 1 plus the sum of: the MIPS payment adjustment factor divided by 100, and if applicable, the additional MIPS payment adjustment factor divided by 100. Readers are referred to section III.I.2.c which discusses the circumstances under which the MIPS payment adjustment does not apply.

# (b) Application for Non-Assigned Claims for Non-Participating Clinicians

CMS finalizes for the first time a policy regarding application of the MIPS payment adjustment for non-assigned claims for non-participating clinicians. Beginning with the 2019 MIPS payment year, the MIPS payment adjustment will not apply to non-assigned claims for non-participating clinicians, an approach consistent with the policy for application of the value modifier. A non-assigned claim is one where non-participating clinicians choose not to accept assignment for a claim, Medicare makes payment directly to the beneficiary, and the physician collects payment from the beneficiary. If the MIPS payment adjustment was applied to non-assigned claims it would not affect payment to the MIPS eligible clinician; it would only affect Medicare payment to the beneficiary. CMS believes that beneficiary liability should not be affected by the MIPS payment adjustment and does not expect that this policy will affect a clinician's decision to participate in Medicare or to otherwise accept assignment for a particular claim.

# (c) Waiver of the Requirement to Apply the MIPS Payment Adjustment to Certain Payments in Section 1115A Models

CMS finalizes that beginning in the 2019 payment year the MIPS payment adjustment factors (including the additional payment adjustment for exceptional performance) will not apply to certain payments made under a Center for Medicare & Medicaid Innovation (CMMI) model for the duration of the model's testing. CMS makes this proposal using the waiver authority under section 1115A(d)(1) of the Act; it is concerned that without the waiver, the testing and evaluation of the payment and savings impacts of model-specific payments made under CMMI models may not be possible. The waiver will not apply to payments made outside of a CMMI model. CMS

<sup>&</sup>lt;sup>11</sup> These figures are below the actual 2017 performance cited earlier in this section (mean of 74.01 points and median of 88.97 points).

will provide public notice when new model-specific payments subject to the waiver are announced on the QPP website (www.qpp.cms.gov) and in a *Federal Register* notice.

(d) Exclusion of MIPS Eligible Clinicians Participating in the MAQI Demonstration

Also finalized is waiver of MIPS reporting and payment adjustment requirements for certain eligible clinicians participating in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration. CMS announced the MAQI Demonstration in conjunction with the release of the proposed rule and made the demonstration contingent on the waivers being finalized. The MAQI Demonstration will begin in the late fall of 2018 and will operate for 5 years. <sup>12</sup> Beginning the demonstration in 2018 means that eligible clinicians will be evaluated to determine whether they meet the criteria to be excluded from MIPS reporting requirements for the 2018 performance year for the 2020 MIPS payment year. CMS anticipates making these determinations by January 2019 at the latest.

The MAQI Demonstration is designed to test whether excluding MIPS eligible clinicians who participate in certain payment arrangements with Medicare Advantage Organizations (MAOs) from the MIPS reporting requirements and the MIPS payment adjustment will increase or maintain participation in these payment arrangements, which are similar to Advanced APMs. CMS finalizes use of the authority in section 402(b) of the Social Security Amendments of 1968 to waive requirements of section 1848(q)(6)(E) of the Act and the associated implementing regulations to waive the payment consequences of the MIPS and to waive the associated MIPS reporting requirements in 42 CFR part 414, subject to conditions outlined in the demonstration.

In order to attain waiver of the MIPS reporting requirement and payment adjustment, CMS finalizes that the combined thresholds for Medicare payments or patients through Qualifying Payment Arrangements with MAOs and Advanced APMs that a participating clinician must meet match 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 waivers also prohibit reporting under the MIPS by eligible clinicians who participate in the MAQI demonstration, and as a result these clinicians will not receive performance feedback. CMS says this is necessary to prevent a potential gaming opportunity for participating clinicians to intentionally report artificially poor performance under the MIPS while they are operating under waivers from MIPS payment consequences, then later receive artificially inflated quality improvement points under MIPS when the waivers have expired. Clinicians who participate in the demonstration but are not excluded from MIPS (whether through participation in the demonstration or otherwise) continue to be MIPS eligible clinicians who are subject to the MIPS reporting requirements and payment adjustment as usual.

Many commenters urged CMS to use the MAQI Demonstration to allow another path towards QP status and provide eligible clinicians with the 5 percent incentive payment offered to QPs.

<sup>&</sup>lt;sup>12</sup>The demonstration is created using authority under section 402 of the Social Security Amendments of 1968 (as amended). The demonstration announcement is available at: <a href="https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-">https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-</a>

items/2018-07-12.html.

CMS notes that this would have introduced new costs without adequate evidence of offsetting savings from the demonstration's intervention, which it believes would be inappropriate. CMS commits to communicating with clinicians so they can better understand their options under the QPP and Medicare's other value-based arrangements.

#### (e) Example of MIPS Adjustment Factors

Figure 3, copied below from the final rule, illustrates how scores will be converted into adjustment factors for 2021 payment. The finalized performance threshold is 30 points, and the applicable percentage is 7 percent. As shown, clinicians with a final score of 30 receive a 0 percent adjustment. The scale for other scores is not completely linear for two reasons. First, all clinicians with a final score between 0 and ½ of the performance threshold (0 and 7.5 in the example) receive the lowest negative adjustment of -7 percent. Second, the linear sliding scale line for the positive adjustment factor is affected by the budget neutrality scaling factor. If the budget neutrality scaling factor is greater than 0 and less than or equal to 1.0, then the adjustment factor for a final score of 100 would be less than or equal to 7 percent. If the scaling factor is above 1.0, but less than or equal to the specified limit of 3.0, then the adjustment factor for a final score of 100 would be higher than 7 percent. CMS anticipates that with a performance threshold of 30 points, the scaling factor would be less than 1.0 and the payment adjustment for clinicians with a final score of 100 would be less than 7 percent.

CMS indicates that for Figure 3, the illustrative budget neutrality scaling factor is 0.159; MIPS eligible clinicians with a final score of 100 would receive an adjustment factor of 1.11 percent (7.0 percent X 0.159).

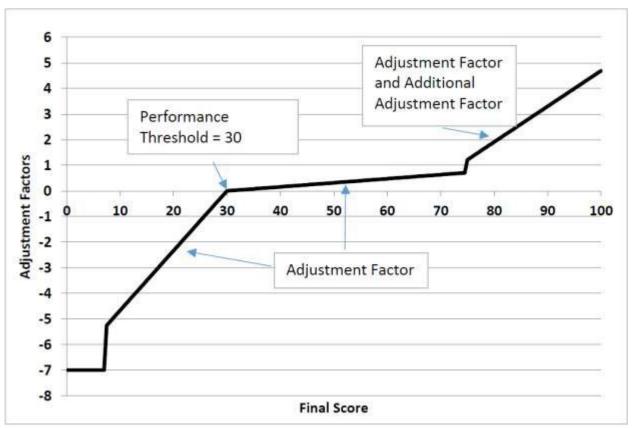
The additional performance threshold is 75. A score of 75 would receive an additional adjustment factor of 0.5 percent and the factor would increase to the statutory maximum of 10 percent for a perfect final score of 100, with a separate scaling factor applied to ensure distribution of the \$500 million payments. CMS also indicates that for Figure A, the illustrative scaling factor for the additional adjustment is 0.358; a clinician with a final score of 100 will receive an additional adjustment factor of 3.58 percent (10 percent X 0.358), and therefore a total adjustment of 4.69 percent (1.11 percent + 3.58 percent).

The actual MIPS payment adjustments will be determined by the distribution of performance scores; the greater the number of clinicians above the threshold, the more the scaling factors will decrease, and vice versa.

Table 56 in the final rule compares the point system and associated adjustment adopted for the transition year, the 2020 MIPS payment year, and the 2021 payment year as finalized.

Readers are referred to the proposed rule for examples of how MIPS eligible clinicians can achieve a final score at or above the finalized 30-point performance threshold. CMS notes that the final scoring algorithms are unchanged from the proposed rule with the exception of the small practice bonus in the quality performance category (increased from 3 points to 6 points. The only policy change reflected in Figure 3 and Table 56 is with respect to the exceptional performance threshold, which is finalized and a score of 75 and not 80 as had been proposed.

FIGURE 3: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2021 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor would be 7 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality, but cannot be higher than 3.0. MIPS clinicians with a final score of at least 75 points would also receive an additional adjustment factor for exceptional performance. The additional adjustment factor is also illustrative. The additional adjustment factor starts at 0.5 percent and cannot exceed 10 percent and is also multiplied by a scaling factor that is greater than zero and less than or equal to 1. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

# k. Third Party Intermediaries<sup>13</sup>

#### (1) General Considerations

CMS proposed to retitle §414.1400 from "Third party data submissions" to the more broadly descriptive "Third party intermediaries". CMS also proposed to require, by amending §414.1400(a)(4), that a third party intermediary's principal place of business and retention of associated CMS data must be within the U.S. This requirement is consonant with federal and agency security standards and policies to which CMS must adhere. Finally, CMS proposed to

<sup>&</sup>lt;sup>13</sup> Previously finalized policies are found at (82 FR 53806 through 53819).

newly define the term "third party intermediary" as an entity that has been approved under §414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the Quality, Improvement Activities, or Promoting Interoperability performance categories.

No commenters addressed the new section title or the requirement for intermediaries (and their associated CMS data) to be located in the US, and CMS finalizes the changes as proposed. Related to the proposed definition, one commenter appeared to advocate that MIPS-eligible clinicians should be prohibited from using online or software-based third party intermediaries that lack attorneys to advise clinicians on the provisions of MACRA; and that MIPS-eligible clinicians should be permitted to use online or software-based third party intermediaries only through an EHR dashboard. CMS judged these suggestions inappropriate and/or out of scope of the final rule. Another commenter suggested that third party intermediaries should be allowed to opt in to MIPS reporting at the TIN/NPI level on behalf of clinicians eligible to do so. (The finalized opt-in policy is discussed in section III.I.3.c(5) of the rule.) CMS agrees that once a clinician or group who will utilize a third party intermediary for MIPS performance data submission has decided to affirmatively elect MIPS participation, the third party intermediary must be able to transmit that decision to CMS on behalf of the clinician(s). CMS, therefore, amends §414.1400(a)(4)(iv) to reflect the requirement for a third party intermediary to be able to transmit a MIPS opt-in election to CMS. CMS proceeds to finalize the new definition of third party intermediary as proposed at §414.1305.

CMS also proposed to update its certification requirements for MIPS data submission. The existing requirement for a third party intermediary to certify all submitted data as true, accurate, and complete to the best of its knowledge would remain unchanged. However, the existing requirement for the certification to occur at the time of data submission and accompany the submission would be changed to require that certification be made in a form and manner and at such time as specified by CMS. CMS proposed the change because recent experience has shown the current requirement not to be operationally feasible for CMS. Having received no comments, CMS finalizes the certification requirements as proposed at §414.1400(a)(5).

#### (2) Modifications to OCDR Requirements

Definition. CMS notes that the number of QCDR self-nominations and their measure submissions have been growing rapidly. CMS proposed beginning with MIPS performance year 2020 to update the definition of a QCDR to read "an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients." CMS believes that the updated definition would help to ensure that QCDR owners have sufficient quality improvement, measure development, and clinical expertise to support continued progress towards higher standards for QCDRs and their measures.

CMS received numerous comments, and many were supportive; a few urged CMS to implement the changed definition for performance year 2019. Concerns and objections were also received, as noted below along with CMS' responses.

- CMS should provide definitions or other clarifications about how clinical and quality measure expertise will be evaluated. CMS offers examples such as serving on an NQF Technical Expert Panel; ability to create and use multi-strata and composite measures; ability to risk-adjust its own QCDR outcomes measures; and ability to reliably collect, retain, aggregate, disseminate, and analyze data from their clinicians.
- CMS should establish processes specific for denying applications and/or measures that appear to lack clinical input rather than an overall requirement for clinical expertise. CMS reiterates that the definition requires QCDRs to demonstrate clinical expertise.
- Allowing technical entities (e.g., health IT vendors) to partner with outside clinical consultants could allow the former to bypass the intent of the clinical expertise requirement. Data from small vendors may be skewed to special populations while data from very large vendors may mask real differences among specialties and patient subpopulations. CMS states that the QCDR definition applies equally whether or not the QCDR partners with others. Appropriate partnerships should mitigate the risks of skewed or uninformative data.
- Meeting the definition will be a barrier to potential entrants to the QCDR market, restricts the free market, and discriminates against QCDRs not dominated by physicians. CMS disagrees, noting that technology-led QCDR owners can meet the definition by gaining clinical expertise through partnerships; partnership structure and agreement details are left to the participants, not dictated by CMS. CMS specifically disagrees with a proposed criterion that the QCDR entity have a physician-majority Board of Directors.
- The new definition and its timeline will force some existing QCDRs to leave the market. CMS will not be "grandfathering" any existing approved QCDRs. CMS will notifythose whose most recently submitted information would not satisfy the new definition. Deferring implementation until performance year 2020 is intended to give QCDRs sufficient time to make changes to satisfy the new definition.
- CMS should create separate definitions for QCDRs sponsored by technology companies and medical specialty societies. CMS disagrees, indicating that the definition sets criteria for all QCDRs that are achievable and that will enable the goal of continuous healthcare quality improvement.
- CMS should develop a process by which a clinician who perceives lack of support from a QCDR (e.g., repeated data reporting issues) can trigger an investigation by CMS. CMS suggests the clinician contact the QPP Service Center at QPP@cms.hhs.gov.

CMS finalizes at §414.1305 the new QCDR definition as proposed, effective for performance year 2020 and subsequent years.

Demonstrating Preparedness. CMS proposed that beginning with the 2020 performance year, a QCDR must have at least 25 participants by January 1 of the year prior to the performance period rather than the current requirement of January 1 of the performance year. CMS believes that satisfying the updated requirement would assure clinicians that their intermediaries are prepared to accept their performance data on a timeline that will result in successful, timely MIPS data submission by the intermediary to CMS on the clinicians' behalf. Many commenters disagreed citing burden creation for QCDRs serving small specialties; inhibition of new QCDR applications; and adequacy of the current requirement to demonstrate preparedness. Suggestions

included dropping the requirement entirely and that CMS reach out to stakeholders to develop a feasible and effective timeline.

CMS disagrees with the objections raised. CMS regards meeting the updated requirement (having 25 participants already successfully submitting data to the intermediary) as a proxy for r QCDRs to demonstrate their prior registry experience and their capability to accept, aggregate, calculate, provide feedback to their participants on, retain, and submit the data to CMS on the behalf of MIPS eligible clinicians. CMS has experienced QCDR lack of preparedness under the current requirement, including QCDRs withdrawing during a performance period. CMS finalizes the proposal without modification by redesignating §414.1400(c)(2) as §414.1400(b)(2)(i) the proposal to improve QCDR readiness to accept data from clinicians in a timely manner for on-time submission to CMS.

QCDR Self-Nomination Period. CMS intends for the approved list of QCDRs and their approved measures to be published annually before the start of each MIPS performance year. QCDRs must seek approval by self-nominating each year and must provide all information required by CMS at the time of self-nomination. Stakeholders and CMS have found the current 90-day self-nomination period, between September 1 and November 1 of the year prior to the performance year, to be insufficient for CMS to complete its reviews and for QCDRs to respond to CMS requests for additional information. CMS, therefore, proposed to revise the self-nomination period to run for 60 days, from July 1 until September 1 of the year preceding the performance period; the change would begin with performance year 2020.

Most commenters were opposed. Some would support only if CMS awarded multi-year approval of QCDRs and their measures. CMS responds that annual approval better supports aligning QCDR measures with final rule policy changes each year, particularly given the relative newness of the MIPS processes and requirements and their continued evolution. Stakeholders cited that the time to prepare the upcoming year's proposal is truncated and impedes the collection of data required to support new measure proposals. CMS counters that the time for QCDRs to respond to follow-up queries from CMS is increased and that relevant publications can be used in lieu of data to support new measure requests. CMS also offers to meet with QCDRs before the self-nomination period opens to provide feedback on potential new measures. Commenters also requested retaining a 90-day period (i.e., July 1 to October 1), deferring implementation until performance year 2021, allowing 30 days for QCDRs to appeal CMS decisions, and prohibiting changes to QCDR-related policies until after the final QPP rule is issued each year; CMS denied all of these requests. CMS finalizes the updated self-nomination period as outlined for implementation beginning with the 2020 MIPS performance year by amending §414.1400(b)(1).

QCDR Measure ID Use. To address stakeholder confusion, CMS proposed to specify that QCDRs must include their CMS-assigned measure ID number when posting their approved QCDR measure's specifications and when submitting data on the measure to CMS. The same ID number must be used by all other QCDRs that have received approval to report that measure to CMS. A supportive comment was received and CMS finalizes the requirement at §414.1400(b)(3)(ii).

QCDR Measure Requirements. CMS proposed to consolidate previously finalized standards and criteria for QCDR measure selection and approval at §414.1400(e) and (f) and at §414.1400(b)(3). CMS further proposed beginning with performance year 2019 to apply additional criteria drawn from the MIPS Call for Quality Measures Process when considering QCDR measures for possible inclusion in MIPS. CMS views doing so as an adjunct to improving the reliability and validity of new measures and accelerating movement towards using consistent, higher quality selection standards and criteria for all MIPS quality measures, including QCDR measures. The proposed additional QCDR measurement criteria are:

- Measures that are beyond the measure concept phase of development.
- Preference given to measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.
- Measures that address the payment for patient and caregiver experience.
- Measures that address efficiency, cost and resource use.
- Measures that address significant variation in performance.

Commenters varied in their support, sharing observations and suggestions including:

- CMS should offer multi-year approval of QCDR measures, enhancing stability and reducing redundancy; minor modifications made by QCDRs during the approval period would not trigger a requirement for measure resubmission.
- CMS should consider setting the expectation that all measures would achieve endorsement by a national, consensus-based entity within a specified time period.
- CMS should create a review process that facilitates sufficient clinical expert review of measure importance and relevance.
- CMS should not foster further alignment of QCDR selection criteria with MIPS Call for Quality Measures process, so as not to discourage QCDRs from submitting measures that fill critical gaps in traditional quality measurement (e.g., outcome measures for rare conditions and events).
- To allow more time for intermediaries to add newly approved measures into inventories and software, CMS should switch to a rolling QCDR measure review and approval process (e.g., like that of the Call for Quality Measures' rolling submission process).
  - o Alternatively, CMS should reduce the Quality category performance periodlength (e.g., 90 days rather than 12 months).
- CMS should require measure developers to include a section for each measure that specifies attribution process and criteria for clinicians and TINs.

CMS responds that multi-year approvals may actually increase redundancy by delaying substitution of newer, more robust measures for existing measures. CMS entertains the concept of an annual comparison of all existing measures against all related measures submitted during the self-nomination period to arrive at an updated and more robust set. CMS intends to support measure harmonization and already requires measure submitters to seek endorsement by a national consensus-based entity. CMS cites existing outreach efforts to provide review and feedback to QCDRs about potential new measures (e.g., calls and meetings with CMS to preview

measures). CMS is committed to facilitating progressively more stringent and meaningful measure quality for all MIPS and QCDR measures. CMS clarifies that QCDRs are asked during measure submission to assign the measure to a National Quality Strategy domain. CMS disagrees that a rolling review process is appropriate for QCDR measures, and notes that rolling review usage is unrelated to the Quality category performance period duration. CMS agrees with the importance of attribution clarity and will incorporate attribution-related feedback to QCDRs as part of CMS measure reviews. CMS notes that reliability and feasibility testing is being considered for future addition as a QCDR measure approval criterion.

CMS finalizes as proposed: consolidation of QCDR selection and approval criteria at §414.1400(b)(3); applying selected criteria from the MIPS Call for Measures Process (listed above) to the QCDR approval process; and implementing the new and additional criteria during the QCDR self-nomination period beginning with MIPS performance year 2019.

Shared Measure Use by Multiple QCDRs. CMS allows one or more QCDRs to request permission from another QCDR to use an existing measure owned by the latter entity—a policy intended to reduce overlap among measures and potentially to enhance benchmark reliability by increasing cohort size for a measure. Some QCDR owners are charging fees to other QCDRs for permission to report on the owner's measure. CMS believes that QCDR measures approved for MIPS reporting, like actual MIPS measures, should be freely available for MIPS reporting by other QCDRs. CMS, therefore, proposed to condition QCDR approval for MIPS reporting on the execution of a license agreement by the measure's owner with CMS beginning with the 2019 MIPS performance year. The agreement would permit any approved QCDR to submit data on the shared measure to MIPS for each applicable payment year. Refusal to enter into a license agreement would trigger rejection by CMS of the owner's measure and, potentially, approval by CMS of a similar measure instead. CMS further proposes to codify that the same CMS-assigned QCDR measure ID must be used by all QCDRs reporting on a shared measure.

Nearly all commenters opposed this proposal; reasons were varied but most commonly related to unsubsidized costs incurred in developing measure; intellectual property rights violations; including uncontrolled sublicensing by CMS or other vendors; insufficient time before implementation for QCDR owners to decide whether to continue in the market; and creating economic disincentives for measure innovation. CMS disagrees with most comments and provides detailed responses. CMS acknowledges suggestions including encouraging licensing agreements between QCDRs (not involving CMS); establishing a CMS pilot program testing how to encourage collaboration among QCDRs; developing and using a "measure complexity score" or a cost-based algorithm to regulate licensing fees; and adopting a model where entities are designated to support specific clinical domains.

CMS is not finalizing the proposal to condition QCDR measure approval in part on the execution by the QCDR of a licensing agreement with CMS beginning with performance year 2019. CMS intends to continue to look for policy solutions to unintended consequences of the current regulations and will arrange listening sessions with stakeholders to better understand their concerns.

# (3) **Oualified Registries: Self-Nomination**<sup>14</sup>

CMS proposed two policy changes regarding self-nomination by qualified registries beginning with performance year 2020:

A qualified registry would be required to have at least 25 participants by January 1 of the year prior to the performance period rather than the current requirement of January 1 of the performance year.

The self-nomination period for qualified registries, currently from September 1 until November 1 of the year prior to the performance year, would instead run from July 1 until September 1 of the year preceding the performance period.

CMS would continue to require that each registry provide all required materials as well as additional CMS-requested information at the time of self-nomination. CMS received no comments on the proposed changes and finalizes the changes as proposed by redesignating §414.1400(h)(2) as §414.1400(c)(2) and amending §414.1400(c)(1).

# (4) Health IT Vendors

Policies have been established previously by CMS regarding health IT vendors (or other authorized third parties) that obtain data from MIPS eligible clinicians (81 FR 77377 through 77382). Health IT vendors are classified as third party intermediaries and are subject to CMS' requirements for intermediaries. Consistent with the new definition of third party intermediary, CMS proposed to codify the definition of a health IT vendor at §414.1305 to read: "an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT)." CMS also proposed to indicate at §414.1400(d) that a health IT vendor seeking approval as a third party intermediary would be required to meet any relevant criteria established by CMS, including data submission in the form and manner specified by CMS.15 CMS received no comments on these changes and finalizes them as proposed.

#### (5) CMS-Approved Survey Vendors

CMS proposed that entities seeking to be survey vendors (e.g., CAHPS surveys) for any CMS-approved MIPS performance period would be required to submit a survey vendor application, in a form and manner specified by CMS, for each MIPS performance period in which the vendor wishes to transmit data. Entities would be required to meet all CMS' deadlines for submitting their applications and all supplemental materials. CMS proposed additional criteria that a potential vendor must demonstrate for performance year 2019 and subsequent years; the vendor must:

• Have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

<sup>&</sup>lt;sup>14</sup> Established policies are described at 82 FR 53815-53818.

<sup>&</sup>lt;sup>15</sup> CMS also notes that a health IT vendor may also be a health IT developer under the ONC Health IT Certification Program. Vendors may maintain a range of data transmission, aggregation, and calculation services or functions (e.g., facilitating health information exchange).

- At least 3 years of experience administering mixed-mode surveys including mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);
- o At least 3 years of experience administering surveys to a Medicare population;
- At least 3 years of experience administering CAHPS surveys within the past 5 years;
- Experience administering surveys in English and one of the following languages Cantonese, Korean, Mandarin, Russian, or Vietnamese;
- Use equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and
- o Employ a program manager, information systems specialist, call center supervisor, and mail center supervisor to administer the survey.
- Have certified it has the ability to maintain and transmit quality data in a mannerthat preserves the security and integrity of the data.
- Have successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors.
- Have submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and
- Have agreed to participate and cooperate, and has required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors.
- Have sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

The few commenters were supportive, and suggested that validated CAHPS survey versions be developed for at least the top ten primary languages used by Medicare beneficiaries. CMS finalizes its proposals at §414.1400(e). 16

# (6) Auditing of Third Party Intermediaries Submitting MIPS Data

CMS does not propose any changes to previously finalized policies concerning audit processes for third party intermediaries submitting MIPS data. CMS notes that the existing provision at §414.1400(j) is redesignated in the final rule as at §414.1400(g) and contains no substantive changes.

<sup>&</sup>lt;sup>16</sup> CMS appears to have made a minor wording change to one criterion (change underlined): "Experience administering surveys in English and <u>at least</u> one of the following languages Cantonese, Korean, Mandarin, Russian, or Vietnamese;

#### (7) Remedial Actions and Termination of Third Party Intermediaries

CMS proposed to consolidate existing relevant policies in a section to be titled "Remedial actions and termination of third party intermediaries" at §414.1400(f) and to amend, clarify, and streamline those policies consistent with the intended functions of this section: 1) identifying noncompliance with third party intermediary criteria, and 2) recognizing issues potentially impacting CMS' ability to accurately use the data submitted by the intermediaries.

CMS proposed to take one or more remedial actions upon determining that a third party intermediary (i.e., a QCDR, health IT vendor, qualified registry, or CMS approved survey vendor) no longer meets one or more of the applicable criteria for their approval by CMS, or has submitted data that is inaccurate, unusable, or otherwise compromised. CMS could determine data to be inaccurate, unusable, or otherwise compromised if the data were found to include TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and to affect more than three percent (but less than 5 percent) of the total number of MIPS eligible clinicians for which data were submitted by the third party intermediary.

CMS proposed that the potential remedial actions available to CMS, after providing written notice to the intermediary, would include (i) requiring submission to CMS by a specified date of a Corrective Action Plan that addresses identified deficiencies or data issues and details efforts to prevent recurrent problems, and (ii) public disclosure of the intermediary's data error rate if that rate is 3 percent or greater, and not removing the error rate from the CMS website until the rate falls below 3 percent.

CMS further proposed to terminate (immediately or with advance notice) a third party intermediary from MIPS data submission for one or more of the following reasons:

- CMS has grounds for remedial action.
- CMS has not received a CAP within the CMS-specified time.
- The intermediary fails to correct the deficiencies or data errors by the CMS-specified date.

Finally, CMS proposed to remove its probation policy along with its definition of probation and all references to probation.

There were relatively few comments as follows:

- CMS should create a safe harbor policy to minimize impact on clinicians when a data issue outside of their control occurs due to actions of their third party intermediary, and automatically consider the clinicians to have satisfied Quality reporting requirements.
- Agreement with removing the probation policy.
- Disagreement with removing the probation policy, allowing CMS to invoke immediate termination without having first applied probation.
- Termination during a performance period would produce undue hardship on the intermediary's eligible clinicians.
- CMS should more clearly define "data error", describe how the data error rate is calculated, and prepare a report differentiating data errors from "other issues" that should be brought to the intermediary's attention.

CMS prefers to deal with data issues on a case-by-case basis than through a safe harbor policy. CMS anticipates taking other remedial action(s) prior to termination but retains immediate termination as an option for use in egregious cases. CMS would consider in its decision-making about termination the impact of the timing of termination relative to an upcoming or ongoing performance period. CMS provides references to additional material about data inaccuracies and data error rates (the 2019 Qualified Clinical Data Fact Sheet and the 2019 Qualified Registry Fact Sheet) located at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Resources.html. CMS clarifies that the 3 percent data error rate threshold is based on the total number of MIPS eligible clinicians for which data were submitted by the third party intermediary. CMS finalizes without modification the proposals at §414.1400(f).

#### (8) Burden Reduction

Maximum and minimum burden estimates for Qualified Registry Self-Nomination are detailed in the rule and summarized in Table 62 in the rule, ranging from \$8,695 to \$40,131 (total for all registries per self-nomination period).

Maximum and minimum burden estimates for QCDR Self-Nomination are detailed in the rule and summarized in Table 63 in the rule, ranging from \$108,590 to \$214,032 (total for all registries per self-nomination period).

## 1. Public Reporting on Physician Compare

#### (1) General Considerations

CMS continues a phased approach to public reporting of MIPS- and APM-related data for QPP year 3 on the Physician Compare Initiative website, reporting 2019 data, as available, in late 2020. Utilization data (information related to items and services furnished to Medicare beneficiaries) also are added annually to the Physician Compare downloadable database. (https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/) To be reported, all data must first meet CMS' established reporting standards (see §414.1395(b)), and clinicians are provided with an opportunity for review and correction before the data are released publicly. Although all information submitted under MIPS is available for public reporting, only selected data will appear on either the public-facing profile pages or in the database to avoid overwhelming website users. CMS continues to make data selection and display decisions through statistical testing and website user testing plus consultation with the Physician Compare Technical Expert Panel. CMS asserts that Physician Compare data reporting encourages quality improvement by clinicians and assists beneficiaries with healthcare decision-making.

#### (2) MIPS Reporting on Physician Compare by Performance Category

*In General.* As finalized for 2018 and all future years, MIPS final scores along with results for each MIPS category (Quality, Cost, Improvement Activities, and Promoting Interoperability) are reported publicly by CMS for all MIPS eligible clinicians. Further, aggregate information for all

eligible clinicians is added to the website periodically, including ranges for final scores and ranges for performance by category.

*Quality*. CMS reaffirms its existing policy that all MIPS Quality performance category measures are available for public reporting. CMS proposed two changes for performance year 2019 intended to encourage the reporting of new measures, as follows:

- Revise §414.1395(c) so that results of newly introduced quality measures will not be publicly reported for the first two years that the measure is in use; and
- Update the terminology for public reporting standards from "submission mechanisms" to "collection types" at §414.1395(b).

Most commenters supported not publicly reporting results of newly introduced quality measures for the first two years in which the measures are used. A few supported alternative times (e.g., one and three years). One commenter suggested that publicly reported measures whose guidelines changed during the performance year be flagged so that the public can consider potential impacts of such changes. Comments also were made supporting data transparency. No comments were received about the proposed terminology change to "collection types".

CMS continues to believe a two-year reporting delay for results of new measures strikes a proper balance between data accuracy and appropriately informing beneficiaries to aid their healthcare decision-making. CMS does not believe flagging measures with changed guidelines is needed since changes significant enough to render a measure no longer reflective of the standard of care will cause the measure to be suppressed from MIPS scoring. In support of data transparency, CMS notes making multiple educational efforts to assist beneficiaries in understanding publicly reported data. CMS finalizes the changes as proposed for the 2019 performance year (at §414.1395(c and b), respectively).

Cost. CMS proposed a single change for performance year 2019 for Cost category reporting: to revise §414.1395(c) so that results of newly introduced cost measures will not be publicly reported for the first two years that the measure is in use. Most commenters were supportive, while a few offered alternative timelines (e.g., one or 3 years). One commenter recommended that the new episode-based cost measures — distinct from the remaining cost measures (e.g., Medicare Spending Per Beneficiary) — not be publicly reported until there is time to gain experience with data collection and analysis. CMS continues to believe a two-year reporting delay for results of new measures strikes a proper balance between data accuracy and appropriately informing beneficiaries to aid their healthcare decision-making. CMS does not believe that the episode-based cost measures should be treated differently from other cost measures. CMS finalizes without modification the proposed two-year deferral of publicly reporting results of newly adopted Cost category measures by revising §414.1395(c).

Improvement Activities. Existing policies provide that successful completion of the Improvement Activities performance category requirements is reflected on Physician Compare as an indicator. In contrast to the Quality and Cost categories, first year activities are publicly reported for this category. CMS did not propose any changes to the MIPS Improvement Activities performance category for performance year 2019.

Promoting Interoperability. An indicator for "high" performance was added to the "successful" indicator for public reporting of 2018 data (appearing in late 2019). CMS proposed to eliminate the "high" performance indicator beginning with 2019 data (to be reported in late 2020), as the differentiation of "high" from "successful" was problematic during user testing. Most commenters were supportive. CMS clarifies that the "successful" indicator applies to all individuals and groups whose Promoting Interoperability scores are above zero. CMS notes that the "high" indicator did not meet standards for public data reporting for 2017. CMS finalizes the proposed deletion of the "high" performance indicator, noting that the indicator will not be reported for 2017, 2018 or 2019 publicly reported data (2017 data will not appear until late in 2018). CMS concludes by stating that no comments were received in response to the proposed rule's invitation to comment about the type of EHR utilization performance stakeholders would like to be added to Physician Compare.

# (3) Benchmarking

*In General*. CMS considers benchmarks as important reference points facilitating comparisons across clinicians by Physician Compare users. For performance year 2018, CMS finalized a policy implementing the Achievable Benchmark of Care (ABC<sup>TM</sup>) methodology for annual use with all MIPS categories to set benchmarks by measure and collection type using the most recently available data for each year. CMS also finalized using the ABC<sup>TM</sup> benchmarks in combination with the equal ranges method in creating 5-star ratings for all available measures. More information about the ABC<sup>TM</sup> and equal ranges methodologies, including the Benchmark and Star Rating Fact Sheet, is available on the Physician Compare website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/Downloads/PC-Benchmark-Star-Ratings.pdf).

Historical Data-Based versus Performance Year-Based Benchmarks. CMS believes that star ratings and their underlying benchmarks aid beneficiary understanding of the Physician Compare data and assist clinicians with understanding their own data, as well as allowing comparing themselves to peers. CMS initially established that benchmarks would be constructed using only the most recently available data (i.e., from the performance year itself) to assure that benchmarks would reflect current measure specifications. This approach, however, precludes benchmark release to clinicians before the performance year starts. Believing that measure stability has increased over time, CMS proposed that benchmarks be built by incorporating historical data (rather than the most recent) into the ABC<sup>TM</sup> methodology, beginning with QPP Year 3 (2019 data for 2020 public reporting). Each measure would use data from a baseline period, defined as the 12-month calendar year that is two years prior to the performance period. (For example, performance year 2019 benchmarks would be calculated using 2017 performance year data and be published by January 1, 2019.) CMS would substitute current performance year data for baseline period data if the baseline period data were unavailable for a measure(s). The historical benchmarks would be published before the beginning of the relevant performance period, permitting clinicians to understand the performance required to receive a 5-star rating before data collection begins.

Some commenters were supportive. Others noted that historical benchmarks may inadvertently incentivize clinicians who were high spenders initially and that MIPS year-to-year measure

variation remains too unstable for historical benchmarking. CMS states that measures for which data do not meet CMS' standards for public reporting will not be reported, providing protection against a number of possible data deficiencies. CMS believes that year-to-year variation should now be at an acceptable level and notes that initial analysis has not found evidence for incentivizing initial high spenders. CMS asserts that the best alternative for situations when historical data are inadequate is to utilize the current performance year for benchmark creation, as has been done in the early years of MIPS. CMS finalizes introducing historical benchmarks where appropriate for 2019 data reported in 2020 and subsequent years.

QCDR Measure Benchmarks. Currently on Physician Compare, star ratings are shown for MIPS measures but not QCDR measures; the latter are publicly reported as percent performance rates. CMS notes that the number of QCDR measures and the extent of data suitable for public reporting is increasing rapidly; CMS asserts that star ratings for QCDR measures would add to their value, enhance website user experience by aligning performance reporting formats, and expand the information available to beneficiaries for healthcare decision-making. CMS, therefore, proposed to determine a benchmark and 5-star rating by measure and collection type for QCDR measures by using the ABC<sup>TM</sup> and equal ranges approaches. CMS proposed a two-step implementation, first using the most recent data (2018 performance data, available for reporting in late 2019) and then transitioning to historical benchmarking (as proposed above for MIPS historical benchmark creation) beginning with 2019 data (available for reporting in late 2020) and continuing for subsequent years.

One commenter was supportive of the proposal. Others were concerned that differences in a QCDR's rating methodology and the ABC<sup>TM</sup>/equal ranges combination would create confusion and possibly mislead patients, and that small QCDR measure sample sizes would be too small for valid public reporting. Also noted was the potential for divergent benchmarks, one for MIPS scoring and one for public reporting. CMS responds that confusion is already inherent since baseline methodology varies by QCDR owner and measure that may be improved by deriving star ratings that are based on a consistent methodology for all measures. QCDR measures will be subjected to the same statistical testing as MIPS publicly reported testing, during which small sample size adjustments are made as indicated. CMS finalizes the proposal to expand star rating creation using the ABC<sup>TM</sup> and equal range approach combination as feasible and appropriate beginning with the performance year-based benchmarking for 2018 data and historical baseline-based benchmarking thereafter as data quality and availability permit.

Voluntary Reporting. CMS proposed no changes to policies for publicly reporting data that are voluntarily submitted for any MIPS category by clinicians not subject to MIPS payment adjustments (e.g., those who meet the low-volume threshold). Any voluntarily submitted data are considered available for public reporting after clinicians are offered a 30-day preview period. During the preview period, the clinicians may opt out of public reporting; their data will be posted should they not opt out during the preview period.

APM Data Reporting. CMS proposes no changes to existing policies. Data will continue to be publicly reported on Physician Compare including the names of eligible clinicians in Advanced APMs, the names and performances of Advanced APMs, and the names and performances of

APMS that are not considered "Advanced" (e.g., Medicare Shared Savings Program Track 1). CMS also will continue to link clinicians and their APMs on the website.

#### 3. Overview of the Alternative Payment Model (APM) Incentive

#### a. Introduction and Background

CMS begins by outlining the key features of the APM incentive payment pathway of the QPP. These features are based upon Section 1833(z) of the Act and regulations finalized in the 2017 QPP final rule (81 FR 77399-77491).

- For payment years 2019 and 2020, eligible clinicians can become Qualifying APM Participants (QPs) under the Medicare Option if their Advanced APM participation (measured by payments or patient counts) exceeds predetermined (statutory and regulatory) thresholds. QPs are excluded from the MIPS portion of the QPP. All Advanced APMs are sponsored by CMS.<sup>17</sup>
- For payment years 2021 and thereafter, eligible clinicians also can reach QP status under the All-Payer Combination Option if their combined participation in Advanced APMs and Other Payer Advanced APMs (measured by payments or patient counts) exceeds predetermined (statutory and regulatory) thresholds. QP status reached under the All-Payer option also confers exclusion from MIPS.
  - Payment arrangements that may qualify as Other Payer Advanced APMs include those between eligible clinicians and Medicare Health Plans, Title XIX programs, CMS Multi-Payer Models, and what CMS terms "Remaining Other Payers".
- For each payment year from 2019 through 2024 in which QP status is achieved, the QP receives a lump sum incentive payment equal to 5 percent of their prior year's estimated aggregate payments for Part B covered professional services.
- Beginning in 2026, QPs receive a higher annual fee schedule update than non-QPs.<sup>18</sup>
  - o No incentive payment or higher update is available for payment year 2025.

CMS goes on to describe the criteria for defining an Advanced APM. The criteria are based on statutory requirements from MACRA and all must be met.

- Participants are required to use CEHRT.
  - o All APM Entities within an Advanced APM must require at least 50 percent of eligible clinicians to use CEHRT to document and communicate clinical care.
- Payment for covered professional services must be based at least in part on quality measures comparable to those of the MIPS Quality performance category.
- Participating APM Entities must bear risk for more than nominal monetary losses <u>or</u> be an expanded Medical Home Model (under section 1115A(c) of the Act).<sup>19</sup>

CMS notes receiving unsolicited general comments about Advanced APMs requesting:

• Accelerated development of Advanced APM opportunities, especially for specialists and non-physician MIPS-eligible clinicians;

<sup>&</sup>lt;sup>17</sup> APMs having payers other than Medicare and meeting similar criteria are termed "Other Payer Advanced APMs".

<sup>&</sup>lt;sup>18</sup> Beginning in 2026, the update to the "qualifying APM conversion factor" is set at 0.75% for QPs and the update to the nonqualifying APM conversion factor is set at 0.25% for non-QPs.

<sup>&</sup>lt;sup>19</sup> As yet, no medical home models have been expanded under Section 1115A(c) of the Act.

- Definition of a clear pathway for clinician transition from MIPS to MIPS APMs to Advanced APMs; and
- Testing and implementation of models recommended by the Physician-Focused Payment Model (PFPM) Technical Advisory Committee (PTAC) to the Secretary, along with provision of feedback and technical assistance to stakeholders developing PFPMs to accelerate the PTAC review process and increase the likelihood of testing by CMS.

CMS responds that several models began during 2018, others added participants, and model development continues. CMS asserts that transitioning to APMs is voluntary for clinicians and that providing transition options allows clinicians to customize their choices of pathways and timelines. CMS pledges to continue outreach and education efforts about APMs. CMS states that testing by the Innovation Center of a PTAC-recommended model exactly as proposed is unlikely, but notes that features of the recommended PFPMs may be incorporated into models developed by the Innovation Center. CMS declines to provide technical assistance to stakeholders prior to model submission and does not believe that the requested 60-day window for the Secretary and CMS to respond to PTAC recommendations is operationally feasible.

Lastly, CMS finalizes a proposed technical revision to the QP definition at §414.1305, rewording the definition to replace the previously deleted term "Advanced APM Entity". No comments on this proposal were received, and CMS states that the rewording has no substantive policy effects.

## b. Advanced APM CEHRT Usage Criterion

Currently, all APM Entities within an Advanced APM must require at least 50 percent of eligible clinicians to use CEHRT to document and communicate clinical care with patients and other healthcare professionals. CMS proposed to increase the required CEHRT usage for performance year 2019 and subsequent years to at least 75 percent. CMS believed the change to be consistent with their Medicare-wide Promoting Interoperability initiative and that nearly all existing Advanced APMs already require CEHRT usage by 75 percent or more of their clinicians.

Commenters who supported the proposal cited CEHRT usage as key to the success of APMs. Other commenters requested delay or phased-in adoption of the increase related to the simultaneous requirement for 2019 that clinicians finish upgrading their EHRs from the 2014 Edition of CEHRT to the 2015 Edition. Some cited ongoing multi-year APM contracts that began under the 50 percent requirement while others cited CEHRT-related operational challenges for small or rural practices. Finally, many commenters observed that EHRs commonly used by non-physician practitioners are not designed to meet certified EHR standards; thus requiring an even higher level of CEHRT usage would create a barrier to Advanced APM participation for many non-physicians.

CMS responds that clinicians have known for several years about the required CEHRT upgrade and cites data showing 9 in 10 clinicians already have 2015 Edition CEHRT available to them from their EHR developer. CMS also notes that the 75 percent requirement applies at the model level, so that an APM entity may have some subgroups (e.g., non-physicians) with lower CEHRT usage yet overall still satisfy the criterion at the entity level. CMS concludes by finalizing as proposed increasing the Advanced APM CEHRT criterion threshold from at least

50 percent to at least 75 percent beginning January 1, 2019 (see §414.1415(a)(i)). CMS will monitor the effect of the increase for unintended effects on small and rural practices as well as non-physician practitioners.

## c. Clarifying MIPS-Comparable Quality Measures

General Quality Measures. Advanced APMs are required to base payment to eligible clinicians on at least one MIPS-comparable quality measure, and CMS has previously set criteria for such measures at §414.1415(b).<sup>20</sup> Having learned of unintended interpretations of the criteria, CMS proposed to revise them for performance year 2020 and subsequent years, retaining those that clearly emphasize that measures must be evidence-based, reliable, and valid, namely: finalized on the MIPS final list of measures; endorsed by a consensus-based entity (e.g., NQF); or otherwise determined by CMS to be evidence-based, reliable, and valid.

Most commenters supported the proposal; some suggested multiple MIPS-comparable measures should be required for inclusion by Advanced APMs. Another suggested that measures endorsed by the Core Quality Measure Collaborative (CQMC) be considered MIPS-comparable. Concern also was raised that allowing CMS alone to determine whether measures are evidence-based, reliable, and valid (as in the third proposed criterion above) effectively bypasses the established vetting processes for quality measures (e.g., NQF endorsement or peer-reviewed publication).

CMS responds that most Advanced APMs utilize multiple MIPS-comparable measures but that requiring only one allows maximum flexibility for Advanced APMs to require measures that are most applicable to their specific patient populations. CMS notes that the NQF is currently the consensus-based entity for endorsing healthcare performance measures for CMS as defined under section 1890(b) of the Act; and thereby believes that CQMC-endorsed measures cannot be considered MIPS-comparable for the purposes of the QPP. Finally, CMS asserts that the Innovation Center's internal committee process for evaluating measures as evidence-based, reliable, and valid does not bypass established vetting processes but instead allows innovative measures to be adopted for use by Advanced APMs before those measures complete the established but slower vetting processes. CMS finalizes the revised criteria at §414.1415(b)(2), effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases clinician payment must either be finalized on the MIPS final list of measures; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.

Outcome Measures. At least one measure upon which Advanced APMs base payment must be an outcome measure unless CMS determines that an applicable outcome measure is not available. CMS proposed that beginning on January 1, 2020, the required outcome measure must also be evidence-based, reliable, and valid, using the same revised criteria described above.

<sup>&</sup>lt;sup>20</sup> The criteria are: used in the MIPS quality performance category; endorsed by a consensus-based entity; developed under the QPP; submitted in response to an annual MIPS Call for Quality Measures; or any other measures so determined by CMS (§414.1415(b)). At least one criterion must be met.

<sup>&</sup>lt;sup>21</sup> CMS refers to OPP measures that are evidence-based, reliable, and valid as "MIPS-comparable".

Commenters were generally supportive of the proposal. One commenter, noting little variation in current surgical outcome measures, suggested an alternative quality framework including facility, patient-reported, registry, and claims-based measures. Another commenter voiced concern that CMS is inappropriately emphasizing outcome over process measures since meaningful outcome measures are lacking for many specialties.

CMS responds that the quality framework for each Advanced APM should incorporate the types of measures that best assess the practice and payment changes being tested in the APM. CMS views the requirement for each Advanced APM to include at least one evidence-based, reliable, and valid outcome measure (as defined by the proposed revised criteria) to be a desirable component of each Advanced APM's quality framework. CMS disagrees that outcome measures are being overemphasized and notes that an Advanced APM is not required to include an outcome measure when no applicable outcome measure meeting the criteria is available in advance of the model's performance start date. CMS finalizes at §414.1415(b)(3), effective January 1, 2020, the proposal that at least one of the quality measures upon which an Advanced APM bases clinician payment must be finalized on the MIPS final list of measures; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid. Similarly, CMS finalizes the proposal that at least one outcome measure upon payment is based must be finalized on the MIPS final list of measures; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.

The changes to standards for MIPS-comparability of both the required quality and outcome measures are not retroactive; models determined to be Advanced APMs for prior performance years would not be affected. CMS adds that MIPS-comparability of future QCDR outcome measures also will be assessed using the revised criteria.

#### d. Financial Risk Standard Setting for QP Performance Periods 2021-2024

Advanced APMs are required to bear more than nominal risk for monetary losses. The generally applicable revenue-based nominal amount standard initially was set at 8 percent or greater for QP Performance Periods 2017-2018 and later extended through 2020. The standard is based on the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities and applies only to those APMs expressing risk in terms of revenue. CMS proposed to retain the 8 percent standard for QP Performance Periods 2021 through 2024. The generally applicable total expenditure-based nominal amount standard was set at 3 percent or greater beginning with 2017 and without a specified date for expiration or increase; no change in this standard was proposed by CMS for 2019.

Many commenters were supportive, noting the value to APM participants of consistency of risk levels over time. A few suggested that the standard be revised to include only average estimated total Part B revenue rather than total Part A and Part B combined. These commenters cited that the APM incentive payment itself is based only on Part B payments and they contended that basing the risk requirement on Part A and Part B revenues combined disadvantages APM entities with hospital participants (requires greater risk-bearing). Some commenters advocated for a lower revenue-based risk standard for small and rural practices. Others asked for the investment/business risk accepted by non-physician practitioners when joining Advanced APM

entities to be counted along with the APM's performance-based risk toward meeting the financial risk-bearing standard.

CMS states that basing the generally applicable revenue-based nominal amount risk-bearing standard only on Part B revenue would be inappropriate for APM entities having both Part A and Part B revenues, and that entities whose participants earn only Part B revenue are not affected by basing the standard on combined Part A and Part B revenues. CMS will monitor the revenue standard's impact on small and rural practices to consider whether creating a special lower standard is warranted. Finally, CMS repeats prior assertions that (1) creating an objective and enforceable business risk standard would be inordinately complex and (2) costs associated with business risk do not correlate with an APM entity's performance, so that incorporating business risk into performance-based APM financial calculations would not be appropriate.

CMS finalizes, as proposed, maintaining the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Part A and Part B revenue of all APM Entity providers and suppliers for QP Performance Periods 2021 through 2024 by amending §414.1415(c)(3)(i)(A). CMS also notes having solicited input on whether it should consider raising the revenue-based nominal amount standard to 10 percent, and the expenditure-based nominal amount standard to 4 percent starting for QP Performance Periods in 2025 and subsequent years. CMS states that the supportive comments received will be considered in future decision-making about raising the generally applicable nominal amount standards.

#### e. QP and Partial QP Determinations: Operational Changes

Claims run-out period. CMS performs QP status determinations at three snapshot dates during each performance year (March 31, June 30, and August 31). A clinician meeting any QP threshold (e.g., patient count) at any snapshot date earns QP status for the entire year. QP determinations include a 90-day claims run-out so that status results are released about 4 months after the snapshot dates. Consequently, August 31 snapshot results are not available until just before the start of the upcoming MIPS data submission period on the following January 1. For clinicians who unexpectedly learn that they have failed to reach QP status, little time remains to ensure that their MIPS performance data are complete and ready for submission. CMS proposed to reduce the claims run-out period to 60 days beginning in 2019, allowing earlier determination of QP status. Claims analysis by CMS showed that the percentage of completely processed claims dropped by only 0.5 percent with the shorter run-out period, suggesting that few if any status determinations would be substantively and negatively impacted.

Many commenters supported shortening the claims run-out period to accelerate the QP determination process, citing the importance of knowing as soon as possible that QP status has been achieved for the year or that MIPS participation will be required. CMS finalizes without modification the proposal to allow for claims run-out for 60 rather than 90 days before making QP status determinations beginning with the March 31, 2019 snapshot date.

MIPS election by Partial QPs. MIPS-eligible clinicians achieving Partial QP status may elect to be exempt from MIPS participation for that year. Clinicians achieving Partial QP status as part of an APM Entity group are treated as MIPS-exempt for the year unless the APM Entity

explicitly elects to participate at the group level in MIPS. Clinicians who become Partial QPs as individuals, however, are considered MIPS-exempt by inference -- that is, only if they do not submit any data to MIPS during the year. CMS proposed to align the entity-level and individual-level Partial QP election processes by requiring an explicit, affirmative choice for MIPS participation in all cases; otherwise the group or individual, respectively, would be treated as MIPS-exempt.

Most commenters supported the proposal while one found it potentially confusing, believing that some clinicians might not be aware of having achieved Partial QP status and the process for MIPS exemption. The latter commenter outlined an alternative approach in which CMS would calculate a MIPS final score for each individual clinician Partial QP; the score would then be used only if it generated a positive payment adjustment for the clinician (i.e., a negative payment adjustment would not be applied to a Partial QP). CMS responds that clinician confusion under the CMS proposal should be minimal since QP status for each clinician is readily available through the QPP website, and views the CMS proposal is operationally simpler. CMS, therefore, finalizes that an individual clinician who does not make an explicit affirmative election to participate in MIPS will be treated as MIPS-exempt.

# f. Continued Implementation of the All-Payer Combination Option

#### (1) Overview

Beginning with QPP payment year 2019, MIPS-eligible clinicians also can reach QP status under the All-Payer Combination Option if their combined participation in Advanced APMs (i.e., CMS-sponsored) and Other Payer Advanced APMs, as measured by payments or patient counts, exceeds predetermined statutory and regulatory thresholds.<sup>22</sup> OP status reached under the All-Payer option confers exclusion from MIPS. Payment arrangements potentially qualifying as Other Payer Advanced APMs include those between eligible clinicians and Medicare Health Plans, Title XIX programs, CMS Multi-Payer Models, and what CMS terms "Remaining Other Payers" (e.g., commercial payers). CMS reviews in detail the policies and processes applicable to the All-Payer option as finalized in prior QPP rules. Determinations of Other Payer Advanced APM status are made through the Payer Initiated and Eligible Clinician Initiated processes; requests for QP status determinations under the All-Payer option also are handled through these two processes. For 2019 CMS proposed to extend processes and timelines already developed for obtaining and using information to make determinations about payment arrangements involving Title XIX, Medicare Health Plans, or CMS Multi-Payer Models, to the Remaining Other Payers category. <sup>23</sup> CMS also made proposals to continue aligning Advanced APM and Other Paver Advanced APM policies.

<sup>&</sup>lt;sup>22</sup> Tables 57 and 58 in the rule show the thresholds; Figures 4 and 5 depict the QP determination decision trees by payment year for both the Medicare and All-Payer Combination options.

<sup>&</sup>lt;sup>23</sup> The 2018 finalized All-Payer Combination policies are available at 82 FR 53874-53876 and 82 FR 53890-53891.

# (2) Other Paver Advanced APM Criteria

Increasing CEHRT Usage. Analogous to Advanced APM Entities, all APM Entities within an Other Payer Advanced APM must require at least 50 percent of their eligible clinicians to use CEHRT to document and communicate clinical care with patients and other healthcare professionals. CMS proposed the same CEHRT usage criterion increase for Other Payer Advanced APMs, from at least 50 percent to at least 75 percent, as was proposed for Advanced APMs. However, the Other Payer proposed CEHRT usage increase would start in 2020 rather than the proposed 2019 start date for Advanced APMs.

While a few commenters supported the proposal, many viewed the increase as burdensome as well as premature given that Other Payer Advanced APM participation by clinicians will not begin until 2019. Some commenters suggested phased implementation to accommodate multi-year APM contract cycles already underway. CMS responds that the widespread adoption of CEHRT argues against added burden from increasing the required usage. CMS also notes that the 2020 start date allows enough time to adjust multi-year contracts as needed. CMS finalizes the proposal to raise the Other Payer Advanced APM CEHRT usage criterion as proposed to at least 75 percent beginning with performance year 2020.

Documenting CEHRT Usage. CMS has learned that CEHRT usage is common within Other Payer Advanced APMs but also that payer-clinician payment arrangements often do not specify that CEHRT be used. CMS, therefore, proposed that each Other Payer Advanced APM or its clinicians must provide evidence, starting in 2019, that the mandated level of CEHRT minimum usage is being required of participants, even when usage is not specified in payment arrangement documents. Commenters were supportive and CMS finalizes the proposal at §414.1420(b).

MIPS-Comparable Quality Measures. Other Payer Advanced APMs are required to base clinician payment on at least one MIPS-comparable quality measure, and on at least one available and applicable outcome measure that also is MIPS-comparable. CMS proposes to modify the comparability criteria to parallel those proposed for usage by Medicare's Advanced APMs: finalized on the MIPS final list of measures; endorsed by a consensus-based entity (e.g., NQF); or otherwise determined by CMS to be evidence-based, reliable, and valid. The revised criteria would become effective beginning on January 1, 2020. The changes would not be retroactive; models already determined to be Other Payer Advanced APMs using the prior criteria would not be affected. CMS notes that MIPS-comparability of future QCDR outcome measures also would be assessed using the revised criteria.

Commenters were few but generally supportive. One commenter suggested that all MA Star Rating measures be deemed evidence-based, reliable, and valid.<sup>24</sup> CMS responds by stating a belief that all active MA Star Rating quality measures are in fact evidence-based, reliable, and valid for use at the health plan level, but that changing a measure's unit of analysis to the provider level may affect a measure's reliability and validity. CMS goes on to finalize the proposal for revisions to the MIPS-comparability criteria for Other Payer Advanced APM quality and outcome measures at §414.1420(c)(2 and 3).

<sup>24</sup>MA plans meeting the relevant criteria are considered Other Paver Advanced APMs rather than Advanced APMs.

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Financial Risk Standard Setting. Other Payer Advanced APMs are required to bear more than nominal risk for monetary losses. The Other Payer generally applicable revenue-based nominal amount standard initially was finalized as at least 8 percent for QP Performance Periods 2019-2020 and as applicable only to models that expressly define risk in terms of revenue. CMS proposed to extend the 8 percent revenue-based standard through performance period 2024. The expenditure-based nominal amount standard for Other Payer Advanced APMs initially was set at 3 percent or greater beginning with 2017 without a specified date for expiration or increase, and no change was proposed by CMS for 2019. Commenters supported the proposal. CMS finalizes maintaining the generally applicable nominal amount revenue-based standard for Other Payer Advanced APMs at 8 percent for QP Performance Periods 2021 through 2024 byrevising §414.1420(d)(3)(i).

Investment Payments. Stakeholders have asked that business risk costs (e.g., care coordinators, IT acquisition and data analytics) be included by CMS when implementing the Other Payer Advanced APM financial risk standards. CMS did not propose to do so for 2019 nor specifically solicit comments on this topic. CMS, however, received and reviewed related comments. Commenters expressed concerns that CMS continues not to include investment payments in the definition and calculation of risk, failing to acknowledge the sizeable investments in start-up and overhead costs incurred by APM Entities and clinicians when operating APMs. Some suggested that CMS should develop a method for identifying and quantifying investment risk.

CMS reiterates that investment/business risk costs associated with Other Payer Advanced APM participation are not counted towards meeting risk standards. CMS maintains that creating an objective, enforceable nominal amount business risk standard would be inordinately complex. CMS also asserts that business risk costs do not correlate with an APM entity's performance, so that incorporating business risk into performance-based APM financial calculations would not be appropriate. CMS does note that Other Payer Advanced APM payment arrangements can be structured in ways that recognize investment/business costs including:

- Partial pre-payment of expected shared savings is made to entities and/or clinicians (analogous to the Medicare ACO Investment Model<sup>26</sup>); or
- Payment is made specifically to encourage participating APM Entities to continue to make staffing, infrastructure, and operations investment as a means of practice transformation.

However, CMS emphasizes that these structured investment payments will not be considered financial risk when CMS determines if an entity's payment arrangement meets the Other Payer Advanced APM financial risk criterion.

# (3) Other Payer Advanced APM Multi-Year Determinations

Individuals or APM Entities are responsible for submitting the information necessary for CMS to perform Other Payer Advanced APM determinations; the payers involved may voluntarily

<sup>&</sup>lt;sup>25</sup> The Other Payer Advanced APM generally applicable nominal financial risk standard also mandates a marginal risk of at least 30 percent and a minimum loss rate of no more than 4 percent. No changes to these requirements were proposed for 2019.

<sup>&</sup>lt;sup>26</sup> More information is available at https://innovation.cms.gov/initiatives/ACO-Investment-Model.

submit the information on behalf of their participants.<sup>27</sup> Determinations are valid for one year only. Stakeholders have told CMS that annual submission is burdensome, noting that other payers often execute multi-year contracts. CMS proposed to retain annual submission beginning with submission periods for performance 2020,<sup>28</sup> with modifications.

- Having received an initial Other Payer Advanced APM determination, a requester whose
  initial submission described a multi-year payment arrangement subsequently would only
  be required for each successive year to provide CMS with information about any changes
  to the arrangement relevant to the established criteria for Other Payer Advanced APMs
  (e.g., CEHRT usage).
- In the initial submission for a multi-year arrangement, the requester must agree that the official certifying the submission will review the submitted information at least once annually; will identify any changes from the initial submission; and will submit updated information to CMS for any changes relevant to the established Other Payer Advanced APM criteria.
- Absent receiving changes involving the established criteria for a given year, CMS would continue the initial determination of Other Payer Advanced APM status for that year and each successive year until the earlier of the end of the multi-year arrangement or 5 years.

Commenters supported all of the provisions of the modified proposal. CMS finalizes the proposal as modified for both the Payer Initiated and Eligible Clinician Initiated processes for requesting Other Payer Advanced APM determinations beginning performance year 2020.

# (4) Remaining Other Pavers Process and Timeline

In 2018, CMS finalized processes and timelines for making Other Payer Advanced APM determinations involving Title XIX, Medicare Health Plans, and CMS Multi-Payer Models. CMS deferred, however, establishing policies for the Remaining Other Payers (e.g., commercial and private plans) until 2019, other than finalizing that those payers could begin requesting determinations prior to the start of the 2020 QP performance period (January 1, 2020) and each year thereafter. For 2019 CMS proposed process details for determination requests by the remaining payers through the Payer Initiated process.

- The process would be voluntary.
- The remaining payers would be required to submit their requests for determinations using a form adapted for their use from the existing Payer Initiated Submission Form.
- The Remaining Other Payers Submission Period would open on January 1 and close on June 1 of the calendar year preceding the relevant QP performance period.
- The requesting payer would be notified by CMS if the information submitted is incomplete and given 15 business days to respond.
- Payers would be notified promptly of determination decisions; decisions would be final.
- CMS would add Remaining Other Payer Advanced APMs to the Other Payer Advanced APM List maintained on the CMS website.

<sup>&</sup>lt;sup>27</sup> Individuals, entities, and pavers submitting information are all termed "requesters".

<sup>&</sup>lt;sup>28</sup> Submission periods occur in 2019 and 2020 for the 2020 performance period.

CMS notes that comments were few but supportive. CMS finalizes the proposed process details for Remaining Other Payer Advanced APM determinations without modification. Finalized timelines for determination requests by all payer categories under both the Payer Initiated and Eligible Clinician Initiated processes are summarized in Table 59 in the rule, reproduced below.

TABLE 59: Finalized Other Payer Advanced APM Determination Process for								
Medicaid, Medicare Health Plans, and Remaining Other Payers for QP Performance								
Period 2020								
	Payer Initiated Process	Date	Eligible Clinician (EC) Initiated Process*	Date				
	Guidance sent to states, then Submission Period Opens	January 2019	Guidance made available to ECs, then Submission Period Opens	September 2019				
	Submission Period Closes	April 2019	Submission Period Closes	November 2019				
Medicaid	CMS contacts states and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and states and posts Other Payer Advanced APM List	December 2019				
	Guidance made available to Medicare Health Plans, then Submission Period Opens	April 2019	Guidance made available to ECs, then Submission Period Opens	September 2020				
Medicare	Submission Period Closes	June 2019	Submission Period Closes	November 2020				
Health Plans	CMS contacts Medicare Health Plans and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and Medicare Health Plans and posts Other Payer Advanced APM List	December 2020				
	Guidance made available to Remaining Other Payers, then Submission Period Opens	January 2019	Guidance made available to ECs, then Submission Period Opens	September 2020				
Remaining Other Payers	Submission Period Closes	June 2019	Submission Period Closes	November 2020				
	CMS contacts Remaining Other Payers and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and Remaining Other Payers and posts Other Payer Advanced APM List	December 2020				

<sup>\*</sup>Note that APM Entities or eligible clinicians may use the Eligible Clinician Initiated Process.

# (5) CMS Multi-Paver Models Process Change

CMS previously established that payers having payment arrangements aligned with a CMS Multi-Payer Model could request Other Payer Advanced APM determinations regarding their aligned arrangements using model-specific forms through the Payer Initiated process. CMS proposed to eliminate this submission option for performance year 2020 and subsequent years.

Instead, the aligned payers would use the proposed Remaining Other Payer process, if finalized, or the already finalized Title XIX or Medicare Health Plans request processes, whichever is most applicable to their specific payment arrangement. CMS received no comments on this proposal and finalizes the proposal without modifications.

# (6) <u>Threshold Scores for OP Status Determinations under the All-Payer Combination</u> Ontion

Background. Beginning with performance year 2019, eligible clinicians may become QPs under the All-Payer Combination Option as well as under the already established Medicare Option. The latter includes participation only in Advanced (Medicare-sponsored) APMs while the former combines Medicare Option participation with Other Payer Advanced APM participation. CMS previously finalized that under the All-Payer Combination option, clinicians may request their QP determinations to be made at the individual level while APM Entities may request assessment at the APM Entity (group) level. QP status will be determined at both levels when both the individual and the entity submit requests; QP status will be awarded based upon the higher of the two threshold scores.<sup>29</sup> However, eligible clinicians for whom QP status is assessed under the Medicare Option solely at the individual level, also will be assessed only at the individual level under the All Payer Combination Option.<sup>30</sup> Threshold scores are calculated for three snapshot dates in each performance year (March 31, June 30, and August 31) for clinician groups on Advanced APM Participant Lists and for individual clinicians on Affiliated Practitioner Lists. 31 At both the individual and entity levels. CMS performs sequential OP status determinations in the following order, using only those methods for which complete data are available: Medicare Option payment method then patient count method followed by All-Payer Combination option payment method then patient count method. An individual or group can reach QP status by meeting the threshold score for any one of these determinations.

TIN level QP Determinations. For performance year 2019, CMS proposed to add an alternative under which TIN-level QP status determinations could be requested under the All-Payer Combination Option. The TIN-level alternative would only apply when all clinicians who have reassigned their billing rights under the TIN participate in the same (single) APM Entity. Further, the TIN-level alternative would apply only if the entire TIN has met the Medicare threshold portion of the All-Payer Combination option based upon the TIN's participation in a single (Medicare-sponsored) Advanced APM entity. CMS proposed to utilize the clinician's highest threshold score achieved (individual, TIN, or APM Entity level) when making QP status decisions. CMS received many positive comments and finalizes as proposed the option for status determinations under the All-Payer option to be made at the TIN level (as well as at the individual and APM Entity levels). CMS also finalizes that the highest threshold score achieved will be used in making final QP status determinations.

<sup>&</sup>lt;sup>29</sup> Threshold Score calculations are discussed in detail at 81 FR 77453-77458, 81 FR 77474-77478, and 82 FR 53876-53892.

<sup>&</sup>lt;sup>30</sup> These are clinicians in Advanced APMs for which QP determinations are guided by an Affiliated Practitioner List, as well as those participating in multiple Advanced APM entities when no single entity achieves QP status through group-level assessments.

<sup>&</sup>lt;sup>31</sup> Affiliated Practitioner Lists are used in lieu of APM Participant Lists when the APM participants are hospitals (e.g., Comprehensive Care for Joint Replacement, CJR).

Relationship between Threshold Scoring and Payment and Patient Count Calculations. The All-Payer Combination Option has Medicare and Other Payer component thresholds that must each be met. CMS asserts that some stakeholders remain confused about how the payment and patient count methods are used in the threshold scoring process under the All-Payer option. CMS, therefore, in the proposed rule's preamble stated that clarification would be provided by adding §414.1440(d)(4); doing so would eliminate ambiguity and would reaffirm the existing process to be:

- The minimum Medicare threshold needed to qualify for an All-Payer option QP determination may be calculated using either payments or patient counts.
- The subsequent Other Payer calculation also may use either payments or patient counts, regardless of the method used for the minimum Medicare calculation.
- For both the minimum Medicare and subsequent Other Payer threshold calculations, the method most advantageous to the clinician will be utilized in QP calculations.

However, in the regulation text of the proposed rule, CMS added the clarifying language by amending §414.1440(d)(1) rather than adding new section §414.1440(d)(4). Commenters supported the clarifying language. CMS is finalizing adding clarifying language consistent with the policy articulated above, with the technical correction of doing so by amending §414.1440(d)(1) instead of adding new section §414.1440(d)(4).

Weighting Methodology. For the Medicare component of QP threshold scoring under the All-Payer option, CMS previously established a weighting methodology to apply when a clinician's entity-level score exceeds his or her individual-level score.<sup>32</sup> The methodology is designed to credit the clinician with the entity score for the Medicare patients he or she treated under that entity, regardless of whether his or her All-Payer Combination total threshold score (Medicare and Other Payer components) is calculated at the individual or entity level. CMS proposed for 2019 to extend the weighting methodology for use when a TIN's Entity-level Medicare component threshold score exceeds its TIN-level score, using the formula below. CMS would calculate the TIN's Medicare component QP threshold score twice (with and without the weighting multiplier), and use the higher result when calculating the total All-Payer threshold score for the TIN. The weighting methodology would only apply to a TIN when that TIN is a subset of the eligible clinicians in the APM Entity.

(APM Entity Medicare Threshold Score x TIN Medicare Payments or Patients) + TIN Other Payer Advanced APM Payments or Patients

TIN Payments or Patients (All Payers except those excluded by statute, e.g., Department of Defense)

Commenters supported the weighting methodology extension and CMS finalizes the extension and the associated formula.

<sup>&</sup>lt;sup>32</sup> A full explanation of the methodology is provided in the 2018 QPP final rule (82 FR 53881-53882), and example calculations are discussed at 82 FR 53882 using simulated data from Table 43.

Technical Corrections. CMS proposed several corrections to rectify technical and typographical regulation text disparities. Of note, CMS reconciles risk percentage disparities involving §§414.1420(d)(3)(i) and 414.1420(d)(3)(ii)(B) so that the regulation text correctly reflects that the total risk criterion percentage for an Other Payer Advanced APM to bear must be at least 3 percent of the expected expenditures for which the APM is responsible. Several supportive comments were received. CMS finalizes the risk percentage technical correction (as well as all others as outlined in the proposed rule).

# (g) Burden Estimates Related to the APM Incentive Payment Program

Updates to previous burden estimates are provided below:

- Partial QP Elections: Increase to APM Entities of \$1,431;
- Payer Initiated Process: Decrease to Medicaid, MA and other payers of \$75,803; and
- Eligible Clinician Initiated Process: Increase to APM Entities and clinicians of \$66,885.

One new burden estimate has been added:

• All-Payer Combination Option QP Determinations: New, to APM Entities, TINs, and clinicians of \$165,902.

### IV. Regulatory Impact Analysis

### A. RVU Impacts

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than \$20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, CMS makes adjustments to preserve budget neutrality.

CMS estimates of changes in Medicare allowed charges for PFS services compare payment rates for 2018 with payment rates for 2019 using 2017 Medicare utilization for all years. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician would be different from the average, based on the mix of services the physician provides. As usual, CMS asserts that the average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

Prior to 2015, the annual update to the PFS conversation factor (CF) was previously calculated based on a statutory formula (the Sustainable Growth Rate methodology that was largely overridden each year by Congressional action). MACRA established the update factor for calendar years 2015 through 2025. For 2019, the specified MACRA update had been 0.5 percent, before applying other adjustments. Section 53106 of the Bipartisan Budget Act of 2018 revised the update adjustment factor for 2019 to 0.25 percent before applying any other adjustments.

The CF for 2019 is \$36.0391, which reflects the 0.25 percent update adjustment factor specified under BBA of 2018 and a budget neutrality adjustment of -0.14 percent (2018 conversion factor of \$35.9996\*1.0025\*0.9986). The 2019 anesthesia conversion factor is \$22.2730, which reflects the same adjustments and an additional adjustment due to an update to the malpractice risk factor for anesthesia specialty. See Tables 92 and 93 from the final rule, are reproduced below.

Table 92: Calculation of the Final 2019 PFS Conversion Factor						
Conversion Factor in effect in 2018 \$35.9996						
Statutory Update Factor	0.25 percent (1.0025)					
2019 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)					
2019 Conversion Factor \$36.0						

TABLE 93: Calculation of the Final 2019 Anesthesia Conversion Factor						
2018 National Average Anesthesia Conversion		\$22.1887				
Update Factor	0.25 percent (1.0025)					
2019 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)					
2019 Practice Expense and Malpractice Adjustment	0.27 percent (1.0027)					
2019 Conversion Factor		\$22.2730				

Table 94 (included at the end of this section) shows the estimated impact of changes in the components of the RVUs on total allowed charges, by specialty. The allowed charges shown in the table are the Medicare PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary).

#### 2019 PFS Impact Discussion

The most widespread specialty impacts of the RVU changes are generally related to changes to RVUs for specific services resulting from the misvalued code initiatives, including the establishment of RVUs for new and revised codes. CMS notes that the estimated impacts for many specialties differ significantly between the proposed and final rules. This is due in large part to CMS not finalizing its E/M proposal for 2019 that would have established a single E/M payment rate for new patients and a single PFS rate for established E/M visits levels 2-5 as well as other adjustments.

Some specialties, including, for example, clinical psychologists, vascular surgery, interventional radiology, and podiatry will see increases relative to other specialties. CMS attributes these changes to increases in value for particular services, updates to supply and equipment pricing, and implementation of new payment policies associated with communication technology. Other specialties, including diagnostic testing facilities, independent labs, pathology, and ophthalmology will experience decreases in payments relative to other specialties for similar reasons as well as continued implementation of code-level reductions being phased-in over several years (e.g., allocation of indirect PE for some office-based services).

Column F of Table 94 shows the estimated 2019 combined impact on total allowed charges by specialty of all the RVU and other changes. These impacts range from an increase of 3 percent for clinical psychologists, increase of 2 percent for clinical social worker, interventional radiology, podiatry, and vascular surgery to a decrease of 5 percent for diagnostic testing facility, and decrease of 2 percent for independent laboratory and pathology.

TABLE 94: 2019 PFS Estimated Impact on Total Allowed Charges by Specialty

TABLE 74. 2017 ITS Estimated I						
(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact*	
Allergy/Immunology	\$239	0%	-1%	0%	-1%	
Anesthesiology	\$1,982	0%	0%	0%	0%	
Audiologist	\$68	0%	1%	0%	1%	
Cardiac Surgery	\$293	0%	0%	0%	0%	
Cardiology	\$6,616	0%	0%	0%	0%	
Chiropractor	\$754	0%	-1%	0%	-1%	
Clinical Psychologist	\$776	0%	3%	0%	3%	
Clinical Social Worker	\$728	0%	3%	0%	2%	
Colon and Rectal Surgery	\$166	0%	1%	0%	1%	
Critical Care	\$342	0%	-1%	0%	-1%	
Dermatology	\$3,489	0%	1%	0%	1%	
Diagnostic Testing Facility	\$734	0%	-5%	0%	-5%	
Emergency Medicine	\$3,121	0%	0%	0%	0%	
Endocrinology	\$482	0%	0%	0%	0%	
Family Practice	\$6,207	0%	0%	0%	0%	
Gastroenterology	\$1,754	0%	0%	0%	0%	
General Practice	\$428	0%	0%	0%	0%	
General Surgery	\$2,090	0%	0%	0%	0%	
Geriatrics	\$197	0%	0%	0%	0%	
Hand Surgery	\$214	0%	0%	0%	0%	
Hematology/Oncology	\$1,741	0%	-1%	0%	-1%	
Independent Laboratory	\$646	0%	-2%	0%	-2%	
Infectious Disease	\$649	0%	0%	0%	-1%	
Internal Medicine	\$10,766	0%	0%	0%	0%	
Interventional Pain Mgmt	\$868	0%	1%	0%	1%	
Interventional Radiology	\$384	1%	1%	0%	2%	
Multispecialty Clinic/Other Phys	\$149	0%	0%	0%	0%	
Nephrology	\$2,188	0%	0%	0%	0%	
Neurology	\$1,529	0%	0%	0%	0%	
Neurosurgery	\$802	0%	0%	0%	0%	
Nuclear Medicine	\$50	0%	-1%	0%	-1%	
Nurse Anes / Anes Asst	\$1,242	0%	0%	0%	0%	
Nurse Practitioner	\$4,060	0%	0%	0%	0%	
Obstetrics/Gynecology	\$637	0%	0%	0%	0%	
Ophthalmology	\$5,451	0%	-1%	0%	-1%	

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes		(E) Impact of MP RVU Changes	(F) Combined Impact*
Optometry	\$1,309	0%	-1%	0%	-1%
Oral/Maxillofacial Surgery	\$67	0%	0%	0%	0%
Orthopedic Surgery	\$3,741	0%	0%	0%	0%
Other	\$31	0%	4%	0%	4%
Otolaryngology	\$1,222	0%	0%	0%	0%
Pathology	\$1,165	0%	-1%	0%	-2%
Pediatrics	\$61	0%	0%	0%	0%
Physical Medicine	\$1,107	0%	0%	0%	0%
Physical/Occupational Therapy	\$3,950	0%	-1%	0%	-1%
Physician Assistant	\$2,438	0%	0%	0%	0%
Plastic Surgery	\$376	0%	0%	0%	0%
Podiatry	\$1,974	0%	2%	0%	2%
Portable X-Ray Supplier	\$99	0%	1%	0%	1%
Psychiatry	\$1,187	0%	1%	0%	1%
Pulmonary Disease	\$1,714	0%	0%	0%	0%
Radiation Oncology and Radiation Therapy Centers	\$1,765	0%	0%	0%	-1%
Radiology	\$4,907	0%	0%	0%	0%
Rheumatology	\$541	0%	0%	0%	0%
Thoracic Surgery	\$357	0%	0%	0%	0%
Urology	\$1,738	0%	1%	0%	1%
Vascular Surgery	\$1,141	0%	2%	0%	2%
Total	\$92,733	0%	0%	0%	0%

<sup>\*\*</sup> Column F may not equal the sum of columns C, D, and E due to rounding.

The following is an explanation of the information for Table 94:

- Column A (Specialty): Identifies the specialty for which data is shown.
- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on 2017 utilization and 2018 rates. Allowed charges are the Medicare fee schedule amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all specialties to arrive at the total allowed charges for the specialty.
- <u>Column C (Impact of Work RVU Changes):</u> This column shows the estimated 2019 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- <u>Column D (Impact of PE RVU Changes):</u> This column shows the estimated 2019 impact on total allowed charges of the changes in the PE RVUs.

- <u>Column E (Impact of MP RVU Changes):</u> This column shows the estimated 2019 impact on total allowed charges of the changes in the MP RVUs.
- <u>Column F (Combined Impact)</u>: This column shows the estimated 2019 combined impact on total allowed charges of all the changes in the previous columns

For illustrative purposes, CMS shows the estimated specialty level impacts associated with implementing its finalized policies for E/M coding and payment in 2019, rather than delaying until 2021. Table 95 in the final rule shows the estimated impacts of adopting single payment rates for new and established patient E/M visit levels 2-4, keeping separate rates for new and established patient E/M visit level 5 and adopting add-on codes with equal rates to adjust for the inherent visit complexity of primary care and non-procedural specialty care. These impacts range from an increase of 10 percent for podiatry, increase of 5 percent for otolaryngology and psychiatry to a decrease of 5 percent for diagnostic testing facility, and decrease of 3 percent for critical care, gastroenterology, nuclear medicine, ophthalmology, and physical/occupational therapy.

# **B.** Impacts of Other Proposals

The expected impacts of some of the changes in this final rule (other than those associated with changes in RVUs or the update factor) are discussed in previous sections of this summary. This includes the effect of changes related to telehealth, payments to provider-based departments of hospitals paid under the PFS, WAC-based payments for Part B drugs, regulations associated with the ambulance fee schedule, clinical laboratory fee schedule, AUC criteria for advanced diagnostic imaging services, and the physician self-referral law, among other proposals.

#### C. Changes Due to the Quality Payment Program

CMS estimates in the final rule that approximately 54 percent of the nearly 1.5 million clinicians billing to Part B (797,990) will be assigned a MIPS score for 2021 because others will be ineligible for or excluded from MIPS. This is more than 10 percentage points higher than what CMS estimated using legacy data from PQRS. Table 97, reproduced below, provides the details of clinicians' MIPS eligibility status for 2021 MIPS payment year using the proposed and finalized assumptions. CMS notes it was difficult to predict whether clinicians will elect to optin to participate in MIPS with the proposed policy; CMS assumed 33 percent of the optin eligible clinicians that participated in PQRS will elect to optin to the MIPS program. Using the updated data, CMS observed a decrease of about 14,000 clinicians compared to the proposed rule in the "opt-in eligibility" category.

Table 97: Description of MII Proposed and Finalized Assu		is for CY 20	21 MIPS Pa	yment Yea	r Usingthe	
1 Toposeu unu 1 manzeu 1155u		Proposed rule estimates		Final Rule estimates †		
		Legacy data*		QPP Year 1 data		
Eligibility Status	Predicted Participation Status in MIPS Among Clinicians*	Number of Clinicians			PFS allowed charges (\$ in mil)****	
Required eligibility	Participate in	186,549	43,546	199,236	47,653	
(always subject to a MIPS	MIPS					
payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Do not participate in MIPS	31,921	7,605	17,376	3,916	
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group)	Submit data as a group	389,670	10,262	553,475	13,662	
Opt-In eligibility	Elect to opt-in and	42 025	2,099	27,903	1,380	
a positive, neutral, or negative adjustment because the individual or group exceeds the low- volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	submit data					
<b>Total Number of MIPS Eligi</b>	ble Clinicians	650,165	63,512	797,990**	66,611	
Not MIPS eligible						
Potentially MIPS eligible (not subject to payment adjustment for non- participation; could be eligible for one of two reasons: 1) meet group eligibility or 2) opt-in eligibility criteria)	Do not submit as a group	482,574	11,695	390,244	9,290	
Below the low-volume threshold (never subject to payment adjustment; both	Not applicable	88,070	690	77,617	404	

		Proposed rule estimates		Final Rule estimates †		
		Legacy data	ı*	QPP Year	1 data	
Eligibility Status	Predicted Participation Status in MIPS Among Clinicians*	Number of Clinicians				
individual and group is below all3 low-volume threshold criteria)						
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	302,172	13,688	209,403	9,735	
Total Number of Clinicians I	Not MIPS Eligible	872,816	26,073	677,264	19,429	
Total Number of Clinicians ( MIPS Eligible)	(MIPS and Not	1,522,981	89,585	1,475,254	86,040	

<sup>\*</sup>Participation in MIPS defined as previously submitting quality or EHR data for PQRS. Group reporting based on 2016 PQRS group reporting.

† These estimates reflect the finalized policies, which differ from the proposed rule (that is, change in MIPS eligible clinician types and those identified as QPs).

In the aggregate, CMS estimates that for the 2021 payment year, it would redistribute about \$310 million in payment adjustments on a budget neutral basis. The maximum positive payment adjustments are 4.7 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. CMS observes that the decrease in the funds available for redistribution and the maximum positive payment adjustment from the proposed rule to the final rule is due to the change in the data sources used to estimate final scores for MIPS eligible clinicians and the decrease in the additional performance threshold. CMS estimates that 91.2 percent of eligible clinicians will have a positive or neutral payment adjustment and 8.8 percent will have a negative payment adjustment. Table 99, reproduced below, shows the impact of payments by practice size and whether clinicians are expected to submit data to MIPS.<sup>33</sup> CMS estimates that clinicians in small practices (1-15 clinicians) participating in MIPS would perform as well as or better than mid-size practices.

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<sup>\*\*</sup> Updated Estimated MIPS Eligible Population

<sup>\*\*\*</sup> Facility-based eligible clinicians are not modeled separately in this table and are captured in the individual eligible category. This table does not consider the impact of the MAQI Demonstration waiver. This table also does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 22,000 clinicians and \$3.7 billion in PFS allowed charges).

<sup>&</sup>lt;sup>33</sup> The proposed rule estimated MIPS participation and performance using historical PQRS and EHR data and the final rule presents the results from the analysis of MIPS 2019 performance period data, which was not available in time for the analysis of the proposed rule.

Table 99: MIPS Estimated Payment Year 2021 Impact on Total Estimated Paid Amount by Participation Status and Practice Size\*

Practice Size*	Number of MIPS	Percent Engine Clinicians with Positive or Neutral	Clinicians with a	Fligible	Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount**			
Among th	ose submi	tting data***	-					
1) 1-15	140,251	80.1%	47.2%	19.9%	1.2%			
2) 16-24	41,226	86.1%	41.4%	13.9%	1.1%			
3) 25-99	185,140	89.8%	48.6%	10.2%	1.3%			
4) 100+	413,997	96.1%	69.0%	3.9%	2.0%			
Overall	780,614	91.2%	58.8%	8.8%	1.5%			
Among th	Among those not submitting data							
1) 1-15	15,680	0.0%	0.0%	100.0%	-6.3%			
2) 16-24	629	0.0%	0.0%	100.0%	-6.6%			
3) 25-99	860	0.0%	0.0%	100.0%	-6.6%			
4) 100+	207	0.0%	0.0%	100.0%	-6.9%			
Overall	17,376	0.0%	0.0%	100.0%	-6.4%			

<sup>\*</sup>Practice size is the total number of TIN/NPIs in a TIN

CMS estimates that approximately 165,000 to 220,000 clinicians will become QPs and a total of \$600 to \$800 million in incentive payments will be made for the 2021 payment year.

#### **Limitations of CMS Analysis**

Importantly, CMS describes several limitations to the analysis underlying the tables. CMS bases its analyses on the data prepared to support the 2018 performance period initial determination of clinician and special status eligibility, participant lists using the APM Participation List for the first snapshot date of the 2018 QP performance period, the 2018 QPP Year 1 data and CAHPS for ACOs. CMS updated its analysis in the final rule by using actual MIPS performance data. CMS notes the scoring model does not reflect the growth in Advanced APM participation between 2018 and 2019 because that data are not available at the detailed level needed for the scoring analysis. CMS also notes that given these limitations and others, there is considerable uncertainty around its estimates.

<sup>\*\* 2016</sup> and 2017 data used to estimate 2019 performance period payment adjustments. Payments estimated using 2016 and 2017 dollars.

<sup>\*\*\*</sup>Includes facility-based clinicians whose quality data is submitted through hospital programs.

# D. Impact on Beneficiaries

CMS notes that there are a number of changes in this final rule that would have an effect on beneficiaries. In general, CMS believes that many of the changes will have a positive impact and improve the quality and value of care provided to beneficiaries.

Most of the policy changes could result in a change in beneficiary liability as relates to coinsurance. For example, the 2018 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is \$109.80 which means in 2018 a beneficiary would be responsible for 20 percent of this amount, or \$21.96. Based on this final rule, using the estimated 2019 CF, the 2019 national payment amount in the nonfacility setting for CPT code 99203 is \$109.92 which means that in 2019, the beneficiary coinsurance would be \$21.98.

#### **E. Estimating Regulatory Costs**

Because regulations impose administrative costs on private entities, CMS estimates the cost associated with regulatory review, such as the time needed to read and interpret the proposed rule. CMS assumes that the total number of unique reviewers for this year's rule will be comparable to the number of unique commenters on last year's proposed rule. CMS also assumes that each reviewer reads approximately 50 percent of the rule. CMS estimates that the cost of reviewing this rule is \$107.38 per hour, including overhead and fringe benefits. In addition, CMS assumes that it would take about 8 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is \$859 (8.0 hours x \$107.38) and the total cost of reviewing this regulation is \$5,102,275 (\$859 x 5,943 reviewers).