

Physician Fee Schedule Final Rule for 2020

Summary Part II: Updates to the Quality Payment Program (Section III.K of CMS-1715-F)

On November 15, 2019, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a final rule relating to the Medicare physician fee schedule (PFS) for CY 2020¹ and other revisions to Medicare Part B policies (84 FR 62998-63563). The finalized policies generally will take effect on January 1, 2020. The addenda to the final rule along with other supporting documents are only available through the Internet at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

HPA is providing a summary in two parts. Part II summarizes section III.K of the final rule: Updates to the Quality Payment Program. Previously covered in Part I were sections I through III.J. and IV of the final rule, and Section V, the interim final rule. Part I included payment policies under the PFS; Medicare Shared Savings Program requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; establishment of an Ambulance Data Collection System; Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and amendments to Physician Self-Referral Law Advisory Opinion Regulations. The interim final rule covers policies related to the administration of esketamine.

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¹ Henceforth in this document, a year is a calendar year unless otherwise indicated.

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III. Other Provisions of the Regulations

K. CY 2020 Updates to the Quality Payment Program

1. <u>Introduction and Background</u>

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) ended the Sustainable Growth Rate (SGR) formula for updates to the Physician Fee Schedule (PFS), and established the Quality Payment Program (QPP) as a pathway to move physicians from volume-driven to value-based care for Medicare beneficiaries. The evolution of Medicare's payments to physicians and the foundations of the QPP are described in the QPP Year 1 (2017) proposed rule (81 FR 28167-28169). Key features of the QPP are as follows:

- Two participant tracks: the Merit-based Incentive Payment System (MIPS) and the Advanced Alternative Payment Models (APMs);²
- Payment adjustments for MIPS-eligible clinicians based on their reported data for four performance categories: Quality, Cost, Improvement Activities (IA) and Promoting Interoperability (PI); per statute, adjustments increase in size over time until stabilizing at ± 9 percent for payment year 2022;
- Through 2024, lump sum ("bonus") APM incentive payments to clinicians whose participation in Advanced APMs exceeds pre-set thresholds that increase over time per statute ("APM Qualifying Participants" or QPs)
 - Also per statute, the bonus is to be replaced in 2026 by a higher annual PFS update percentage for QPs than non-QPs (0.75 vs. 0.25 percent, respectively);
- Two-year lag between each *performance* year and its corresponding *payment* year; and
- QPP annual updates that are implemented as part of the PFS rulemaking process.

² QPP participants currently include the following practitioner types: physician (as defined in section 1861(r) of the Act), physician assistant (PA), nurse practitioner (NP), clinical nurse specialist (CNS), certified registered nurse anesthetist (CRNA), physical therapist, occupational therapist, clinical psychologist, qualified speech-language pathologists, qualified audiologists, and registered dieticians and nutrition professionals.

Performance years and payment years are defined as 12-month calendar year periods. During 2020, MIPS payment adjustments will be applied and APM incentive payments made will be made based upon QPP Year 2 (2018) performance period data. MIPS adjustments will range from -5 to +5 percent and will be applied to payments made to clinicians for covered Part B professional services furnished during 2020. Some clinicians who meet a separately-specified threshold also will receive an additional positive adjustment in 2020 for exceptional 2018 MIPS performances.³ The MIPS adjustment percentage will continue to increase annually until reaching -9 to +9 percent for payment year 2022, and the exceptional performance bonus will continue through payment year 2024.⁴ The 2020 APM incentive payment will be calculated as 5 percent of a QP's covered Part B professional services furnished during 2019, and will remain at 5 percent through payment year 2024.

The 2020 performance period will correspond to the 2022 payment year, and, as noted above, the MIPS payment adjustments will be ± 9 percent to be applied to 2022 payments to physicians. CMS estimates that approximately 879,966 clinicians will be MIPS-eligible clinicians during the 2020 performance period and about 348,000 will not be MIPS eligible. The final numbers will depend on factors including how many clinicians are excluded from MIPS (based on their status as QPs or Partial QPs),⁵ the extent of reporting by groups (rather than as individuals), and the number who elect to opt in to MIPS.⁶ A detailed breakout of participation estimates by MIPS eligibility status categories is provided in Table 122 of the rule, reproduced at the end of Part I of this summary.

Budget neutrality is required within the QPP by statute. CMS estimates that positive and negative payment adjustments distributed in payment year 2022 will each total \$433 million (down from \$584 million estimated for payment year 2021). As in prior QPP years, an additional \$500 million will be available for distribution for exceptional performance. The actual exceptional payment amounts will be finalized based on the final population of MIPS eligible clinicians for the 2022 MIPS payment year and the distribution of their composite final scores.

CMS estimates that the maximum possible positive payment adjustment attainable for payment year 2022 will be 6.2 percent combined from the MIPS base adjustment and the adjustment for exceptional performance. CMS projects that 92.5 percent of eligible clinicians will have a positive or neutral payment adjustment and 7.5 percent will have a negative payment adjustment. Finally, CMS estimates that between 210,000 and 270,000 clinicians will meet thresholds to

³ The "exceptional" threshold is determined annually. The adjustment amount starts at 0.5 percent, increases on a linear sliding scale to a maximum of 10 percent, and is subject to a scaling factor to maintain budget neutrality. The exceptional performance payment amount is dependent upon the distribution of the final MIPS composite scores of all clinicians for the relevant performance year.

⁴ Partial QPs are exempt from MIPS reporting requirements, but they are not eligible to receive the APM but Incentive Payment. Instead, they may elect to report to MIPS and, if they elect to report, would are scored under MIPS and receive a MIPS payment adjustment.

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⁶ A clinician or group that exceeds at least one but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and submit data to MIPS.

become QPs, resulting in total lump sum APM incentive payments of \$535-600 million for the 2022 QPP payment year. The APM bonus remains at 5 percent and will be applied to a QPs' covered Part B professional services furnished during 2021, the calendar year immediately preceding the payment year.

2. Key Provisions for QPP Year 4

Changes to the QPP for 2020 are reviewed in Section III.K of the PFS final rule. CMS identifies the following as finalized major provisions, discussed further later in this summary:

- Applying a new MIPS Value Pathways (MVPs) framework to the QPP beginning with the 2021 performance year (QPP Year 5);
- For the MIPS Quality performance category, strengthening the Qualified Clinical Data Registry (QCDR) measure standards, requiring more rigorous measure testing, harmonization, and clinician feedback beginning in 2020
- For the MIPS Cost performance category, adding eight new evidence-based cost measures and retaining but revising the Total Per Capita Cost of Care (TPCC) and the Medicare Spending Per Beneficiary measures (MSPB Clinician);
- Under the All Payer APM Combination Option of the APM incentive pathway, defining an Aligned Other Payer Medical Home Model, to which the Medicaid medical home model financial risk and nominal amount standards will be applied by CMS when making Other Payer Advanced APM status determinations; and,
- Under the All Payer APM Combination Option of the APM incentive pathway, modifying the definition of marginal risk rate so that the average marginal risk rate would be used when making Other Payer Advanced APM status determinations.

The MIPS category weights reflect parameters set in statute, within which the Secretary may make certain adjustments. The Bipartisan Budget Act of 2018 (BBA 2018) extended the flexibility given to the Secretary through the 2021 performance period. Beginning with the 2022 performance period (2024 payment year), BBA 2018 requires the cost performance category to be weighted at 30 percent and the performance threshold to be set at the mean or median of the final scores for all MIPS eligible clinicians with respect to a prior period as specified by the Secretary.

The category weights finalized for QPP Year 4 are shown below.

Performance Category	2020 MIPS Performance Year QPP Year 4	2021 MIPS Performance Year QPP Year 5
Quality	45%	Deferred to future rulemaking
Cost	15%	Deferred to future rulemaking
Improvement Activities (IA)	15%	15
Promoting Interoperability (PI)	25%	25

3. MIPS Program Details

a. Transforming MIPS: MIPS Value Pathways (MVPs)

(1) Defining and Implementing MVPs

CMS proposed to apply a new MVP framework to future QPP proposals beginning with those for the 2021 MIPS performance period (84 FR 40732 through 40745). CMS noted that having previously emphasized flexibility in MIPS had inadvertently produced a complex program that has failed to yield the robust practitioner performance information needed to move more quickly towards value-based care. CMS stated that standardization gained through applying the MVP framework would enhance accountability across the wide range of existing clinical practice sizes, specialties, and composition. CMS proposed to define a MIPS Value Pathway as a subset of measures and activities specified by CMS (§414.1305), and stated that all MVPs would share the following key features:

- Connecting measures and activities across the 4 MIPS performance categories and aligning them to specific clinical conditions and/or the practitioners who treat them;
- Incorporating an administrative claims-based quality measure set focusing on population health as a base requirement for each pathway;
- Providing actionable data and feedback to clinicians (e.g., outlier analysis); and
- Enhancing information provided to patients including at the individual clinician level (e.g., patient reported outcome measures or PROMs, experience of care survey scores).

(2) MVP Comment Themes

CMS posed numerous conceptual and operational questions about the MVP framework in the proposed rule. Areas of emphasis included: 1) Constructing MVPs: approaches, definitions, development, and specifications; 2) Selecting measures and activities for various MVPs; 3) Determining MVP assignment to clinicians and groups; and 4) Operational plan for transitioning from the current MIPS structure to the MVP framework. CMS received over 2,000 comments, and themes expressed by commenters included the following:

- Conceptual support for the goals of the MVP framework including simplifying MIPS; reducing burden; making the MIPS program more meaningful for clinicians; reducing barriers for clinicians to transition more rapidly into APMs; and helping patients compare practitioner performances to assist them in making well-informed choices when selecting clinicians.
- Conceptual opposition to the MVP framework based upon the proposed timeline, the extent of change being proposed, the need for multiple MVPs within many specialties and failure to reduce clinician burden, and reduction in the ability of clinicians to choose performance measures relevant to their practices.
- Specific concerns including creating confusion and destabilizing MIPS by introducing too much change too quickly, how equity would be created and maintained across all of

⁷ Consumer Assessment of Healthcare Providers and Systems (CAHPS®) is an AHRQ program in which a suite of surveys, usually defined by type of care or site of service, focus on aspects of quality that consumers are best qualified to assess (e.g., provider communication skills).

- the MVPs, and how the mandatory, claims-based, population health, measures would be chosen.
- Specific recommendations to allow clinicians to choose to participate in MVPs as a
 voluntary reporting option under MIPS, either during a defined transition period from the
 current MIPS structure to the MVP framework or as a permanent MIPs reporting option;
 to delay MVP implementation for one or more years (rather than in 2021); and to create
 processes for automatic credit for multiple Promoting Interoperability and Improvement
 Activities measures; and to allow credit in multiple MIPS performance categories by one
 measure.

An overarching, frequently-repeated theme heard from commenters was the critical need for stakeholder engagement during all aspects of the development and implementation of the MVP framework

(3) CMS Responses to MVP Commenters

CMS shares its responses to some of the over 2,000 comments received and states that the remaining comments will be retained for future consideration as MVP-related policies evolve. Highlights from the responses provided by CMS include the following:

- MVPs will streamline and accelerate transition to APM participation, reducing barriers and burden for clinicians and allowing them to achieve the rewards of APM QP status.
- No proposals were made by CMS about whether MVP participation would be optional or mandatory, and CMS will consider the feedback offered about this topic in the future.
- CMS agrees that a single MVP may fail to meet the needs of all clinician types and all clinicians in a given specialty and states a desire to work with stakeholders to determine the number of MVPs needed for specialists.
- CMS expresses interest in working with stakeholders to identify foundational measures applicable across specialties so that all clinicians are held accountable for a core set of measures, facilitate practitioner comparison by beneficiaries and caregivers.
- CMS agrees that equity across MVPs is critical though offers no plan to do so other than through collaboration with stakeholders.
- CMS would consider customized MVP Promoting Interoperability measures in the future, after a uniform initial set is created.
- CMS agrees that stakeholder engagement with CMS will be necessary throughout the MVP framework development and implementation processes.

CMS concludes the comment and response process by finalizing with modification the proposed definition of an MVP as "a subset of measures and activities" <u>established through rulemaking</u>, rather than the proposed rule's wording of "<u>as specified by CMS"</u> (§414.1305). CMS asserts that the finalized regulatory language is meant to indicate the agency's intention to specify MVPs with stakeholder input "to the extent possible". CMS further mentions that outreach to stakeholders in the future may take multiple forms, such as public listening sessions, webinars, and office hours sessions.

b. Group Reporting

Both the MIPS and APM Incentive pathways of the QPP have specific provisions governing reporting of performance data by clinicians aggregated to various levels, including individual practitioner, group practice, or APM model participant entity. CMS proposed technical changes to the regulations applicable to group reporting to remove duplicative language and to align the overall MIPS regulations for group and virtual group reporting with reporting regulations specific to the MIPS Promoting Interoperability performance category.

Commenters were supportive but requested several clarifications to which CMS responds that: 1) a group or virtual group whose members have different CEHRT products will need to run reports from each product then manually aggregate the results into a single report; 2) a group or virtual group who shares the same CEHRT product will generate a single report of aggregated data; and 3) the group or virtual group must submit data for all of the group's MIPS-eligible clinicians for whom the group has data in their CEHRT.

- c. MIPS Performance Category Measures and Activities
- (1) Quality Performance Category (§414.1330 through §414.1340)
- (a) Measure Selection and Changes to Measures for the 2020 Performance Period

CMS calls attention to Appendix 1 of the rule, MIPS Quality Measures and its Table Groups that catalogue the groups of MIPS measures with their finalized changes for performance year 2020 (unless otherwise noted) and future years:

- Three new measures were finalized for inclusion and are found in Table Group A.
 - International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia,
 - o Multimodal Pain Management, and
 - o Functional Status Change for Patients with Neck Impairments.
- Addition of Adult Immunization Status was not finalized since the relevant clinical guidelines are in the process of revision.
- The proposed population health measure All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions, found in Table Group A, was not finalized based upon multiple concerns raised by commenters (further discussed below).
- The modifications to numerous existing specialty sets and 7 new specialty sets proposed were finalized without changes and are found in Table Group B.
- The 55 previously finalized quality measures proposed for removal were reduced to 42. Thirteen will continue as previously specified for performance year 2020. Details are available in Table Group C and discussed below under Measure Removal Criteria.
- The 78 previously finalized quality measures with substantive changes proposed for 2020 are found with their finalized 2020 specifications in Table Group D.
- Substantive changes were proposed for the measure Preventive Care and Screening:
 Tobacco Use: Screening and Cessation Intervention. CMS has decided to redesignate the
 CMS Web Interface Measure Specifications collection type for this measure (Q226) as

pay-for-reporting in the Shared Savings Program for performance years starting in 2019 and will exclude the measure from MIPS scoring for the 2019 MIPS performance period (discussed further below).

Measure Addition for 2021 Performance Period: Population Health

CMS proposed to add the claims-based measure titled All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions beginning with the 2021 performance period. If finalized, CMS would consider this a population-health measure that would be available for use in the MVPs planned for implementation in 2021. CMS noted that delaying adoption of this measure until 2021 would allow time for its consideration by the MAP, and also would allow time for further development by CMS of the global/population health measure set envisioned for the MVPs. Commenters expressed multiple concerns, of which some are highlighted below along with responses by CMS.

- The value of adding population health measures to a program for individual or group reporting by clinicians is unclear. The results for the population are beyond the individual clinician's control.
 - o CMS disagrees, stating that all MIPS-eligible clinicians have a meaningful responsibility to improve the health of their communities.
- The proposed measure requires a large sample size to achieve reliability, results cannot be tracked in real time, and does not provide timely, actionable feedback to the clinician.
 - CMS responds that there is still benefit to the Medicare program even without real-time tracking. CMS notes that the proposed measure is claims-based and calculated by CMS, so imposes no added data collection burden.
- The measure is inadequately risk-adjusted and lacks reliable attribution specifications.
 - o CMS offers no specific response.
- Fraud and abuse laws restrict options for care coordination but the proposed measure assumes that effective care coordination is performed.
 - o CMS states a belief that the care coordination required to perform well on the proposed measure is well within the fraud and abuse legal framework.
- The proposed measure has not yet been reviewed by the Measures Application Partnership (MIP) or the National Quality Forum (NQF).
 - o CMS intends to seek MAP and NQF input.

Considering the many concerns raised, including methodological issues, CMS is not finalizing the proposed addition of the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure for MIPS performance year 2021. CMS states an intention to propose this measure for adoption again through future rulemaking after MAP and NQF review is completed.

Specialty Measure Set Changes

Seven new specialty measure sets were proposed for addition: Endocrinology, Nutrition/Dietician, Pulmonology, Chiropractic Medicine, Clinical Social Work, Audiology, and Speech Language Pathology. Several sets recognize the expansion of MIPS-eligible practitioner types for the 2019 performance period (e.g., Speech-Language Pathology). CMS finalizes these additions as proposed and they are shown in Table Group B.

Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

CMS heard from stakeholders that the 2018 CMS Web Interface measure numerator guidance for this measure is inconsistent with the intent of the CMS Web Interface version of this measure as modified for the 2018 performance year (82 FR 54164) and is unduly burdensome. CMS notes that the numerator discordance precludes historical benchmarking for the measure. CMS will exclude the Web Interface version of this measure from MIPS eligible clinicians' quality scores for the 2018 performance period. For performance year 2019, CMS finalizes its proposal to update the numerator guidance as shown in Table Group DD. While this is a scoring change made after the start of the performance period, CMS believes that not to make the change would be contrary to the public interest. CMS expects to be able to benchmark and score the CMS Web Interface version of this measure (pay-for-performance) for the 2019 MIPS performance period and the 2021 MIPS payment adjustment.

(b) Other Quality Performance Category Issues

Final Score Contribution

The BBA of 2018 provided that corresponding adjustments be made to the Quality and Cost performance categories for payment years 2022-2024 so that their combined total scoring weight equals 60 percent. CMS proposed to weight the Quality category at 40, 35, and 30 percent for payment years 2022, 2023, and 2024, respectively. As a result, the corresponding Cost category weights would be set at 20 percent for the 2022 MIPS payment year, 25 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year. Support for the proposed changes to the Quality weight was mixed. CMS further notes that commenters raised related concerns about the proposed Cost scoring weights, citing methodological and attribution issues and feedback frequency questions.

Given commenters' concerns, CMS does not finalize the proposed changes to the Quality and Cost category weights. CMS will retain the Quality weight at 45 percent for the 2020 performance period/2022 payment year (and the Cost weight at 15 percent for that year, discussed in more detail later in the rule). CMS will revisit category weighting of the Quality and Cost categories in future rulemaking.

Data Completeness Criteria

CMS increased the data completion threshold for satisfactory Quality category measure submission from 50 percent in 2018 to 60 percent for performance period 2019 for Qualified Clinical Data Registry (QCDR) measures, MIPS Clinical Quality Measures (CQMs), and electronically-specified CQMs (eCQMs). Based upon further analysis of data completion rates for the 2017 performance year, shown in Table 42 below (reproduced from the rule), CMS proposed to increase the completion threshold from 60 to 70 percent for performance year 2020. Analogously, CMS proposed to raise the Quality category data completeness threshold from 60 to 70 percent for Medicare Part B claims-based measures for performance year 2020. CMS asked for comments on both completion threshold increases, particularly for an alternative threshold of 80 percent.

Many commenters were supportive, particularly since the proposed changes were data-driven. Concerns were raised about increasing costs and burden especially for small practices; the

timeline for posting MIPS CQM and QCDR measures; the lack of CMS guidance to clinicians on how to select the percentage of their patients for whom they will submit data; and the added burden imposed by the 70 percent threshold for measures that require very large amounts of data to be collected. CMS notes that the completion rates for small practices suggests most are already meeting the 70 percent threshold. CMS states that it will consider earlier public posting of MIPS CQM and QCDR measures, and that guidance is available to assist clinicians on how to submit their data in a consistent manner. CMS also states that the volume of data required by specific measures is not relevant to the data completeness threshold.

CMS finalizes the data completeness thresholds to 70 percent for performance year 2020 for MIPS CQMs, and eCQMS as well as for Medicare Part B claims-based measures (§414.1340). Also, several technical changes to better align regulatory wording with current MIPS terminology are finalized. CMS closes by stating their intention to continue to raise the data completion threshold in future rulemaking.

TABLE 42: CY 2017 Data Completeness Rates for MIPS Individual Eligible Clinicians, Groups, and Small Practices

Average data completeness rate- Individual Eligible Clinician	Average data completeness rate- Groups	Average data completeness rate- Small Practices
76.14	85.27	74.76

Selective Data Submission

Using selection criteria to present clinician performance data in a more favorable light than complete data reporting would support is referred to as "cherry picking". CMS has concluded based upon queries received that misunderstanding may exist about data reporting obligations for clinicians. CMS emphasizes that all MIPS data submitted by or on behalf of a MIPS eligible clinician, group, or virtual group must be certified as true, accurate and complete (see §§414.1390(b) and 414.1400(a)(5)). CMS proposed to enhance the clarity of complete, accurate data submission by adding §414.1340(d), which would state that unrepresentative data would not meet the true, accurate and complete data requirement. CMS received no comments and the revision of §414.1340 is finalized as proposed.

Preparation for MVPs

CMS has previously outlined criteria to guide anyone interested in submitting new quality measures for potential inclusion in MIPS: for example, measures that have completed reliability, feasibility, and validity testing and that are outcomes-based (82 FR 53636). CMS continues to encourage new measure submitters to electronically specify their measures as eCQMs. As part of preparing for MVP implementation in 2021, CMS proposed that MIPS quality measure stewards would be required to link their MIPS quality measures to existing and related cost

⁸ 2019 MIPS Quality User Guide, available at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/558/2019%20MIPS%20Quality%20User%20Guide.pdf

measures and Improvement Activities (IAs) whenever feasible and applicable. CMS received few but supportive comments and finalizes the proposal, without modifications.

Measure Removal Criteria

CMS has previously established criteria for MIPS quality measure removal (83 FR 59763) and proposed to add two more for 2020. First, CMS proposed to remove measures that have not met case minimum and reporting volumes required for benchmarking after having been in the measure inventory for two consecutive CY performance periods. CMS states a belief that low reporting may be a marker for failure to provide meaningful measurement to clinicians but would reserve the ability to retain a low-reported measure if review identified a suitable rationale

A few commenters were supportive but most were negative about the new removal criterion. Concerns included: 1) two years is insufficient time for a final judgment on a measure's utility; 2) criteria for measure removal have changed over the short history of the MIPS program; low reporting does not always equate to low value, particularly for a measure that addresses a significant proportion of a subspecialty's outcomes.

CMS disagrees, having tracked some of the lowly- reported measures since they were first added under the MIPS predecessor Physician Quality Reporting System (PQRS). CMS emphasizes that removal based on the proposed criterion would be reviewed on a case-to-case basis to avoid the loss of measures of high value to clinician subsets from the measure inventory. CMS finalizes the new removal criterion as proposed.

Second, CMS also proposed to remove any MIPS quality measure if it is not available for use by all MIPS-eligible clinicians (or their reporting third party intermediaries), such as when a measure steward restricts access to the measure by QCDRs. Limiting measure access can lead to increased reporting burden for clinicians and their intermediaries, as well as reduce the reliability of measure benchmarking. Commenters were supportive and CMS finalizes the criterion for removal of measures in cases were measure stewards limit access to the measures.

CMS additionally notes having sought comment on a 1-year delay of removal of any of the measures proposed for removal for 2020. After considering the comments received about the 2-year removal criterion, CMS has removed some measures that were proposed for removal on this basis. CMS will go forward with removing 42 measures while retaining 13 in the Quality measure inventory. The retained measures are discussed further in Table Group C.

Topped out Measures

CMS previously established a 4-year timeline for topped out measure identification that may end with proposed measure removal from the MIPS inventory (82 FR 53637 through 53640). The MIPS Quality Benchmarks file contains measures that have advanced along the 4-year timeline. While extremely topped out measures are eligible for removal in the next rulemaking cycle, CMS may choose to retain them for compelling reasons, such as limited availability of other measures for a particular specialty. CMS invited comment about raising the data completeness threshold for retained extremely topped out measures and about alternative approaches to

⁹ Available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html.

manage such measures. CMS has elected not to summarize and respond to the comments received in this rule but may consider the comments in future rulemaking.

Measure Update Process Alignment

Currently, the update cycle for MIPS quality measures and the eCQM annual update process are separate, and CMS discussed but did not propose alignment. Alignment would require that CMS collect measure specifications earlier in the year for its annual measure review, potentially prior to NQF endorsement decisions being made and/or the release of new clinical guideline versions. CMS invited comment about whether to pursue alignment of the two updates. CMS opts not to summarize comments received or offer any responses in this rule. Comments may be incorporated into future rulemaking.

CAHPS for MIPS Survey Modifications

CMS made no formal proposals for change in the CAHPS for MIPS survey but invited comment about adding narrative reviews by patients of clinicians to the survey at both the group and individual clinical levels. CMS acknowledges the inputs received but does not discuss them further, and states that the comments may incorporated into future policies.

RFI Potential Opioid Overuse Measure

CMS has developed and field tested an eCQM titled Potential Opioid Overuse to capture the extent of long-term, high-dose opioid prescribing. Testing supported the feasibility, reliability, validity, and usability of the measure, but EHR vendors have raised implementation concerns including that some of the measure's data elements are inconsistently captured during typical clinical workflows. To salvage this potentially important measure, CMS invited comment from technical implementers on multiple questions about the measure, detailed in section III.K.3.c.(1) of the proposed rule, such as how best to manage the embedded dosing calculations. CMS chooses not to summarize and respond to comments received and plans for ongoing development of this measure.

(2) Cost Performance Category (§414.1350)

As discussed below, CMS finalizes its proposal to add 10 new episode-based measures and finalizes revisions to the existing Medicare Spending Per Beneficiary Clinician and Total Per Capita Cost measures.

(a) Weight in the Final Score

As noted previously, the Bipartisan Budget Act of 2018 provided that corresponding adjustments be made to the quality and cost performance categories for payment years 2022-2024 so that their combined total scoring weight equals 60 percent. Accordingly, CMS proposed to weight the cost category at 20, 25, and 30 percent for payment years 2022, 2023, and 2024, respectively. CMS stated a belief that this steady but gradual and predictable series of increases would allow clinicians to adequately prepare for the final 30 percent weight while gaining experience with new and revised cost measures. CMS considered maintaining the current 15 percent weight for payment years 2022-2023 but expressed concern about the more abrupt increase to 30 percent that then would be required for 2024 to be statutorily compliant.

Some commenters supported the cost category weighting progression as proposed. Many, however, did not, based upon the following concerns:

- The category weight should not be increased until CMS can provide more detailed and actionable performance data to clinicians;
- There are issues with many measures regarding appropriate attribution, reliability, and adjustment for social and complexity risk factors;
- The current measures do not appropriately capture the cost of care for costly procedures and highly complex patients; and
- Any change should be deferred during the transition to MVPs.

CMS responds that 1) the cost measures currently in use in MIPS represent the best available measures; 2) significant attention was given to all of the important issues mentioned by the commenters, including attribution and risk adjustment, as part of the measure development process; 3) CMS continues to investigate ways to best accommodate the issue of social and patient complexity adjustment in measures; and 4) CMS is likely to utilize many of the current cost category measures in the MVPs, so that the cost weighting should not be contingent upon MVP development.

Most importantly, however, CMS agrees with commenters that the cost category weight should not be increased until CMS can provide more detailed and actionable performance data to clinicians. CMS notes that such feedback is crucial for achieving clinician success in the cost category scoring and it is committed to improve the feedback that includes more granular and real-time data. CMS decides <u>not</u> to finalize increasing the cost category weight as proposed and finalizes to continue the weight at 15 percent for performance year 2020.

(b) Attribution: General Aspects

CMS considers attribution as a fundamental element of cost-based measures. Attribution helps to ensure that all costs are in fact captured as defined by the measure, but also that assignments of costs are made only to those clinicians who can meaningfully influence those costs and thereby should be held accountable. During past rulemaking, CMS has both reviewed attribution methodology in the preamble and included it in the regulatory text for each measure.

Beginning with the current rulemaking cycle (for the 2020 performance period), CMS finalizes its proposal to include the attribution methodology with the measure specifications. CMS believes this approach will: 1) reduce complexity since all specifications would be in a single place; 2) facilitate making non-substantive changes (e.g., updated diagnosis codes) outside of rulemaking; and 3) align with the approach used for quality performance category measures.

¹⁰ Specifications are publicly available at https://qww.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-basedprograms/macra-mips-and-apms/macra-feedback.html during the public comment period for the proposed rule, and become available in final form at https://qpp.cms.gov/about/resource-library after the final rule is published.

¹¹ CMS follows the standard pre-rulemaking process for new measures when proposing substantive changes to measures owned and developed by CMS, including resubmission to the Measures Under Consideration (MUC) list and reconsideration by the MAP. Non-substantive changes are addressed by CMS on a case-by-case basis.

CMS further notes that identifying the level of attribution (i.e., TIN/NPI or TIN) is most appropriately included in each cost measure's specifications and proposes a policy similar to that proposed for attribution methodology. Beginning with the current rulemaking cycle, CMS finalizes its proposal to include the level of attribution in measure specifications; information about attribution level would thereby be publicly available along with attribution methodology. CMS states that by so doing, the attribution methodology and level would more clearly align with whether the reporting clinicians are submitting as groups or individuals. CMS also finalizes its proposal to revise §414.1350(b)(1) to reflect that the current policy of attributing cost measures at the TIN/NPI level, regardless of whether a clinician's performance for purposes of MIPS is assessed as an individual or a group, applies for the 2017 through 2019 performance periods.

(c) Evidence-Based Cost Measures

An episode is a specific instance of an episode group for a specific patient and clinician. 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. The episode group includes diagnostic and treatment-related items and services used acutely and may include after-care, such as items and services used to treat complications. Specific items and services are assigned to each episode group. CMS applies payment standardization rules and risk adjustment when determining the costs of the included items and services.

CMS reprises key elements of the episode-based cost measure development process as implemented by the Agency's contractor. ¹² These include:

- Identification of priority areas for measure development by CMS, the contractor, and the public;
- A Technical Expert Panel (TEP) that provides process and methodologic guidance;
- Clinical subcommittees that work with the contractor to develop the specifications of the measures;
- A Person and Family Committee composed of patients, family members, and caregivers that provides input on prioritizing measures to be developed and on specifications;
- Field-testing of potential measures and analysis of results by the contractor with opportunities for public comment during and after field-testing;
- Measure refinement by the clinical subcommittees based on field-test results; and
- Final review and refinement of new measures by the TEP and formulation of recommendations to CMS about measure implementation.

For performance period 2020 and subsequent years, CMS finalizes its proposal to add 10 new episode-based cost measures that were successfully field-tested in 2018 and reviewed by the MAP, listed in Table 44, reproduced below from the rule. Detailed measure specifications (e.g., assigned items and services, episode triggers) are available at

¹² Details of the process are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-measure-development-process.pdf.

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-ebcm- measure-specs.zip.

TABLE 44: Episode-Based Measures for the 2020 Performance Period and Future Performance Periods

Measure Topic	Episode Measure Type
Acute Kidney Injury Requiring New Inpatient Dialysis	Procedural
Elective Primary Hip Arthroplasty	Procedural
Femoral or Inguinal Hernia Repair	Procedural
Hemodialysis Access Creation	Procedural
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	Acute inpatient medical condition
Lower Gastrointestinal Hemorrhage*	Acute inpatient medical condition
Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels	Procedural
Lumpectomy Partial Mastectomy, Simple Mastectomy	Procedural
Non-Emergent Coronary Artery Bypass Graft (CABG)	Procedural
Renal or Ureteral Stone Surgical Treatment	Procedural

^{*}CMS finalizes this measure only for MIPS eligible clinicians who report as a group or a virtual group (discussed in in III.K.3.c.(2)(b)(vi)(B) of this final rule.

Some commenters expressed concerns about the development of the proposed episode-based measures including the perceived lack of transparency in the process, inadequate field-testing, and limited access to feedback reports. CMS states it aims to be open and transparent in every stage of the measure development process and summarizes the measure development process which included input from stakeholders. CMS does recognize stakeholders' requests for an extended development timeline to allow more opportunities for clinician input and will consider this feedback for future measure development. CMS also acknowledges concerns about risk adjustment for social risk factors and is considering options to account for social risk factors that would allow clinicians to view disparities that would potentially incentivize improvement in care for beneficiaries. CMS notes the analyses done by the measure development contractor found very little to no effect on the predictive power of the risk adjustment models used when variable for social risk factors were included in the models, compared to using the current models. CMS will continue to monitor the potential effect of social risk factors on episode-based measures implemented in MIPS on an ongoing basis.

Some commenters expressed concerns with certain specifications for the Hemodialysis Access Creation episode-based measure including the fact that the surgeon that performs the trigger procedure is not generally responsible for the follow-up management but would still be held accountable under this measure. CMS notes that the measure was developed with expert clinical input from a workgroup to ensure that only costs of care within the reasonable influence of the attributed clinician for the defined patient population are included. Exclusion criteria identify patient characteristics and factors in the patient's medical history that might adversely affect the patient's treatment during the episode, to an extent that is outside the influence of the managing clinician. CMS does not think it is appropriate to retroactively exclude patients who die within 90 days after the end of the episode. CMS does not agree with a recommendation that the inclusion and exclusion criteria should include a clean, pre-trigger period of 12 months where the patient is not identified on a claim with a billing code for outpatient dialysis. CMS is concerned

that this change may also incentivize clinicians to wait until a patient is on dialysis before placing a vascular access to avoid being an attributed episode. CMS also notes that delaying the placement of a suitable vascular access could negatively impact patient outcomes. CMS finalizes the Hemodialysis Access Creation measure as proposed.

CMS agrees with a commenter that the COPD Exacerbation episode measure should include additional codes to capture patients who should be excluded due to a history of lung resection. CMS notes the addition of the suggested codes would remove approximately 260 episodes which represents less than 0.1 percent of all episodes. CMS finalizes the Inpatient COPD Exacerbation measure with the exclusion list expanded to include the recommended lung resection codes which are listed on the MACRA Feedback Page.

CMS also agrees with a commenter and removes CPT code 33406 from the list of episode triggers to the Non-Emergent CABG measure. The code is also added to the list of exclusions for this measure.

(d) Operational List Revisions

The Act requires the Secretary to develop and maintain an operational list of care episode and patient condition groups, and classification codes for such groups, with a target that over time the episodes and groups will account for increasing amounts of Parts A and B expenditures. In January 2018, after extensive stakeholder input, CMS posted its first operational list, consisting of 8 care episode groups and patient condition groups, along with the codes and logic used to define the episode groups. These initial episode and condition groups served as the foundation for CMS' 8 new episode-based cost measures, finalized for use in performance year 2019.

CMS reviews the list annually and no revisions were required during the 2019 rulemaking cycle. CMS finalizes its proposal to revise the operational list beginning in 2020, adding 10 new care episode and patient condition groups that serve as the basis for the 10 new episode-based cost measures proposed for performance year 2020 and subsequent years. Details are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html.

CMS notes it did not receive any specific comments addressing the operational list and finalizes it as proposed.

(e) Measure Revision: Total Per Capita Cost of Care (TPCC)

TPCC is an administrative claims-based cost measure that was used in the Physician Value Modifier Program, one of the legacy CMS initiatives that preceded the QPP. TPCC was finalized by CMS as one of the two cost measures identified for use in QPP Year 1 and it has been utilized again in each subsequent QPP year. CMS undertook reevaluation of TPCC as part of routine measure maintenance, during which stakeholders raised several areas of concern:

• Flawed attribution methodology assigns costs to clinicians over which they have no influence;

- Methodology incompletely and/or inaccurately identifies primary care clinician-patient relationships, resulting in incorrect attribution of primary care services to other clinicians;
- Attribution of costs by the measure to a single clinician or group is counterproductive to shared accountability by all of a patient's treating physicians and could encourage fragmentation of care; and
- Measuring beneficiary risk factors at least one year before the start of the performance period may not capture more recent, serious comorbidities, leading to inaccurate risk-adjustment and underestimation of expected costs for the performance period.

CMS initiated the process for measure revision and TPCC was sent to the TEP that guides the cost-measure development process, after which a revised measure was field-tested in 2018. Informed by input from the TEP and stakeholders as well as the field-testing results, CMS proposed to begin using the revised measure beginning with performance period 2020. CMS discusses the proposed revisions at length (see section III.K.3.c.(2)(v) of the rule), emphasizing the following changes:¹³

- (i) Improving the identification of primary care clinician-patient relationships by using a combination of services over a short time interval that signify the start of a relationship (e.g., office visit plus an electrocardiogram or two sequential office visits);
 - The first qualifying service is termed the "candidate event" and it opens a 1-year-long clinical risk window for the physician furnishing the service. Only that portion of the risk window overlapping with a given performance period is attributed to the identified primary care clinician for that period.
- (ii) Applying exclusion and inclusion lists to the candidate event to categorize clinicians more accurately as providing primary care, or not;
 - For example, a potential candidate event performed by a specialty clinician unlikely to deliver primary care (e.g., a dermatologist) would not open a risk window.
- (iii) Determining the beneficiary's risk score on a rolling basis each month using data from the immediately preceding 1-year period, leading to more accurate risk-adjustment; and
- (iv) Assessing beneficiary costs on a monthly rather than annual basis, so that costs better reflect contemporaneous beneficiary health status.

CMS notes that the revised measure was conditionally supported upon review by the MAP Clinician Workgroup but not supported (with potential for mitigation) by the MAP Coordinating Committee. CMS considered not using either TPCC version for 2020 but was deterred from doing so by concerns about the current paucity of episode-based measures available. CMS proposed to substitute the revised measure for the current TPCC version beginning with performance period 2020.

Some commenters expressed concerns that the revised TPCC includes costs that are outside the reasonable control of a provider, such as drug prices. CMS notes that the revised measure continues to use payment standardized prices to account for differences in Medicare payments

¹³ The proposed and current TPCCs are compared at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-TPCC-measure-specs.zip.

for the same service across suppliers for all services included in the measure, including Part B drugs. The measure does not include Part D costs because these costs are not yet payment-standardized. CMS is considering the feasibility of developing a payment standardization for Part D costs that would account for factors that are outside the control of clinicians.

In response to some commenters' concerns about the revised TPCC attribution methodology, CMS discusses the triggering methodology used for the revised measure. It believes that requiring two claims within a defined, relatively short period and using multiple codes that are indicative of overall health care ensures that clinicians are attributed based on evidence of a sustained relationship rather than a single patient visit. CMS considers it prudent not to attribute patients to clinicians that have been seen for only one visit. In addition, certain specialties unlikely to provide primary care are excluded from triggering events within a clinician group. Detailed information on testing results for specialties attributed within TINS can be found in the MACRA Cost Measures Post-Field Testing materials at https://qpp.cms.gov/about/webinars. CMS notes that for patients with multiple residences during the year, the revisions to the attribution methodology allows clinicians in both locations to be attributed concurrently.

In response to concerns that clinicians in rural areas would have poor performance because of the nature of the area in which they practice, CMS discusses the detailed testing performed by the measure development contractor. The National Summary Data Report showed a similar score distribution for urban and rural clinicians. More information on testing for this measure is available in the measure justification forms available on the MACRA Feedback Page. ¹⁴ This information on testing, also includes analyses to assess the impact of social risk factors that included income, education, employment, race, sex, and dual-eligibility status. CMS notes this analysis indicates that the inclusion of social risk factors in the current risk adjustment model has a minor effect on measure scores.

Many commenters were concerned about the lack of data to improve performance and recommended that the implementation of the measure be delayed at least a year to allow clinicians to review feedback. CMS notes that in July 2019, it provided reports with detailed data on the total per capita cost measure as specified in the 2018 MIPS performance period and it will continue to provide the level of detailed data. CMS will also continue to consider additional ways to off actionable data and feedback in a timely fashion.

After consideration of comments, CMS finalizes its proposal to include the TPCC measure with the revised specifications as proposed beginning with the 2020 performance period.

(f) Measure Revision: Medicare Spending Per Beneficiary Clinician (MSPB)

MSPB also is an administrative claims-based cost measure from the Physician Value Modifier program that was finalized by CMS along with TPCC as the other original QPP Year 1 cost measures, has been utilized again in each subsequent QPP year. CMS undertook reevaluation of MSPB as it did for TPCC as part of routine measure maintenance, during which several areas of concern emerged.

¹⁴ The information is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html

- The attribution methodology did not incorporate the team-based nature of inpatient care;
- The attribution based on the plurality of Part B service costs during an index admission potentially could attribute episodes to specialties providing expensive services instead of those providing overall care management; and
- The measure captured costs for services that are unlikely to be influenced by the clinician's care decisions.

CMS responds to the concerns by proposing a revised MSPB for performance period 2020 and subsequent years. First, CMS proposed to revise the measure's title to Medicare Spending Per Beneficiary clinician (MSPB clinician) to distinguish it from other similarly-named measures used elsewhere in the Medicare program. Second, CMS would change the attribution methodology to distinguish medical from potentially more expensive surgical episodes using the MS-DRG for the measure's index admission. Medical episode attribution initially would be at the TIN level, based upon volume of inpatient E/M services or physician/supplier claims, then to each of the TIN's clinicians who billed at least one of the attributed E/M services. A surgical episode would be attributed to the surgeon who performed any surgical service during the inpatient stay and to the surgeon's TIN. A list linking MS-DRGs to related surgical procedures is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/mspb-clinician-zip-file.zip. Lastly, CMS proposed to add service exclusion lists aggregated by major diagnostic categories (MDCs) of unrelated costs unlikely to be under the influence of the attributed clinician. Examples provided by CMS are exclusion of orthopedic procedures occurring with MDCs 06-07, Gastrointestinal System Disorders, or cardiac valve procedures triggered by MS-DRGs under MDC 04, Pulmonary System Disorders. 15 CMS proposed to substitute the revised MSPB clinician measure for the current MSPB version beginning with performance period 2020.

Several commenters expressed opposition to the inclusion of the revised MSPB and noted that the measure was conditionally supported by the MAP pending review by the NQF. CMS responds that after reviewing the proposed revisions to the MSPB clinician measure, the MAP finalized a recommendation of "conditional support for rulemaking" with the condition that the revised measure be submitted for NQF endorsement. CMS plans to submit the revised measure to a future endorsement cycle and notes that NQF endorsement is not required for cost measures included in MIPS.

In response to comments about a specialty adjustment, CMS clarifies that the MSPB measure currently in use and the revised MSPB clinician measure do not include a specialty adjustment. The revised MSPB clinician has been refined to ensure effective attribution and compare similar clinicians. CMS discusses how distinguishing between medical and surgical episodes and risk adjusting episodes within each MDC allows for more accurate comparison of predicted episode spending as clinicians are compared to other clinicians treating patients with similar characteristics.

¹⁵ The proposed and current MSPBs are compared at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-mspb-clinician-zip-file-zip.

After consideration of comments, CMS finalizes its proposal to include the MSPB clinician measure with the revised specifications as proposed in the cost performance category beginning with CY 2020.

(g) Episode-Based Measure Reliability

Reliability for Episode-Based Measures

CMS has previously established reliability standards for episode-based cost measures: 1) a reliability threshold of 0.4 for all measures; 2) a case minimum of 20 episodes for acute inpatient medical condition episode-based measures; and 3) a case minimum of 10 episodes for procedural episode-based measures. As shown in Table 45, reproduced below from the final rule, the reliability of the 10 proposed new episode-based measures meets the threshold for the majority of reporting groups at the specified case minimums. At the individual reporting level, all of the proposed new episodes meet the reliability threshold at the case minimums except for the Lower Gastrointestinal Hemorrhage measure. CMS considered not moving forward with this measure since MIPS allows for individual as well as group data reporting but proposed to restrict the use of the Lower Gastrointestinal Hemorrhage measure to group reporting. With this caveat, CMS proposed to implement all 10 new episode-based cost measures beginning in 2020 and to retain the established reliability standards.

CMS finalizes all the proposed episode based measures including the Lower Gastrointestinal Hemorrhage episode-based measure in the cost performance category but only for MIPS eligible clinicians who report as a group or a virtual group.

TABLE 45: Percent of TINs and TIN/NPIs that Meet 0.4 Reliability Threshold

Measure name	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Acute Kidney Injury Requiring New Inpatient Dialysis	100.0%	0.58	85.3%	0.48
Elective Primary Hip Arthroplasty	100.0%	0.85	100.0%	0.78
Femoral or Inguinal Hernia Repair	100.0%	0.86	100.0%	0.81
Hemodialysis Access Creation	93.1%	0.63	70.1%	0.48
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	100.0%	0.69	68.0%	0.46
Lower Gastrointestinal Hemorrhage*	74.6%	0.51	0.0%	0.20
Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels	100.0%	0.77	100.0%	0.69
Lumpectomy Partial Mastectomy, Simple Mastectomy	100.0%	0.64	100.0%	0.60
Non-Emergent Coronary Artery Bypass Graft (CABG)	100.0%	0.82	100.0%	0.74
Renal or Ureteral Stone Surgical Treatment	100.0%	0.77	100.0%	0.65

^{*} CMS finalizes this measure only for MIPS eligible clinicians who report as a group or a virtual group.

Reliability for Revised Cost Measures

CMS has previously established reliability standards for the TPCC and MSPB clinician cost measures: 1) a reliability threshold of 0.4 for all measures; 2) a case minimum of 20 beneficiaries for the TPCC; and 3) a case minimum of 35 episodes for the MSPB clinician. CMS states that these standards require moderate reliability without limiting clinician participation. As shown in Table 46, reproduced below from the rule, the reliability of the TPCC and MSPB clinician measures meet the threshold for the majority of clinicians and groups at the existing case minimums. Based on this analysis, CMS did not propose any changes to the case minimums, previously finalized as 35 for the MSPB measure, and 20 for the TPCC measure.

TABLE 46: Percent of TINs and TIN/NPIs that Meet 0.4 Reliability Threshold for the Revised MSPB Clinician and Total per Capita Cost Measures

Measure name	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Medicare Spending Per Beneficiary Clinician	100.0%	0.77	100.0%	0.69
Total Per Capita Cost	100.0%	0.82	100.0%	0.89

(h) Request for Comments on Future Potential Episode-Based Measure for Mental Health

CMS continues to develop episode-based cost measures to meet the needs of clinicians across the entire clinical spectrum. CMS developed through its usual episode measure process an acute inpatient medical condition episode-based measure for the treatment of inpatient psychoses and related conditions to support mental health professionals subject to the QPP. The measure, Psychoses/Related Conditions, was conditionally-endorsed by the MAP Clinician Workgroup but the MAP's Coordinating Committee disagreed and failed to support the measure for rulemaking. Concerns were raised that the measure: 1) had potential to attribute costs to clinicians without control over those costs; 2) was subject to geographic variation in community mental health resources; 3) might not account for scoring impacts of synchronous medical comorbidities; and 4) had a potential to exacerbate exiting mental health care access challenges. CMS and its expert workgroup reviewed the measure, finding that the MAP's concerns were addressed by the measure specifications, and the measure was supported by the Person and Family Committee. CMS provides detailed rebuttals of the MAP's concerns in section III.K.3.c.(2)(b)(vii) of the rule, and notes that the measure tests well for reliability (0.7) for group and individual reporting.

In the proposed rule, CMS solicited comments on the potential use of this new Psychoses/Related Conditions episode-based measure. CMS appreciates the comments it received and it will consider them as it considers the possible inclusion of the Psychoses/Related Conditions episode-based measure in the future.

¹⁶ The measure's specifications are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-ebcm-measure-pecs.zip.

Table 47 in the final rule, reproduced below, provides a summary of the cost measures for the 2020 and future performance periods.

TABLE 47: Summary Table of Cost Measures for the 2020 Performance Period and Future Performance Periods				
Measure Topic	Measure Type	Measure Status		
Total Per Capita Cost (TPCC)	Population-Based	Revised and proposed for 2020 performance period and beyond		
Medicare Spending Per Beneficiary Clinician (MSPB)	Population-Based	Revised and proposed for 2020 performance period and beyond		
Elective Outpatient Percutaneous Coronary Intervention (PCI)	Procedural episode- based	Currently in use for 2019 Performance Period and Beyond		
Knee Arthroplasty	Procedural episode- based	Currently in use for 2019 Performance Period and Beyond		
Revascularization for Lower Extremity Chronic Critical Limb Ischemia	Procedural episode- based	Currently in use for 2019 Performance Period and Beyond		
Routine Cataract Removal with Intraocular Lens (IOL) Implantation	Procedural episode- based	Currently in use for 2019 Performance Period and Beyond		
Screening/Surveillance Colonoscopy	Procedural episode- based	Currently in use for 2019 Performance Period and Beyond		
Intracranial Hemorrhage or Cerebral Infarction	Acute inpatient medical condition episode-based	Currently in use for 2019 Performance Period and Beyond		
Simple Pneumonia with Hospitalization	Acute inpatient medical condition episode-based	Currently in use for 2019 Performance Period and Beyond		
ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI)	Acute inpatient medical condition episode-based	Currently in use for 2019 Performance Period and Beyond		
Acute Kidney Injury Requiring New Inpatient Dialysis	Procedural episode- based	Proposed for 2020 Performance Period and Beyond		
Elective Primary Hip Arthroplasty	Procedural episode- based	Proposed for 2020 Performance Period and Beyond		
Femoral or Inguinal Hernia Repair	Procedural episode- based	Proposed for 2020 Performance Period and Beyond		
Hemodialysis Access Creation	Procedural episode- based	Proposed for 2020 Performance Period and Beyond		
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	Acute inpatient medical condition episode-based	Proposed for 2020 Performance Period and Beyond		
Lower Gastrointestinal Hemorrhage (at group level only)	Acute inpatient medical condition episode-based	Proposed for 2020 Performance Period and Beyond		
Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels	Procedural episode- based	Proposed for 2020 Performance Period and Beyond		
Lumpectomy, Partial Mastectomy, Simple Mastectomy	Procedural episode- based	Proposed for 2020 Performance Period and Beyond		
Non-Emergent Coronary Artery Bypass Graft (CABG)	Procedural episode- based	Proposed for 2020 Performance Period and Beyond		
Renal or Ureteral Stone Surgical Treatment	Procedural episode- based	Proposed for 2020 Performance Period and Beyond		

(3) Improvement Activities (IA) (§414.1355)

CMS has previously defined an improvement activity (IA) to mean an activity that MIPS-eligible clinicians, organizations and other relevant stakeholders identify as improving clinical

practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. IA examples include establishing after-hours access to clinical advice and use of shared decision-making tools, and suggested new activities are solicited by CMS through an Annual Call for Activities. The IA performance category is usually weighted at 15 percent during MIPS scoring but may be reweighted under certain specified circumstances (e.g., participation in a MIPS APM).

a. IA Data Submission (§414.1360(a)(2))

CMS did not propose any changes to current IA data submission mechanisms or data submission criteria for performance period 2020. CMS did propose two changes to IA reporting by groups. First, CMS proposed to increase the group reporting threshold such that at least 50 percent of a group's clinicians (counted as NPIs) would be required to complete an IA for the entire group (as a TIN) to receive IA category credit. This would be an increase from the current requirement that at least one clinician from the group must report in order for the group to receive credit. Support from stakeholders for such an increase has been mixed when proposed in the past. However, CMS states that meeting the higher threshold is readily achievable by groups now that clinicians are familiar with the IA category and can select from over 100 IAs in the activity inventory. CMS also considered alternatives of 25 and 100 percent thresholds, but concluded that 50 percent was reasonable and sufficient to demonstrate a group's collective commitment to practice improvement without adding to clinician burden.

Second, CMS proposed a new requirement that at least 50 percent of the NPIs within a group must perform the same IA for the same continuous 90-day period within a performance year. CMS indicates that a group's patient outcomes are more likely to be positively influenced when a substantial fraction of the group's clinicians engage in the same IA. A separate attestation would be required for each IA that was completed by 50 percent or more of the group's members for the same 90-day period.

CMS received numerous comments and reviews them in considerable detail. Many commenters viewed the 50-percent threshold as far too high, citing the challenge of identifying IAs that are relevant to half of a group's practitioners and that will engage them in practice transformation. Many commenters also voiced concern that the transition from one group member participating to 50 percent of the group was an enormous jump over a very short timeframe, and suggested more gradual increases. Most commenters also were highly skeptical about the ability of group members to synchronize their participation in their chosen IA into a single 90-day period. Commenters raised logistical challenges, such as variable call schedules and clinic days, and stated that the organizational burden would be substantial.

CMS responds that the IA inventory now contains over 100 measures and should be sufficient to allow groups to identify a measure in which one half of their clinicians can participate meaningfully. CMS notes having considered a range of participation thresholds from 25 to 100 percent, settling on 50 percent as a reasonable balance between the importance of group members actively supporting practice transformation through shared IAs and the challenges of bringing their clinicians together to meet the threshold. CMS acknowledges the scheduling issues inherent in identifying a single 90-day period for clinicians to work on the same IA.

CMS states a belief in the importance of IAs as a means for practices to bring clinicians together to improve outcomes for all of their patients. In response to the concerns about shared IA performance over a single 90-day period, CMS outlines a modification such that each participating group member can report the shared IA during a 90-day period of the individual's choice (i.e., at different points in the year). CMS perceives that this modification would alleviate the burden of synchronizing participant performances. CMS goes on to finalize the two criteria for group participation in the MIPS IA performance category as follows: beginning with the 2020 performance year, each IA for which groups and virtual groups submit a yes response must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance year.

b. Criteria for Improvement Activity Removal

To date, IA activities once added have remained in the IA inventory indefinitely. CMS has previously explained that a process for IA activity removal would be needed and states that suggestions for removal could be made through the established Annual Call for Activities process. CMS proposed 7 factors to be considered in decision-making about removing a specific activity, similar to those utilized when considering quality measure removal:

- The activity is duplicative of another existing IA.
- An alternative IA exists that is more closely linked to care quality or clinical practice improvement.
- The activity does not align with current clinical guidelines or practices.
- The activity does not align with at least one from the Meaningful Measures initiative.
- The activity does not align with either the Cost, Quality, or Promoting Interoperability performance categories.
- No clinician has attested to performing the activity for 3 consecutive years.
- The activity is obsolete.

CMS indicated that the proposed factors would be taken into account in removal decisions but would not be applied as rigid requirements. CMS also noted that removal of an IA from the inventory would occur during notice-and-comment rulemaking. CMS further noted that its associated proposal for removing some IAs for the 2020 performance period would be contingent upon finalizing the IA removal criteria.

Support from commenters was mixed. Those opposing one or more of the proposed removal criteria stated

- Requiring that IA align (and remain aligned) with quality, cost, and promoting
 interoperability measures will limit innovation by constraining the development of new
 IAs
- Practices have made significant financial investments to support certain IAs and their investments should not be ignored.
- Activity removal should be restricted to those that have become obsolete or are no longer able to be performed (e.g., participation in a program that has ended).

- Over-pruning the IA inventory will drive MIPS towards a one-size-fits-all structure that would not be applicable across the spectrum of clinical practices.
- The proposed changes are too extensive and being implemented too rapidly, and the ongoing pressure for IA removal will foster the development of IAs that are temporary rather than designed to support long-term practice transformation.

CMS responds by noting that linkage across the MIPS performance categories will be a key component of MVPs; that delaying the adoption of the linkage requirement until MVPs are well-developed is not justifiable given the well-known need to streamline MIPS; that investments should be phased out for IAs that are no longer clinically relevant; and that the requirement for notice and comment rulemaking prior to specific IA removal will offer protection against overly extensive or rapid IA inventory changes. CMS finalizes as proposed the seven factors when considering IA activity deletion.

c. Changes to IAs for 2020 performance year 2020

CMS proposed to add 2, modify 7, and remove 15 activities from the IA inventory for performance period 2020. Full details are provided in Tables A, B, and C, respectively, of Appendix 2 of the rule, including commenter suggestions. The two new activities are Drug Price Transparency and Completion of an Accredited Safety or Quality Improvement Program. The proposed removals were contingent upon finalizing the IA removal criteria and have been finalized. Both of the new activities also were finalized.

d. CMS Study on Improvement Activities and Measurement

CMS began the Study on Improvement Activities and Measurement in 2017, and has recruited new participants annually, to examine clinical quality workflows and data capture using a simpler approach to quality measures. Participants have received full credit (40 points) for the IA performance category. (The study name has evolved to "Study on Factors Associated with Reporting Quality Measures".) CMS proposed to end the study with the end of the 2019 performance period, at which time the sample size and volume of data collected will have met or exceeded the minimum numbers required to achieve the study's goals. If the study is ended as proposed, CMS would also end the IA reporting credit for study participants beginning with the 2020 performance period. Deletion of the study-associated IA credit would be based upon removal factor 7 - the activity is obsolete.) CMS anticipates completing analysis of the study data by Spring 2020 and would proceed to share lessons learned through CMS education and outreach events.

Commenters were generally supportive but urged CMS to conduct similar studies in future years as the QPP continues to evolve. CMS finalizes the proposal to terminate the study and its associated 40-point IA credit for participants. CMS indicates that after the study results are made public, the agency will turn its focus to sharing and applying the lessons learned.

e. Rural definition modification (§414.1305)

Scoring of the IA category is adjusted for MIPS-eligible clinicians who practice in rural areas by awarding double credit for IA activities compared to non-rural practices. CMS proposed to modify the definition of rural used in making the IA scoring adjustments by making a technical correction to reference the correct zip code file used for MIPS IA scoring. The incorrect reference is to the (HRSA) Area Health Resource File, which would be corrected to the Federal Office of Rural Health Policy (FORHP) eligible ZIP codes file. CMS states that no scoring or payment errors have resulted from the incorrect reference, as CMS was using the correct file for the purpose of MIPS scoring even though the incorrect file was named in the associated regulation. CMS received no comments on the proposed file name correction and the regulation will be revised to reference the most recent available version of the FORHP Eligible Zip Code file. ¹⁷

f. Removal of References to Specific Accreditation Organizations (§414.1380)

Scoring of the IA category may also be adjusted for practices that are designated as certified patient-centered medical homes or comparable specialty practices (i.e., giving full credit in the IA category for certified practices). Criteria defining how those practices are determined to be medical homes or comparable specialty practices refer to recognition as such by several accrediting organizations (e.g., National Committee for Quality Assurance or NCQA). CMS proposed to delete the references in regulation to specific accrediting organizations in order to avoid excluding other entities that might operate similar certification programs. Accreditation by organizations that are national in scope and have evidence of being used by a large number of medical organizations as their medical home model would be acceptable to CMS as the basis to award the IA credit.

Commenter support was mixed. Opponents noted the high standards required for medical home and specialty medical home accreditation by the organizations named in the regulations and were concerned about a lowering of standards by allowing more generic accreditation. Opponents also worried that MIPS-eligible clinicians would no longer be able to feel secure about qualifying for the IA category credit. CMS responds that removing references to specific accreditors would not change the certification standards and is merely a means for making the regulation text more neutral. CMS notes that many other organizations besides those named in regulation have nationally-recognized certification programs. CMS goes on to finalize the revised regulation as proposed, removing references to specific accrediting organizations and programs.

¹⁷ https://www.hrsa.gov/rural-health/about-us/definition/datafiles.html.

¹⁸ CMS provides some examples of other suitable patient centered medical home accreditors at https://qpp.cms.gov/mips/improvement-activities.

(4) Promoting Interoperability (PI)

(a) Background, Goals, and Performance Periods

As set in statute, meaningful use of CEHRT is addressed as a distinct performance category within MIPS. Originally termed Advancing Care Information, the category was renamed in 2018 as Promoting Interoperability, to align with similar retitling of CEHRT initiatives within hospitals, Critical Access Hospitals (CAHs), and the Medicaid program. The MIPS PI category underwent major restructuring in 2019, consolidating measures and simplifying scoring, referred to by CMS as the "overhaul". The PI category constitutes 25 percent of the overall MIPS score. CMS identifies the following as priorities within the MIPS PI category for performance year 2020: stability within the category, burden reduction, continued use of 2015 Edition CEHRT, enhancing EHR access by patients to support their healthcare decision-making, and continued alignment of the MIPS PI category with the Medicare PI program for hospitals and CAHs and the Medicaid PI program.

CMS proposed to maintain the PI performance period for performance years 2020 and 2021 as a minimum of one continuous 90-day period, up to and including the full calendar year. CMS stated that this proposal would provide stability within the PI category and would align with the PI program for hospitals and CAHs for those years. Many commenters supported this proposal, and it is finalized by CMS without modification.

(b) Changes to e-Prescribing Objective Measures

CMS addresses two PI measures introduced into use for performance year 2019: 1) Query of Prescription Drug Monitoring Program (PDMP) and 2) Verify Opioid Treatment Agreement. CMS has heard significant and predominantly negative feedback about these measures since their inception. CMS also notes that provisions of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act of 2018) will also affect use of these two measures e.g., requirements for PDMP integration and interoperability. To respond to stakeholder feedback and to take into account the policy implications of the SUPPORT Act, CMS proposed that for performance year 2020: 1) reporting the Ouery PDPM measure would be optional and would be eligible for 5-bonus points, and 2) the Verify Opioid Treatment Agreement measure would be removed. CMS also proposed that beginning with the 2019 performance period, to change the Query PDPM measure's reporting structure from calculated (numerator/denominator) to attestation (yes/no response). 19

The majority of commenters were supportive of the Query PDMP measure changes. In response to questions, CMS clarifies that an exclusion process for the measure is unnecessary since reporting data for the measure would be optional;²⁰ the practitioner prescribing the controlled substance does not need to be the same as the one submitting the query to the PDMP; and, since most PDMP systems are "view only", privacy protection for the patient data therein is likely to

¹⁹ This change may begin in 2019 because 2019 MIPS data reporting does not occur until the first quarter of 2020.

²⁰ An exclusion process would allow clinicians to apply to be exempt from reporting the measure.

be sufficient.²¹ CMS finalizes the PDMP changes as proposed; this change results in increasing the e-prescribing measure score maximum to 10 points.

Nearly all commenters supported the removal of the Verify Opioid Treatment Agreement. CMS finalizes the measure's removal without modification.

(c) Health Information Exchange Objective

Support Electronic Referral Loops by Sending Health Information Measure

This measure was formerly named "Send a Summary of Care" and was given its current name for 2019 reporting. The measure had a potential participation exclusion that was retained for the renamed measure, but CMS did not specify how the points for the renamed measure would be redistributed were the exclusion to be claimed. CMS proposed that the 20 points assigned to the renamed measure would be redistributed to the Provide Patients Access to Their Health Information measure were the exclusion to be claimed.²² The proposed revision would be applicable beginning with the 2019 performance period and subsequent years.²³

Most commenters were supportive of the proposed change. One stated that the redistribution would give an unfair advantage in PI scoring to smaller entities that are more likely to meet the exclusion criteria. CMS counters that the measure has substantial value by enhancing the clinical utility of EHRs. CMS finalizes the point redistribution as proposed.

Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure

For performance year 2019, this measure replaced two existing measures, titled, respectively, the "Request/Accept Summary of Care" and "Clinical Information Reconciliation" measures. A potential participant exclusion was established at that time for the new measure. However, the language of the exclusion subsequently has been misconstrued by some users. CMS, therefore, proposed to revise the exclusion to read "Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period". The revised exclusion language would become applicable beginning with the 2019 performance period and subsequent years. The 20 points currently associated with the measure would continue to be distributed to the Provide Patients Access to Their Health Information measure, were the exclusion to be claimed. If exclusions to both Support Electronic Referral Loops measures are claimed, the combined 40 points would be redistributed to the Provide Patients Electronic Access to Their Health Information measure.

Most commenters were supportive of the proposed change. One commenter stated that the 40-point redistribution would overemphasize the contribution of the Provide Patients Electronic Access to Their Health Information measure to MIPS PI scoring. CMS disagrees and notes that

²¹ This may be even more likely since the SUPPORT Act mandates the use of PDMPs.

²² The exclusion applies to any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

²³ This change may begin in 2019 because 2019 MIPS data reporting does not occur until the first quarter of 2020.

the emphasis placed on the Provide Patients Access measure will encourage patient engagement in their health care. CMS finalizes the point redistribution as proposed.

(d) Public Health and Clinical Data Exchange – Syndromic Surveillance Reporting

CMS makes a technical correction to restate the measure description for the Syndromic Surveillance Reporting measure. The measure description was incorrectly stated in the 2019 PFS final rule as involving data submission from non-urgent settings, when the measure was correctly specified previously as involving data submission from urgent care settings. The correct language is included in Table 48 of the final rule: Objectives and Measures for the Promoting Interoperability Performance Category in 2020.

(e) Scoring Methodology

CMS provides an updated table showing the PI performance category scoring methodology for use in 2020 and subsequent years, inclusive of the finalized changes discussed above. Table 49, reproduced below from the final rule, does not reflect the potential point redistributions if reporting exclusions are claimed as described above.

TABLE 49: Scoring Methodology for the Performance Period in 2020

Objectives	Measures	Maximum Points
	e-Prescribing*	10 points
e-Prescribing	Query of PDMP	5 points (bonus)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information*	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information*	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report to two different public health agencies or clinical data registries for any of the following: Immunization Registry Reporting* Electronic Case Reporting* Public Health Registry Reporting* Clinical Data Registry Reporting* Syndromic Surveillance Reporting*	10 points

^{*}Exclusion available

(f) Additional PI Performance Category Considerations

PI Reporting by Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

CMS previously established a policy for the 2017, 2018, and 2019 performance periods to assign a weight of zero to the PI performance category if CMS determines that there are not sufficient measures applicable and available to these clinician types for MIPS reporting. Should a clinician of a type eligible for reweighting choose to report PI data, that clinician is instead scored for the PI category using their data and the scoring policies currently in effect for other types of MIPS-eligible clinicians.

CMS has analyzed PI data submitted during the 2017 performance period to reassess whether reweighting in fact remains appropriate for NPs, PAs, CRNAs, and CNSs. CMS found a paucity of data that could be definitively linked to individual clinicians of these types. CMS also notes that the PI category measures and scoring have undergone substantial restructuring since 2017. CMS concludes, therefore, that a valid determination as to whether the currently available PI category measures would suffice for meaningful reporting by NPs, PAs, CRNAs, and CNSs is not possible at this time. Therefore, CMS proposed to maintain the established policy of reweighting the PI category to zero for NPs, PAs, CRNAs, and CNSs for the 2020 performance period but to continue scoring any clinician who submits PI data during that period.

Commenters were largely supportive. CMS finalizes the continued PI reweighting to zero for NPs, PAs, CRNAs, and CNSs as proposed.

PI Reporting by Physical Therapists, Occupational Therapists, Qualified Speech-language Pathologists, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition Professionals

For similar reasons, CMS proposed to treat physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals in the same manner as the previously discussed group (NPs, PAs, CRNAs, and CNSs) for potential PI category reweighting for performance year 2020 and subsequent years.

Most commenters supported the proposal. Concern was raised about the lack of applicable measures for these and other nonphysician practitioners (NPPs) who are MIPS-eligible clinicians. A commenter suggested PI reweighting to zero for chiropractors.

CMS responds by encouraging NPPs and their representatives to submit PI measures for approval that are relevant and meaningful to their practices. CMS clarifies that chiropractors differ from the NPPs cited, as the former were in fact able to participate in the Medicare EHR Incentive Program while the latter were not. Through participation in the Medicare EHR Incentive Program, the predecessor to the PI category, chiropractors were able to gain experience and familiarity with reporting measures that served as the basis for PI measures. CMS intends to periodically revisit whether reweighting remains appropriate for all types of NPPs who are MIPS-eligible. CMS finalizes as proposed the PI category reweighting for physical therapists,

occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals.

PI Reporting by Groups of Hospital-Based MIPS-eligible Clinicians

CMS has previously defined a hospital-based MIPS-eligible clinician as one furnishing 75 percent or more of his or her covered professional services in one or more of the following settings, as identified by their Place of Service (POS) codes: inpatient hospital (POS 21), on-campus outpatient hospital (POS 22), off-campus outpatient hospital (POS 19), or emergency room (POS 23) based on claims for a MIPS determination period. The determination period sets the time interval from which claims are collected to make the final determination of "hospital-based". CMS has previously established a policy to assign a weight of zero to the PI performance category for a hospital-based MIPS-eligible clinician. If hospital-based clinicians choose to report PI data, however, the clinicians will be scored using their data under the PI category scoring policies currently in effect for other MIPS-eligible clinicians.

In response to stakeholder concerns about application of the reweighting policy to hospital-based physician groups, CMS proposed for performance year 2020 and subsequent years to define a hospital-based MIPS eligible clinician as one who furnishes 75 percent or more of his or her covered professional services in settings with POS codes 19, 21, 22, or 23 (based on claims for a MIPS determination period) and that the definition would also include a group or virtual group in which more than 75 percent of the NPIs billing under the group's or virtual group's TIN meet the definition of a hospital-based individual MIPS eligible clinician. CMS also proposed conforming changes to other pertinent regulations.

Commenters were supportive. One recommended extending the reweighting policy to apply to all MIPS-eligible clinicians, and CMS declines to make this change. CMS finalizes the changes for hospital-based clinicians as proposed.

PI Reporting by Groups of Non-Patient Facing MIPS-eligible Clinicians

CMS currently defines a non-patient facing MIPS eligible clinician to mean an individual who bills 100 or fewer patient facing encounters, including Medicare telehealth services, during the MIPS determination period, <u>and</u> to mean a group or virtual group provided that more than 75 percent of the NPIs billing under the group's or virtual group's TIN meet the definition of a non-patient facing individual MIPS eligible clinician. For consistency and clarity, CMS proposed to adopt language similar to that proposed for hospital-based clinician groups in the regulations applicable to non-patient facing groups; that is, requiring that 75 percent or more, rather than the current 100 percent, of a non-facing clinician group's members qualify as non-patient facing in order for the entire group to be eligible for PI category reweighting.

Commenters were supportive. One suggested that CMS should make it easier for groups to evaluate whether they may qualify as hospital-based or non-patient facing by enhancing the Quality Payment Program Participation Status Tool on the Quality Payment Program website to show eligibility and special statuses for TINs, in addition to NPIs. CMS concurs and notes having already implemented the suggestion. CMS concludes by finalizing the changes for non-patient facing clinicians as proposed.

(g) Future Direction of the Promoting Interoperability Performance Category

In the 2020 PFS proposed rule, CMS issued six RFIs concerning future changes to the PI category concerning the following:

- Potential Opioid Measures for Future Inclusion in the PI performance category;
- NQF and CDC Opioid Quality Measures;
- Metric to Improve Efficiency of Providers within EHRs;
- Provider to Patient Exchange Objective;
- Integration of Patient-Generated Health Data into EHRs Using CEHRT; and
- Activities that Promote Safety of the HER.

CMS notes having received comments but opts not to summarize or respond to the commenters at this time. Suggested changes may be considered in future rulemaking.

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

The APM scoring standard (§414.1370) applies to MIPS eligible clinicians identified on the Participation List of an APM entity participating in a MIPS APM. It is designed to reduce reporting burden for these clinicians by avoiding duplicative data submission to MIPS and the MIS APMs, and to avoid possibly conflicting incentives between the two. Clinicians participating in MIPS APMs receive quality scores based on their participation in the model. If no quality data are available for scoring, the MIPS categories are reweighted to 75% Promoting Interoperability and 25% Improvement Activities.

CMS expects that the following 10 APMs will satisfy the requirements to be MIPS APMs for the 2020 MIPS performance period. The final determinations will be announced via the QPP website at https://qpp.cms.gov/.

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

In this rule, CMS finalized its proposals for scoring the quality performance category for MIPS APMs.²⁴ CMS has found that many MIPS APMs run on different timelines that do not align with MIPS performance periods and deadlines for data submission, scoring and performance feedback. As a result, it is often not operationally possible to collect and score quality

²⁴ CMS notes that dues to a clerical error, the regulations text corresponding with the proposals discussed in this section of this final rule were omitted from the proposed rule. Comments received by CMS indicate that readers understood the proposed policies. CMS finalizes the proposed policies and amends §414.1370(g)(1) accordingly.

performance data for purposes of the MIPS. Although the possibility of reweighting of the quality category was anticipated, CMS does not believe this should occur regularly.

Allowing Clinicians Participating in MIPS APMs to Report on MIPS Quality Measures. CMS finalizes its proposal to allow MIPS APM clinicians to report on MIPS quality measures in the same way that it currently permits them to report for the Promoting Interoperability category under the MIPS APM scoring standard. This policy will begin with the 2020 performance period. Specifically, CMS will attribute one quality score to each MIPS eligible clinician in an APM Entity by looking at both individual and TIN-level data submitted for the eligible clinician and use the highest reported score, excepting scores reported by a virtual group. It will then use the highest individual or TIN-level score attributable to each MIPS eligible clinician in the APM Entity to determine an average, which will be the APM Entity score. A clinician with no quality performance category score will contribute a score of zero to the aggregate APM Entity group score. Only scores reported by an individual clinician or a TIN reporting as a group will be used. Virtual group level reporting is excluded because CMS believes these scores are too far removed from a clinician's performance on quality measures for purposes of the APM scoring standard.

Many commenters supported this proposal. In response to some concerns about the additional reporting burden, CMS acknowledges that this policy may introduce additional burden for some APM participants, but it anticipates this will be limited to those instances where Participants' TINs do not already report separately to MIPS. It also believes any potential burden will be further mitigated by its finalized policy to allow APM Entity-level quality reporting for MIPS (discussed below).

APM Quality Reporting Credit.

Beginning with the 2020 performance period, CMS finalizes its proposal to apply a minimum score of 50 percent (one half of the highest potential score for the quality performance category), called an "APM Quality Reporting Credit", to APM Entity groups participating in MIPS APMs, with the exceptions described below. The credit will be added to any MIPS quality measure scores CMS receives, with a cap of 100 percent for the quality category. For example, if the additional MIPS quality score were 70 percent, it will be added to the 50 percent credit for a total of 120 percent, but the total assigned will be 100 percent.

The APM Quality Reporting Credit will <u>not</u> apply to APM Entities reporting only through a MIPS quality reporting mechanism according to the requirements of their APM. For example, the will not apply to the Medicare Shared Savings Program, which requires participating ACOs to report through the CMS Web Interface and the CAHPS for ACOs survey measures. CMS states because in these cases there isn't any burden of duplicative reporting for participants, and there aren't any additional unscored quality measures for which to give credit. CMS notes that if an APM Entity group in this circumstance fails to report on required quality measures, individual eligible clinicians and TINs in the group are able to report quality measures for purposes of calculating a quality performance score. They remain ineligible for the APM Quality Reporting Credit because no burden of duplicative reporting exists.

Many commenters supported this proposal and a few suggested alternatives for the credit, including raising the credit to 100 percent of the quality performance category and raising the

credit to the minimum number of points required to ensure APM Entities receive a neutral payment adjustment under the APM scoring standard. CMS does not believe that participation in a MIPS APM is sufficient demonstration of quality performance to warrant a score of 100 percent and it would not meet the statutory requirements that CMS measure "performance" on quality measures under the quality performance category (section1848(q)(5)(E)(i)(I) of the Act). CMS acknowledges it did consider an approach where the credit would guarantee MIPS APM participants a MIPS score equal to or greater than the performance threshold for a QPP performance year but believes that would give MIPS APM participants a competitive advantage within MIPS as the performance threshold increases over time. CMS believes a credit of one-half of the performance reflects the intent of rewarding a specific performance activity and not to guarantee a specific outcome within the MIPS program.

Some commenters disagreed with the proposal because it would have the effect of raising the performance threshold and make it more difficult for other MIPS eligible clinicians to receive a top score. CMS acknowledges this but based on its review of the data, it believes this approach will reward MIPS APM participants for the quality reporting they do within their APM, without unduly advantaging them relative to this MIPS performance threshold. CMS does not anticipate this policy will have any negative impacts on other MIPS eligible clinicians.

Additional Reporting Option for APM Entities.

CMS finalizes its proposal that if an APM Entity has reported quality measures to MIPS through a MIPS submission type and uses a MIPS collection type on behalf of the APM Entity group, it will use that quality data to calculate an APM Entity group level score for the quality performance category. It does this recognizing that some APMs currently require participants to report on MIPS quality measures, and believes this approach ensures that all participants in an APM Entity group receive the same final MIPS score, while reducing reporting burden to the greatest extent possible.

Bonus Points and Caps for the Quality Performance Category.

Under previously adopted policies, CMS applies bonus points when scoring the quality performance category at the APM Entity group level. Under the policies finalized in this rule, these adjustments will already be factored in when calculating an individual or TIN-level quality performance category score before the quality scores are rolled-up and averaged to create the APM Entity group level score. Therefore, CMS believes that it is inappropriate to continue to calculate these adjustments at the APM Entity group level in cases where an APM Entity group's quality performance score is reported by its composite individuals or TINs. However, in the case of an APM Entity group that reports on MIPS quality measures at the APM Entity group level, CMS will continue to apply any bonuses or adjustments that are available to MIPS groups for the measures reported by the APM Entity and to apply these adjustments at the APM Entity group level.

Special Circumstances.

Currently, clinicians subject to MIPS APM scoring are not eligible under the extreme and uncontrollable circumstances policies established for other MIPS-eligible clinicians. CMS finalizes its proposal to allow these clinicians eligible for the extreme and uncontrollable circumstances policies. This policy will be effective with the 2020 performance year and apply

only to the quality performance category. In general, clinicians under these special circumstances may qualify for zero percent weighting of the quality performance category. However, CMS finalizes the following policies with respect to weighting and scoring the quality performance category for a MIPS APM clinician under special circumstances.

- A clinician who could quality for zero percent weighting of the quality category will not receive a zero percent weighting of the quality performance category if they are part of a TIN reporting at the TIN level that includes one or more MIPS-eligible clinicians who do not qualify for a zero percent weighting. The TIN will not need to report data for the qualifying MIPS eligible clinician, but will continue to report for the group, and all clinicians in the TIN will count towards the TIN's weight when calculating the aggregated APM Entity score for the quality performance category.
- For a solo practitioner who qualifies for zero percent weighting or in a case where all MIPS eligible clinicians in a TIN qualify for the zero percent weighting, reporting on the quality performance category will not be required and the category will be assigned a weight of zero when calculating the APM Entity's quality performance category score.
- If quality performance data were reported for one or more TIN/NPIs in an APM Entity group, a quality performance category score will be calculated and applied to all MIPS eligible clinicians in the group. The quality performance category will be weighted at zero percent if all clinicians in all TINs of an APM Entity group qualify for a zero percent weighting.

Request for Comment on APM Scoring Beyond 2020.

CMS sought comment on potential policies to be included in future rulemaking to further address the changing incentives for APM participation under MACRA. It seeks to design the APM scoring standard to continue to encourage appropriate shifts of MIPS eligible clinicians into MIPS APMs and eventually into Advanced APMs while ensuring fair treatment for all MIPS-eligible clinicians. CMS notes that as the QP threshold increases in future years, more Advanced APM participants may be subject to MIPS under the APM scoring standard, while at the same time the MIPS performance threshold will be increasing and thereby reducing the impact of the APM scoring standard on participants' ability to achieve a neutral or positive payment adjustment under MIPS.

CMS also sought comment on the following approaches it is considering for the 2021 performance year:

- Sunsetting the proposed APM Quality Reporting Credit after a specific number of years;
- Sunsetting the proposed APM Quality Reporting Credit for MIPS APMs that are not also Advanced APM track;
- Sunsetting the proposed APM Quality Reporting Credit for APM Entities in one-sided risk tracks; and
- Retaining different APM Quality Reporting Credits for Advanced APMs and MIPS APMs.

CMS received general support on finding ways to continue to reward APM participation without giving APM participants an undue advantage within MIPS. CMS notes it did not receive any

specific comments about the potential options listed above and discussed in the proposed rule about the APM Quality Reporting Credit.

Exclusion of Virtual Groups from APM Entity Group Scoring.

Current policies exclude virtual groups' MIPS scores when calculating APM Entity group scores. For clarity, CMS finalizes its proposal to clarify this exclusion in the regulatory text at §414.1370(e)(2).

MIPS APM Performance Feedback. MIPS-eligible clinicians who are scored under the APM scoring standard receive performance feedback from CMS. Citing confusion with reporting on the 2017 performance year, CMS intends to better align treatment of Shared Savings Program ACOs and their participant TINs with other APM Entities and, where appropriate, with other MIPS groups. Therefore, in addition to other performance feedback, CMS will provide TIN-level performance feedback to ACO participant TINs including information available to all TINs participating in MIPS, including the applicable final scores for MIPS-eligible clinicians billing under the TIN, regardless of their MIPS APM participation status.

d. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

For the 2022 MIPS payment year (2020 performance period) CMS proposes to build on the scoring methodology adopted for the transition years, recognizing that as it moves forward with the MIPS Value Pathways (MVP) Framework it is likely to propose changes to the scoring methodology in future rulemaking. Specifically, CMS expects in the future to revisit and remove the 3-point floor, bonus points, and assigning points for measures without a benchmark.

Scores developed for each of the four MIPS performance categories are used to calculate a final score, which is translated into the MIPS adjustment.

(b) Scoring the Quality Performance Category

CMS finalizes its proposals to extend a number of policies for scoring the quality performance category to payment year 2022 that the current regulatory text at §414.1380(b) limits to payment years ending in 2021. In addition, CMS finalizes its proposal to change the method used to calculate performance benchmarks for certain measures to avoid encouraging inappropriate treatment.

- <u>3-Point Floor</u>. For the 2022 payment year, CMS finalizes its proposal to continue the 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period.
- Scoring Measures that Do Not Meet Case Minimum, Data Completeness, and Benchmarks Requirements. Table 50 in the final rule summarizes the scoring policies for the 2020 MIPS performance period for measures that are submitted but cannot be scored because they do not meet case minimum or data completeness requirements (Class 1 measures), or because they do not have a benchmark (Class 2 measures). These are previously adopted policies

that do not apply to Web interface or administrative claims measures. As previously adopted, the 2020 performance period will be the first for which CMS will assign zero points to measures that do not meet data completeness requirements (Class 3 measures), except that small practices will continue to receive 3 points.

- Incentives to Report High-Priority Measures. CMS finalizes its proposal to maintain for the 2022 payment year the cap on high-priority bonus points, which is set to equal 10 percent of the total possible measure achievement points that the MIPS eligible clinician could receive in the quality performance category. High-priority measure bonus points do not apply for CMS Web Interface reporters. CMS clarifies that in order for a measure to qualify for high-priority bonus points it must meet established case minimum and data completeness requirements and not have a zero performance; it does not need to have a benchmark.
- Incentives to Use CEHRT to Support Quality Performance Category Submissions. CMS finalizes its proposal to continue for the 2022 payment year the assignment of bonus points for end-to-end electronic reporting. The policy only applies to data 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 believes that in the future under the MVP policies it will be possible to incorporate eCQMs without providing these bonus points.
- Improvement Scoring. CMS finalizes its proposal to continue previously adopted policy for improvement scoring for the 2022 payment year. Specifically, it will compare the eligible clinician's quality performance category achievement percent score for the 2020 performance period to an assumed quality performance category achievement percent score of 30 percent if the MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent for the 2019 MIPS performance period.

CMS acknowledges stakeholders' concerns about these policies and will take them into future consideration. CMS notes that it anticipates that the MVP framework will allow it to remove some of the scoring complexity associated with the MIPS program, including removing caps and bonuses.

Modifying Benchmarks to Avoid Potential for Inappropriate Treatment.

A proposed change for the 2020 performance period would modify the way benchmarks are calculated for certain measures. Benchmarks are established by collection type, using performance data from all available sources, including MIPS-eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

Responding to concerns that benchmarks for some measures may incentivize inappropriate treatment of some patients in order for clinicians to score in the highest decile, CMS proposed to use a flat percentage benchmark for certain measures. The measures of concern are those with a benchmark that is set at very high or maximum performance in the top decile, where in order to achieve the highest performance level clinicians may be encouraged to over treat patients regardless of the individual patient's circumstances.

Specifically, CMS proposed to establish benchmarks based on flat percentages in cases where it determined that a measure's otherwise applicable benchmark could potentially incentivize

inappropriate treatment. Under the proposal, any performance rate at or above 90 percent would be in the top decile and any performance rate above 80 percent would be in the second highest decile, and so forth for the remaining deciles. CMS believes the measures involved are high-priority or outcome measures for clinicians to focus on and it wants to avoid having clinicians receive a low score when they adhere to the most appropriate treatment. It identified the flat percentage approach as simple and straightforward and similar to the method used to set benchmarks in the Shared Savings Program, and for some MIPS measures that are collected through the CMS Web Interface.

In order to identify the measures to which the flat percentage benchmark would apply, CMS' medical officers would assess if there are patients for whom it would be inappropriate to achieve the outcome targeted by the measure benchmark. This assessment would consider whether the measure specifications allow for clinical judgment to adjust for inappropriate outcomes, if the benchmarks for any of the measure's collection types could put patients at risk by setting a potentially harmful standard for top decile performance, or whether the measure is topped out. The assessment would take into account all available information, including the medical literature, published practice guidelines, and feedback from clinicians, groups, specialty societies, and the measure steward. CMS would propose the modified flat benchmark through rulemaking. The proposed policy would be effective beginning with the 2020 performance period.

CMS identified two measures for which it proposed to use benchmarks based on flat percentages to avoid potential inappropriate treatment:

- MIPS #1 (NQF 0059): Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) and
- MIPS #236 (NQF 0018): Controlling High Blood Pressure.

CMS determined that these measures lack comprehensive denominator exclusions and risk-adjustment or risk-stratification, and therefore could encourage over treatment of patients in order to meet numerator compliance. CMS believes that all benchmarks associated with these measures could be affected. Specifically, it proposed to use the flat percentage benchmarks for all collection types where the top decile for any measure benchmark is higher than 90 percent under the performance-based benchmarking methodology. Based on the 2019 performance period benchmarks, CMS anticipated using the flat percentage benchmark for the Medicare Part B claims and the MIPS CQM collection types for these two measures.

Several commenters supported this proposal and had additional recommendations for implementation. CMS recommends stakeholders contact them through the MIPS service center (QPP@cms.hhs.gov) to identify a measure they believe meets the requirements for a flat percentage benchmark; CMS will consider these in future rulemaking. CMS notes that it intends to apply this policy to all measures with the potential for inappropriate treatment based on the patient's circumstances and it does not think it is appropriate to apply this standard broadly to "topped out" measures. CMS agrees with commenters that using a data driving approach to establishing benchmarks is preferred but it does not believe it has sufficient information to conduct analysis involving risk stratifications and other modifications for the 2020 performance period. It is interested in working with stakeholders to better understand alternative methods.

Several commenters did not support this proposal to set benchmarks using a flat percentage because the approach would not provide the same adjustment to all collection types and would lead to inconsistent evaluation of clinicians with some measures having performance compared to peers and some measures having performance compared to a flat threshold. CMS acknowledges that not applying the same benchmarking methodology to all collection types may create some inconsistent evaluation for a single measure but is concerned that if it applies this method to all collection types without regard to the measure performance distribution based on the collection type, it would harm those with top performance for certain collection types. CMS believes it is better to limit the benchmark proposal to those collection types where the top decile is 90 percent or higher. In addition, CMS expects to apply this policy in very limited circumstances where there is a concern for incentivizing inappropriate treatment.

A few commenters did not support CMS' proposal to apply the flat percentage to the proposed measures for diabetes (MIPS #1) and high blood pressure (MIPS #236). A few commenters suggested that addressing exclusions for these measures might solve the issue of inappropriate care. In response, CMS reiterates concerns that stakeholders have raised that clinicians may feel pressure to meet the measure standards at a high level which could result in inappropriate treatment for some patients. CMS notes that the measure steward for these two measures has advised CMS of additional denominator exclusions for the 2022 payment year (see Appendix 1, Table Group D – Previously Finalized Quality Measures with Substantive Changes Finalized for the 2022 MIPS Payment Year).

After consideration of comments, CMS finalizes that beginning with the 2022 MIPS payment year, it will use the flat percentage benchmark as an alternative to its standard methodology for calculating benchmarks by a percentile distribution of measure performance rates for all collection types where the top decile for any measure benchmark is higher than 90 percent and its medical officers assess that there are patients for whom it would be inappropriate to achieve the outcome targeted by the measure benchmark. CMS also finalizes its proposal to apply the flat percentage rate to the following two measures:

- MIPS #1 (NQF 0059): Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) and
- MIPS #236 (NQF 0018): Controlling High Blood Pressure.

Request for Feedback on Additional Policies for Scoring the CAHPS for MIPS Survey Measure.

In the proposed rule, CMS did not propose any changes to the scoring of the CAHPS for MIPS survey measure. It did consider expanding the information collected in the CAHPS for MIPS survey measure (discussed above in this summary & described in section III.K.3.c.(1) of the final rule) and solicited comments on scoring alternatives. One consideration is adding narrative questions to the survey, which would invite patients to respond to a series of open-ended questions and describe their care experience in their own words. CMS is also considering adding a CAHPS for MIPS survey question that would allow patients to provide a score for their overall experience and satisfaction rating related to a recent health care encounter.

CMS received feedback about how to score this measure and on new questions it could potentially add to the CAHPS for MIPS survey question. It will consider this information for future rulemaking.

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

CMS did not propose any changes to the previously adopted policies under which a facility-based measurement scoring option is available to certain facility-based individual clinicians. Clarifying language is finalized for the regulatory text. Table 51 in the final rule, included for informational purposes, displays the Inpatient Hospital Value-Based Purchasing program measures for FY 2021. These measures are used in determining the facility-based quality and cost performance category scores for the CY 2020 MIPS performance period/2022 MIPS payment year.

(d) Scoring the Improvement Activities Performance Category

CMS refers readers to a previous section of the final rule (section III.K.3.c.(3), discussed above in this summary) for discussion of scoring the improvement activities performance category.

(e) Scoring the Promoting Interoperability Performance Category

CMS refers readers to a previous section of the final rule (section III.K.3.c (4), discussed above in this summary) for discussion of scoring the promoting interoperability performance category.

(2) Calculating the Final Score

For the 2021 MIPS payment adjustment, the final score is calculated using the following formula:

(Quality performance category percent score × Quality performance category weight) + (Cost performance category percent score × Cost performance category weight) + (Improvement Activities performance category score × Improvement Activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + the complex patient bonus, not to exceed 100 points.

(a) Complex Patient Bonus for 2022 MIPS Payment Year.

CMS finalizes its proposal to continue for 2022 the complex patient bonus adjustment, which is meant to protect access to services for complex patients and avoid disadvantaging the clinicians who care for them. CMS continues to see this bonus as a short-term solution and discusses previous analyses it undertook to consider whether the data support continuation of the complex patient bonus adjustment, as well as to consider newer work of the Assistant Secretary for Planning and Evaluation regarding socioeconomic status and the quality of care.

Table 52 of the final rule shows the results of CMS' updating its previous analysis looking at the relationship between final scores and two potential indicators of patient complexity: medical complexity as measured through Hierarchical Condition Category (HCC) risk scores; and social risk as measured through the proportion of patients with dual eligible status. This analysis estimates 2022 MIPS payment year scores using 2018 performance period data. (The analysis in the proposed rule estimated 2022 MIPS payment year scores using 2017 performance period data.) In the updated analysis, CMS did not observe a consistent linear relationship for any reporting type or complexity measure and notes that it appears that other unmeasured factors in

addition to HCC and the dual eligible ratio may be impacting MIPS scores in the 2018 data. CMS does, however, see differences from the top and bottom quartile in three of the four comparisons (individual-dual eligible quartiles and in both group reporting comparisons), so it finalizes continuing to use the complex patient bonus in the 2022 payment year.

CMS notes that the complex patient bonus was intended to be a temporary solution and it understands that both HCC risk scores and dual eligibility have some limitations as proxies for social risk factors. CMS acknowledges commenters suggestions, such as using geographic location as a proxy for social risk, for updating the complex patient bonus and will consider this in future years. It will also evaluate additional options based on any updated data or additional information to better account for social risk factors.

(b) Final Score Performance Category Weights

As discussed above in this summary (also discussed in section III.K.3.c.2(a) and III.K.3.c.(1)(b) of the rule), CMS does not finalize its proposals for the performance category weights for the 2022, 2023 and 2024 payment years. For the 2022 MIPS payment year, CMS finalizes a quality performance category weight of 45% and a cost performance category weight of 45%. The table below shows the weights previously finalized for the 2020 and 2021 payment years along with the proposed and final weights for the 2022 payment year (see Table 53 in the final rule). CMS does not finalize weights for the quality and cost performance categories for the 2023 and 2024 payment years.

Finalized Weights by MIPS Performance Category and MIPS Payment Year

	MIPS Payment Year					
	2020 2021 2022 2022					
Performance Category			(Proposed)	(Finalized)		
Quality	50%	45%	40%	45%		
Cost	10%	15%	20%	15%		
Improvement Activities	15%	15%	15%	15%		
Promoting Interoperability	25%	25%	25%	25%		

<u>Flexibility for Weighting Performance Categories</u>. CMS previously adopted policies for redistributing performance category weights under certain circumstances, such as when it cannot reliably calculate a performance category score because there is no measure applicable and available to a clinician or when it cannot reliably calculate a score for the measures in the cost category, among others.

CMS proposed that beginning with the 2020 payment year, it would redistribute the weight of any performance category if it determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for a MIPS-eligible clinician are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician and its agents. The reweighting would not be voided by the submission of data for the Promoting Interoperability performance category as is the case with other significant hardship exceptions.

The proposed reweighting would take into account both what control the clinician had directly over the circumstances and what control the clinician had indirectly through its agents (i.e., any individual or entity, including a third party intermediary as described acting on behalf of or under the instruction of the MIPS eligible clinician). Third party intermediaries would be asked to inform MIPS-eligible clinicians if the intermediary believes data may have been compromised, and to notify CMS of any clinicians so affected. Clinicians would be encouraged to contact CMS directly; CMS notes that knowing submission of compromised data could result in remedial action against the submitter.

CMS proposed that the determination of whether this reweighting applies would be made on a case-by-case basis. Relevant factors would include whether the affected MIPS-eligible clinician or its agents knew or had reason to know of the issue; whether the clinician or agents attempted to correct the issue; and whether the issue caused the data submitted to be inaccurate or unusable for MIPS purposes. If CMS determined that the conditions for reweighting are met, it would notify the clinician through the quarterly confidential reports or other routine QPP communication channels. CMS emphasized that if a MIPS-eligible clinician has submitted compromised data for a performance category after the start of the payment year, the clinician would not qualify for reweighting under this proposal.

After consideration of comments, CMS finalized its proposals. Beginning with the 2018 MIPS performance period and 2020 MIPS payment year, CMS will reweight the performance categories for a MIPS eligible clinician if it determines that data for a performance category that are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the clinician or its agents if it learns the relevant information prior to the beginning of the associated MIPS payment year. CMS also finalizes its proposal that this reweighting policy will not be voided by the submission of data for the Promoting Interoperability performance category.

Commenters supported CMS' proposal and provided suggestions for the types of circumstances where actions by third party intermediaries could lead to data being inaccurate, unusable, or otherwise compromised outside of the control of the clinical or its agents. These included instances where the third party intermediary goes out of business, makes a data submission error or experiences a loss of data. CMS believes that, depending on the specific circumstances and timing, these circumstances could be covered under this policy and encourages MIPS eligible clinicians and their agents to communicate with CMS as soon as possible through the help desk at QPP@cms.hhs.gov. CMS notes that it intends to make determinations on a case-by-case basis based on the related information. CMS emphasizes that it expects that third party intermediaries take reasonable steps to prevent cyberattacks and that depending on the circumstances, CMS may determine that the conduct of the third party intermediary warrants taking remedial action or terminating the third party intermediary in accordance with §414.1400(f). CMS agrees with a commenter that this policy could apply when a third party experiences a natural disaster that causes the MIPS eligible clinician's data to be inaccurate or unusable.

In response to comments urging CMS to notify MIPS eligible clinicians if it receives reports suggesting they may have compromised data, CMS states when it learns of circumstances that suggest MIPS data are inaccurate or unusable, it will aim to provide information to the involved clinicians on an ongoing and timely data. To the extent possible, when CMS learns of

compromised data and has sufficient information to determine the conditions for reweighting have been met, it intends to reweight without requiring any action on the part of the clinician.

CMS reiterates that if an eligible clinician knowingly submits compromised data, they would not be eligible for reweighing because the submission of the data was within the clinician's control. In addition, the submission of compromised data that are not true, accurate or complete may result in remedial action against the submitter.

CMS notes that it previously finalized that if a MIPS eligible clinician is scored on fewer than two performance categories, they will receive a final score equal to the performance threshold §(414.1380(c)). Therefore, if a MIPS eligible clinician is scored on fewer than two performance categories as a result of relighting due to compromised data, they will receive a final score equal to the performance threshold.

Redistributing Performance Category Weights.

CMS previously adopted policies for_redistributing performance category weights. In general, where possible, weights are redistributed to the quality performance category because clinicians have the most experience reporting quality measures. CMS has previously stated that it would be inappropriate to redistribute weight to the cost category because clinicians have limited experience with being scored on these measures.

In this rule, CMS proposed several modifications for the redistribution of category weights for the 2022 payment year. CMS finalizes its proposed redistribution policies with a few modifications to incorporate the general applicable weights for the quality and cost performance that are different from the proposed performance weights. CMS finalizes a quality performance category weight of 45% and a cost performance category weight of 15%. Table 55 in the final rule shows the specific performance category reweighting policies finalized for the 2022 payment determinations. The table shows how weights would be redistributed among the remaining categories under various scenarios such as redistributing the cost category weight among the other three categories or redistributing the quality and promoting interoperability weights between the remaining two categories, and so forth. In the scenario when only the improvement activities and cost performance categories are scored, CMS proposed a weight of 85 percent for the cost category and 15 percent for the improvement activity category (Table 54 in the final rule). CMS agrees with comments expressing concerns about the proposed weight of 85 percent for the cost category and finalizes a weight redistribution of 50 percent for each performance category.

Beginning with the 2023 payment determination, CMS proposed to begin redistributing weight from other categories to the cost category; CMS thought MIPS eligible clinicians would have had more experience with the cost measures. CMS stated that in general, category weights would be redistributed so that the quality and cost performance categories are almost equal. For simplicity, CMS proposed it would redistribute the weight in 5-point increments. If the redistributed weight could not be equally divided between quality and cost in 5-point increments, CMS would redistribute slightly more weight to quality than costs. Tables 56 and 57 in the final rule show the proposed policies for 2023 and 2024 MIPS payment year, respectively.

Several commenters did not support CMS' proposal to begin to redistribute weight to the cost performance scenario for a variety of reasons including the fact that as CMS planned to continue to add more measures to the cost category eligible clinicians will continue to have limited experience with the cost measures. Since CMS decided to maintain the weight at the cost performance category at 15 percent for the 2022 payment years, it has decided not to finalize redistribution policies for the 2023 and 2024 payment years. It will take comments into consideration for future rulemaking.

e. MIPS Payment Adjustments

(1) 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 provided 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). This additional 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).

In estimating the 2024 performance threshold and proposing the thresholds for 2022 and 2023, CMS reviewed actual data for the first year of MIPS (2019 payment/ 2017 performance), and used those data to also model performance under rules for 2021 payment. The mean and median final scores for the 2020 payment year were not available for the proposed rule. Based on the available information (see Table 51 in the proposed rule), CMS proposesd thresholds of 45 points for 2022 and 60 points for 2023. CMS believed this would establish a consistent 15 point increase for years 3 through 6 of the MIPS and would meet the statutory requirement for a gradual and incremental transition to the 2024 performance threshold. In addition, CMS believed this proposal could incentivize higher performance by clinicians.

The previously adopted and proposed performance thresholds for the MIPS payment year, along with CMS' estimate of the 2024 performance threshold from the proposed rule are shown here:

2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year Proposed	2023 MIPS Payment Year Proposed	2024 MIPS Payment Year Estimated	
3 points	15 points	30 points	45 points	60 points	70.74*	
*Mean of the actual MIPS scores for 2019.						

For this final rule, performance scores for 2020 were determined based on the actual final scores. Table 59 from the final rule, reproduced below, shows the mean and median data that CMS used for estimating the performance threshold for the 2024 payment year. CMS notes these values are estimates that may change as it completes the targeted review and due to the reweighting policy for data that are inaccurate, unusable, or otherwise compromised. CMS notes that the increase in the mean and median final scores for the 2020 payment year could be due to policy changes.

TABLE 59: Potential Values for Estimated Performance Threshold for the 2024 MIPS Payment Year Based on the Mean or Median Final Score for the 2019 MIPS Payment Year; 2020 MIPS Payment Year; and 2021 MIPS Payment Year

	2019 MIPS Payment Year* (points)	2020 MIPS Payment Year** (points)	2021 MIPS Payment Year*** (Points)	2022 MIPS Payment Year*** (Points)
Mean Final	74.01	86.91	69.53	76.67
Score				
Median	88.97	99.63	78.72	83.57
Final Score				

^{*} Mean and median final scores based on actual final scores for 2019 MIPS payment year as published in 2019 PFS final rule RIA (83 FR 60048).

Many commenters supported the proposed threshold because it would incentivize clinicians to perform at a high level and that the proposed performance thresholds were a reasonable and gradual increase. A few commenters did not support the proposed performance threshold of 45 points for the 2022 payment year because it did not provide for a threshold that would allow high performing clinicians to achieve the statutory 9 percent positive adjustment. CMS notes that because of the statutory requirement of budget neutrality and the application of a scaling factor, high performers may receive payment adjustments that are less than he applicable percent for the year provided in the statute but it believes its proposals allow a gradual and incremental transition to the estimated performance threshold for the 2024 payment year, as required by statute.

In response to suggestions that the performance threshold remain at 30 points to allow clinicians to adjust to changes in program requirements, CMS does not think this would incentivize the delivery of high quality care and would be to large an increase to the estimated 74.01 points as the performance threshold for the 2024. CMS acknowledges the concerns raised regarding small practices but notes there are special policies available for small practices, such as the small practice bonus that will assist small practices in achieving the performance threshold. CMS also believes there are multiple pathways for clinicians, including specialty practices, to meet or exceed the performance threshold.

After consideration of comments, CMS finalizes its proposal to set the performance threshold at 45 points for the 2022 MIPS payment year and at 60 points for the 2023 MIPS payment year.

(2) Additional Performance Threshold for Exceptional Performance

CMS proposed the additional performance thresholds for exceptional performance for the 2022 and 2023 MIPS payment years to be 80 points and 85 points, respectively, an increase from 75 points previously established for 2021. Clinicians with final scores at or above the additional

^{**} Mean and median final scores based on actual final scores for the 2020 MIPS payment year. Mean and median may change after the completion of targeted reviews and due to the reweighting policy for data that are inaccurate, unusable, or otherwise compromised.

^{***} Mean and median final scores based on estimated final scores from 2021 MIPS payment year as published in 2019 PFS final rule RIA (83 FR 60048) and the 2022 MIPS payment year as estimated in section VII of this final rule.

performance threshold are eligible to share in the \$500 million available for additional payments for exceptional performance.

These proposed thresholds are described as "minimal and incremental" increases over the 2021 additional performance threshold of 75 points. CMS noted that to achieve these points a clinician would have to perform well on multiple categories and would have to submit data for the quality category. It recognized that the higher thresholds may reduce the number of clinicians who receive additional MIPS payment adjustments, but notes that the maximum additional adjustment paid to those who meet the threshold would increase if the \$500 million available for these payments were distributed among fewer clinicians. CMS believes that it is appropriate to further incentivize exceptional performance in years 4 and 5 of the MIPS program.

CMS sought comments on the proposed thresholds and alternatives. CMS considered alternatives that would maintain the exceptional performance threshold for 2022 at 75 points and setting it even higher at 85 points. It also considered proposing 80 points as the threshold for both 2022 and 2023.

Several commenters did not support the proposal to increase the performance threshold for exceptional performance because of the continual changes in the MIPS program and difficulties for specialists and small practices to achieve a higher threshold. CMS disagrees and discusses several policies that support specialists and small practices.

A few commenters supported the proposed increases in the performance thresholds; a few suggested the performance thresholds for exceptional performance should be higher and suggested 85 points for the 2022 payment year. CMS appreciates these comments and notes that a higher additional performance threshold could increase the maximum additional payment adjustment that a MIPS eligible clinician could potentially receive if the available funds (up to \$500 million for the year) are distributed over fewer clinicians. CMS estimates that the number of MIPS eligible clinicians receiving an additional payment adjustment with the additional performance threshold at 80 and 85 points is 533,069 and 390,354 MIPS eligible clinicians, respectively. The maximum payment adjustment would increase from 4.5 to 6.2 percent (additional details available in section VIII.F.10 in this final rule). Given this analysis, CMS believes that increasing the additional performance threshold to 85 points for the 2022 payment year would provide an appropriate incentive for exceptional clinician performance.

After consideration of comments, CMS does not finalize its proposal to set the additional performance threshold at 80 for the 2022 payment year. Instead, CMS finalizes the additional performance threshold at 85 points for the 2022 MIPS payment year. CMS finalizes its proposal to set the additional performance threshold at 85 points for the 2023 MIPS payment year.

(3) Example of MIPS Adjustment Factors

Figure 1, copied from the final rule, illustrates how scores will be converted into adjustment factors for 2022 payment. The performance threshold is 45 points, and the applicable percentage is 9 percent. As shown, clinicians with a final score of 45 points would receive a 0 percent adjustment. The scale for other scores is not completely linear for two reasons. First, all clinicians with a final score between 0 and ½ of the performance threshold (0 and 11.25 in the

example) receive the lowest negative adjustment of -9 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 9 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 9 percent. CMS anticipates that with a performance threshold of 45 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 9 percent.

CMS indicates that for Figure 1, the illustrative budget neutrality scaling factor is 0.203; MIPS eligible clinicians with a final score of 100 would receive an adjustment factor of 1.83 percent (9.0 percent X 0.203). As shown next, however, this clinician would also receive an additional (exceptional performance) adjustment factor.

The exceptional performance threshold is 85. A score of 85 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 1, the illustrative scaling factor for the additional adjustment is 0.395; a clinician with a final score of 100 will receive an additional adjustment factor of 3.95 percent (10 percent X 0.395), and therefore a total adjustment of 5.78 percent (1.83 percent + 3.95 percent).

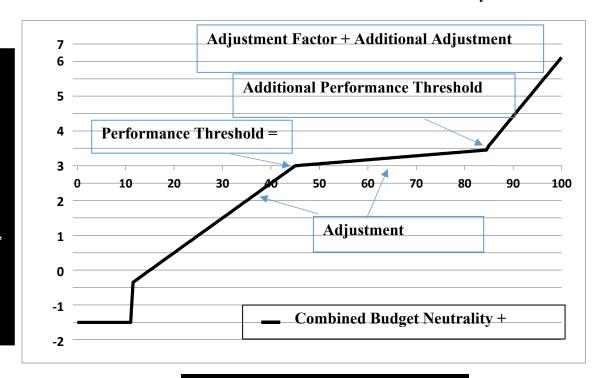
The actual MIPS payment adjustments will be determined by the distribution of performance scores; the greater the number of clinicians above the threshold, the more the scaling factors will decrease, and vice versa.

Table 60 in the final rule compares the point system and associated adjustment adopted for the 2020 MIPS and 2021 payment years as previously finalized, and the 2022 and 2023 payment years as finalized in this rule. For 2023, the performance threshold would increase to 60 points, and the additional performance threshold would be 85 points.

In addition, the final rule includes examples of how MIPS-eligible clinicians can achieve a final score at or above the proposed 45-point performance threshold. The examples reflect a clinician in a small practice submitting 5 quality measures and 1 improvement measure; a group submission that is not a small practice; and a non-patient facing MIPS-eligible clinician.

Adjustment Factors

FIGURE 1: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2022 MIPS Payment Year



Final Score

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 9 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 85 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 exceptional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustrative only, as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

f. Targeted Review and Data Validation and Auditing

(1) Targeted Review

MIPS-eligible clinicians or groups may request a targeted review of the calculation of the MIPS payment adjustment factor and the additional MIPS payment adjustment factor. The request must be made within 60 days from the day CMS makes the adjustment factors available, and ends on September 30 of the year prior to the payment year, or at later date specified by CMS. If CMS determines a review is warranted and requests additional information, this must be received within 30 days of the request. Decisions based on the targeted review are final, and there is no further review or appeal.

CMS proposed several modifications to its targeted review process, all of which are finalized.

a. Who is Eligible to Request Targeted Review. CMS revises §414.1385(a)(1) to permit support staff and third party intermediaries (e.g., a qualified registry, health information technology vendor, or QCDR) to submit a targeted review request on behalf of an eligible clinician or group. Because third party intermediaries do not have access to the performance feedback for clinicians and groups, CMS will share with these designated entities an URL link to the Targeted Review Request Form.

b. Timeline for Targeted Review Requests. CMS revises §414.1385(a)(2) to state that all targeted review requests must be submitted during the targeted review request submission period, which is a 60-day period that begins the day that CMS makes the MIPS adjustment factors available. CMS may extend this period. The change applies to the 2019 performance period and each succeeding performance period.

Some commenters worried that 60 days was not an adequate period of time for clinicians to review performance feedback reports. CMS believes 60 days is sufficient; it bases its opinion on prior experience with targeted review requests which shows that most requests arrive at the beginning of the submission period and very few arrive towards the end.

- c. Denial of Targeted Review Requests. CMS reports having received many duplicative targeted review requests and other submissions that have led to request denials. In §414.1385(a)(3), it establishes conditions under which targeted requests may be denied:
 - The request is duplicative of another targeted review request.
 - The request is not submitted during the targeted review request submission period.
 - The request is outside the scope of targeted review. CMS notes that the scope of targeted review is limited to the calculation of MIPS adjustment factors applicable to the eligible clinician or group for a year.

d. Requests for Additional Information. CMS adds §414.1385(a)(5) which states that a request for a targeted review may include additional information in support of the request at the time it is submitted. Any additional information CMS requests from the MIPS-eligible clinician or group that is the subject of a request for a targeted review must be provided and received by CMS within 30 days of the request. CMS acknowledges that there may be circumstances under which

it may grant an extension; it would do so on a case-by-case basis and the extension request must be submitted before the end of the 30-day period.

The regulation also states that non-responsiveness to a CMS request for additional information may result in a final decision based on the information available. It notes that another *non-duplicative* request for a targeted review may be submitted before the end of the targeted review request submission period. The agency modifies the proposed regulation text to clarify that if another request for targeted review is submitted, it cannot be duplicative of a prior request. The modification is shown above in italic font.

e. Notification of Targeted Review Decisions. CMS notes that decisions based on targeted review are final for which no further review or appeal rights exist. Commenters objected to this policy, but CMS says the statute describes the review process as targeted and informal, and it believes further review is not warranted and could be counterproductive to agency efficiency.

CMS adds §414.1385(a)(8) which states that documentation submitted for a targeted review must be retained by the submitter for 6 years from the end of the MIPS performance period. This aligns with the existing requirement for the auditing of entities submitting MIPS data.

f. Scoring Recalculations. CMS adds §414.1385(a)(6) which states that if a request for a targeted review is approved, CMS may recalculate, to the extent feasible and applicable, the scores of a MIPS-eligible clinician or group with regard to measures, activities, performance categories, and the final score, as well as the MIPS payment adjustment factors. A commenter suggested that if the score, final score or payment adjustment is changed based on targeted review, CMS should issue a written alert that provides details explaining the change; the agency declines to do so suggesting that after it notifies the submitter of a targeted review request of its final decision, the individual or entity should review the performance feedback for updated results.

(2) Data Validation and Auditing

Existing regulations require that MIPS-eligible clinicians and groups that submit data and information for purposes of MIPS must certify that to the best of their knowledge the data is true, accurate and complete. In response to inquiries, CMS notes that using data selection criteria to misrepresent a clinician's or group's performance, referred to as "cherry picking," results in data that are not true, accurate or complete. If CMS believes that cherry picking may be occurring it may subject the clinician or group to auditing, and in the case of improper payment institute a reopening and revision of the MIPS payment adjustment. The regulations regarding data validation and auditing appear at §414.1390.

In response to a comment, CMS may publish aggregate findings of previous audits surrounding cherry-picked data for future educational efforts. Another commenter sought clarification that a clinician who submits data on a single patient to receive the minimum point threshold for a quality measure is not cherry-picking. CMS clarifies that its existing policy takes into consideration that MIPS eligible clinicians may submit data on a single measure in accordance with data submission requirements; however, it believes that if the clinician submits data on a single patient, that patient should be representative.

g. Third Party Intermediaries

(1) Requirements for MIPS Performance Categories That Must Be Supported by Third Party Intermediaries

Under current policy, QCDRs, qualified registries, and health IT vendors *may* submit data for any of the following MIPS performance categories: quality (except for data on the CAHPS for MIPS survey); improvement activities; and promoting interoperability. Beginning with the 2021 performance period and the 2023 MIPS payment year, CMS proposed that QCDRs and qualified registries *must* be able to submit data for each category, and health IT vendors must be able to submit data for at least one category.

Third-party intermediaries would not be required to submit data for the promoting interoperability performance category if they only represent MIPS eligible clinicians, groups and virtual groups that are eligible for reweighting under the promoting interoperability performance category (occupational therapists; qualified speech language pathologists; qualified audiologists; clinical psychologists; and registered dieticians or nutrition professionals). CMS anticipates using the self-nomination vetting process to assess whether the QCDR or qualified registry is subject to the requirement to support reporting the promoting interoperability performance category.

There were comments in support of and opposed to the policy. Opponents believe the policy would result in a large increase in the data that would need to be collected without adding any distinct benefit to MIPS eligible clinicians and groups who already have other methods available for reporting MIPS data. Some QCDRs may incur additional costs from EHR vendors who may charge fees for providing additional necessary reports. There were also concerns that some QCDRs and qualified registries may end their participation in MIPS.

CMS responds that the majority of existing qualified registries and QCDRs already support all three performance categories which require data submission. A small minority of qualified registries and QCDRs may not be able to comply with this requirement, and as a result may elect not to continue in the quality payment program. The added benefit this policy provides to clinicians who want to use a qualified registry or QCDR to support data submission for the three performance categories outweigh the small number of qualified registries and QCDRs that are not able to comply. Although some EHR vendors may charge for reports, CMS believes the costs will be minimal because CEHRT requirements already include the capability to calculate the promoting interoperability measures.

One commenter thought that the proposal to require QCDRs and qualified registries to support the reporting of the quality, Promoting Interoperablity, and improvement activities categories did not account for situations where a health IT vendor acts as both the EHR and QCDR/qualified registry. The commenter asked CMS to exempt organizations that are EHRs that have met the requirements to be considered a QCDRs/Qualified Registries from the proposed requirement for QCDR/Qualified Registries to support all three performance categories if the vendor could support the reporting of Promoting Interoperability and improvement activities categories through their EHR.

asked CMS to exempt EHR vendors that have met the requirements to be considered QCDRs/qualified registries from having to support all three performance categories if the vendors offer the ability to support the reporting of the remaining performance categories through their EHRs. CMS responds that it believes a qualified registry or QCDR should support all three performance categories, regardless of the other types of services they provide and Health IT vendors and other organization who act as an EHR and are also a QCDR or qualified registry would not be exempt from this requirement. CMS' policy goal is to reduce burden on clinicians and groups by ensuring they can use a single third-party intermediary to submit all data on quality, improvement activities, and promoting interoperability and it believes it is important for all approved ACDEs and qualified registries to be able to submit MIPS data in all MIPS performance categories.

CMS is finalizing its policy as proposed.

(2) Approval Criteria for Third-Party Intermediaries

To prevent disruption that occurs when a third-party intermediary withdraws mid-performance period, CMS proposed that approval of a third-party intermediary is contingent on agreeing to provide services for the entire performance period and applicable data submission period. In addition, CMS proposed that the third-party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate data submission mechanism or third-party intermediary according to a CMS approved transition plan.

One comment indicated that it is the clinician's responsibility to transition to another third-party intermediary and that there may circumstances beyond the third-party intermediary's control that are causing it to withdraw from the program. CMS understands that sometimes issues arise outside of the third-party intermediary's direct control affecting its ability to provide services. Nevertheless, CMS believes that a transition plan should be required regardless of the reason that the third-party intermediary is discontinuing services.

CMS is finalizing its policy with a modification: Instead of requiring the transition to an "alternate data submission mechanism or third-party intermediary," the third-party intermediary must support the transition to an "alternate submitter type" or "alternate collection type or third-party intermediary" according to a CMS-approved transition plan. Third-party intermediaries are not required to support the transition of MIPS eligible clinicians, groups, or virtual groups to an alternate collection type for measures on which no data has been collected. If CMS determines that a third-party intermediary has ceased to meet either of these criteria for approval, it may take remedial action or terminate the third-party intermediary.

(3) Qualified Clinical Data Registries (QCDRs)

This section of the rule focused specifically on the above requirements as they affect QCDRs.

Requirement for QCDRs to Support All Three Performance Categories. CMS reiterates that QCDRs must report on all three performance categories. The rule further indicates that as of 2019, approximately 92 QCDRs, or about 72 percent of the QCDRs currently participating in the program, are supporting all three performance categories.

One commenter requested that CMS provide additional clarification regarding the number of measures from each performance category that will be required for approval. Similarly, another commenter requested that CMS define more clearly how improvement activities should be documented to help standardize auditing by third-party intermediaries. In both of these cases, CMS referenced and reiterated its prior rules: QCDRs and qualified registries are required to support the minimum number of measures to meet the reporting requirements of the quality performance category and QCDRs and qualified registries are required to provide information on their sampling methodology.

CMS is finalizing its proposals with technical modifications for clarity and consistency with the existing provisions of § 414.1400.

Requirement for QCDRs to Engage in Activities that Foster Improvement in the Quality of Care. Section 1848(m)(3)(E)(ii)(IV) of the Act requires that QCDRs must support quality improvement initiatives. Beginning with the 2023 MIPS payment year, the QCDRs must provide educational services in quality improvement and leading quality improvement initiatives as a condition of approval.

Several commenters found the proposal to be vague and unclear, and they were concerned about arbitrary comparisons or ranking of QCDRs. A few commenters stated that additional details are necessary regarding what activities would meet the proposed requirement. CMS agreed with these commenters and is not finalizing the proposal. While CMS is not requiring QCDRs to provide quality improvement services as a condition of approval, it will consider proposing this requirement in subsequent rulemaking and advises QCDRs to prepare accordingly.

Enhanced Performance Feedback Requirement. Currently, CMS requires QCDRs to provide timely performance feedback at least 4 times a year on all of the MIPS performance categories that the QCDR reports to CMS. Beginning with 2023 payment year, CMS proposed to require performance feedback "at least 4 times a year," and provide specific feedback to their clinicians and groups on how they compare to other clinicians. The comparison would be limited to the data the QCDR has collected for commonly reported measures. Exceptions to this requirement may occur if the QCDR does not receive the data from their clinician until the end of the performance period. Beginning with the 2023 MIPS payment year, QCDRs are required to attest that they can provide performance feedback at least 4 times a year.

Comments were largely supportive of these proposals that CMS is finalizing without modification (except for the location of these requirements in the regulations). The current performance period begins January 1 and ends on December 31st, and the corresponding data submission deadline is typically March 31st.

In some instances, clinicians wait until the end of the performance period to submit data to the

third-party intermediary, who is then unable to provide meaningful feedback to their clinicians 4 times a year. CMS sought comment on requiring entities using a QCDR to submit data starting April 1 to ensure that the QCDR is providing feedback during the performance period. CMS did not summarize or respond to comments. It will take the comments into consideration as it develops future policies for QCDRs.

QCDR Measures. Newly finalized QCDR measure requirements for approval apply to all QCDR measures, regardless of whether they have been approved for previous performance periods or are new QCDR measures for the 2021 performance period and future years. CMS will not be grandfathering previously approved QCDR measures.

<u>Previously Finalized QCDR Measure Considerations</u>. All previously approved QCDR measures and new QCDR measures are currently reviewed on an annual basis. The QCDR measure review process occurs after the self-nomination period closes on September 1st through a subregulatory process. The rule provides the criteria that were established in 2019 and earlier rulemaking that are currently being used when considering QCDR measures for possible inclusion in MIPS. In the 2020 PFS proposed rule, CMS proposed to codify in regulation a number of those previously finalized QCDR measure considerations.

New QCDR Measure Considerations for Approval

QCDR Measure Availability. QCDRs may seek permission from another QCDR to use an existing and approved QCDR measure. CMS expressed concern about QCDR measure owners limiting the availability of their measures to other QCDRs. CMS proposed that the availability of a measure to QCDRs other than the owner would be a criterion for measure approval.

QCDR owners expressed concern about the proposal and were concerned that borrowers would not come to terms on a licensing agreement or would use a borrowed measure inappropriately or inconsistently, not understand measure specifications or not standardize data methods resulting in inaccurate benchmarking by the borrowing QCDR. Commenters did not want the owner of the measure to be penalized for being unable to come to agreement with a borrower if the borrower did not comply with the terms of a licensing agreement. Some commenters were concerned that a measure would be unavailable if not approved by CMS because it could not be borrowed by another QCDR.

CMS responded that it does not dictate what is to be included in a QCDR measure licensing agreement including compensation for measure licensure. A licensing agreement's terms may include implementation criteria to ensure that the measure is programmed and collected in a way that is consistent with what the QCDR measure owner intends, thereby avoiding concerns with inappropriate or inconsistent implementation.

QCDR measure owners should be able to provide evidence to justify instances where their measure was made available but ultimately could not be borrowed by another QCDR. CMS will consider each case individually. In instances where CMS finds that QCDRs are blocking the use of their QCDR measure from other QCDRs without any evidence that the borrower is unable to meet the measure owner's terms, CMS will likely approve another similar QCDR measure. If a

QCDR measure is not approved, it does not mean that data cannot be collected on by the QCDR for purposes of quality improvement. However, any data collected on that measure would not be applicable for MIPS.

CMS is finalizing its policy as proposed.

QCDR Measure Addressing a Measurement Gap. Prior to measure development, QCDRs should conduct an environmental scan to identify measure gaps. CMS would give giver greater consideration to measures for which the QCDR took these steps.

CMS received one comment that requested clarification on how a performance gap needs to be demonstrated. The response reiterates the proposed rule guidance and directs the commenter to the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System (the Blueprint): https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf. The performance gap may be identified by data submitted to the registry on the given measure, or through current clinical study citations (within the past 5 years). A health care survey would not provide sufficient evidence of a performance gap.

CMS is finalizing its policy as proposed.

QCDR Measures Meeting Benchmarking Thresholds. CMS proposed to provide greater weight in approving QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for two consecutive calendar year reporting periods. Measures not meeting benchmarking thresholds may or may not be approved. CMS notes this policy is parallel to a policy finalized elsewhere in the rule for MIPS measures.

In the case of a low-reported measure that does not meet benchmarking thresholds but is important to a specialty practice, a QCDR may develop and submit a participation plan for CMS consideration. The plan would include the QCDR's detailed plans and changes to encourage more clinicians and groups to submit data on the measure. The plan might include development of a specific education and communication plan; updates to the measure specifications to encourage broader participation (subject to CMS review and approval); or requirements for reporting of the measure as a condition of using the QCDR. CMS would evaluate whether the participation plan was effective in sufficiently increasing reporting volume on the measure for benchmarking.

CMS presents a number of comments that disagree with its proposal:

- Awarding fewer points for reporting non-benchmarked measures will discourage use of these measures for MIPS participants who have few other measures to report.
- It would create a hardship for participating in MIPS and deter the development of new measures.
- A 2-year period is not long enough for some measures to achieve acceptable numbers for adoption or for EHR vendors to complete data integration to support QCDR measures.

CMS responded that a 2-year lifecycle will more directly address the issue of low-reported measures. Maintaining low-reported measures over multiple years is indicative of metrics that are not of interest to the majority of clinicians within a given specialty.

A few commenters requested that CMS delay implementation of the policy arguing that it would be inappropriate to finalize a requirement after the deadline for 2020 QCDR self-nominations. Also, the policy would not allow QCDRs enough time to reevaluate their measure submission strategies. CMS received comments requesting that it delay the effective date of many of its policy proposals. CMS routinely responded that the timeframe for the proposals is appropriate because it will apply for the 2021 performance period and 2023 payments.

CMS is finalizing its policy as proposed.

QCDR Measure Requirements. Two previously finalized QCDR measure "considerations" are now proposed as requirements. Commenters supported this proposal.

CMS is finalizing its policy as proposed.

Linking QCDR Measures to Cost Measures, Improvement Activities, and MIPS Value Pathways (MVP). Beginning with the 2021 performance period, CMS proposed that QCDRs must identify a linkage between their QCDR measures and: (a) a cost measure, (b) an improvement activity, or (c) CMS-developed MVPs. In cases where a QCDR measure does not have a clear link to a performance category, CMS would consider an exception if the potential QCDR measure otherwise meets the QCDR measure requirements. The proposed rule was unclear on whether the linkage is required to just one performance category or all three. CMS clarifies in the final rule that the linkage would be only to one performance category.

Several commenters expressed concerns with the proposal noting that some specialties are not currently included in the cost category and/or MIPS Value Pathways. CMS responded that if a QCDR measure cannot be linked to a cost measure because the specialty is not reflected in the cost measures, the QCDR would note that for CMS' review.

CMS is finalizing its policy as proposed with the clarification noted above that the linkage only needs to be to one performance category, not all three. The final rule indicates that CMS plans to provide education to QCDRs to ensure that they understand the requirement.

Completion of QCDR Measure Testing. Beginning with the 2021 performance period, CMS proposed that all QCDR measures submitted at the time of self-nomination must be fully developed with completed testing results at the clinician level, as defined in the Blueprint. CMS understands the policy will result in additional costs for QCDRs to develop measures.

A few commenters asked whether CMS is requiring full NQF-level specification and endorsement or a feasibility and validity test within the QCDR. CMS responded that it does not currently require QCDR measures to be NQF endorsed in order to be approved for use in the program.

Some commenters are concerned that measure testing will result in additional costs and delays in measure availability. CMS responded that it wants to avoid scenarios that would arise midperformance period by allowing measures that do not meet established standards. QCDRs can collect data on measures for purposes of quality improvement outside of the program, without reporting the data to CMS for purposes of MIPS.

In response to other comments, CMS understands there may be limitations with small specialties and the lack of resources to test measures, but believes it is important to only include measures that are valid, reliable, and feasible in the program. It rejected suggestions for the use of real-world data or the substitution of 12 months of data in lieu of testing. CMS further clarifies that it had not proposed timeframes for measure testing. The testing process for quality measures is dependent on the measure type. If a QCDR believes more than 1 year is needed to complete measure testing at the clinician level, they should delay self-nominating the QCDR measure.

CMS is finalizing its policy as proposed.

Collection of Data on QCDR Measures. CMS proposed that QCDRs must collect data prior to submitting the measure for CMS approval during the self-nomination period. The data collected would have to demonstrate that the measure is valid and reflects an important clinical concept, could be used to demonstrate a performance gap, and is implementable. CMS strongly encouraged QCDRs to collect data for 12 months prior to submission to increase the chance that the measure can be benchmarked.

Some commenters objected to this proposal suggesting that collection of data is not a determinant of clinical importance. Another commenter suggested QCDR measures could be approved under a testing/provisional status during which CMS would allow credit, such as a base 3-5 points or fully meeting improvement activity requirements. A commenter stated that collecting data for a 12-month period may be difficult given the timelines of the MIPS submission cycle during the months of January-March, the requirement for QCDRs to be operational on January 1, and self-nomination deadlines September 1; around which the QCDR's measure development and update processes have been established.

CMS responds that data collection is important because it demonstrates whether a measure is implementable and if there is interest by the clinician community on reporting on that metric. If a QCDR measure has completed testing as outlined in the CMS Blueprint, the QCDR measure would be able to meet this requirement. While CMS encourages 12 months of data, it understands there may be instances where less than 12 months of data may be available.

CMS is finalizing its policy as proposed.

Duplicative QCDR Measures. Beginning with the 2022 MIPS payment year (2020 performance year) CMS proposed that it may reject a duplicative measure not addressed by the QCDR within one year. After the self-nomination period, CMS will review QCDR measures. If similar measures exist, CMS may provisionally approve measures for one year with the condition that the QCDR address certain areas of duplication in order to be considered for the program in

subsequent years. Addressing these areas might require more than one QCDR to collaborate on a single measure.

In response to comments, CMS provides details on the process for eliminating duplication of measures—referred to as "harmonizing." After the close of the self-nomination period, CMS will identify similar QCDR measures for harmonization and then notify the relevant QCDRs through the self-nomination portal. The communication will include CMS' reasons for harmonization, including where duplication exists, points of contact from the other identified QCDRs, and information regarding provisional approval for 1 year.

CMS would request measure harmonization in instances where QCDR measures are identified as similar. QCDR measures are reviewed to identify similarities and differences in areas that include (but are not limited to) the clinical concept being measured, quality action (for example, screening versus screening and follow-up), patient population, clinical setting (place of service), and the clinician type eligible to report on the measure.

In instances where CMS identifies strong qualities in both similar measures, CMS will ask for measure harmonization. In instances where one measure completely overlaps another's clinical concept but includes a more robust quality action, CMS' preference would be to select the more robust QCDR measure (regardless of a given QCDR measure's history within the program). In instances in which a QCDR has simply duplicated another existing approved QCDR measure without modification, CMS would not approve the new duplicative QCDR measure. Harmonization would include informing CMS of a dispute regarding licensing or sharing of roles and responsibilities related to similar measures. In such instances, CMS would evaluate each measure and potentially select the most robust one.

CMS is finalizing its policies as proposed.

QCDR Measure Rejections. In the 2020 PFS proposed rule, CMS proposed 14 QCDR measure rejection criteria (although others could apply) that generally align with finalized removal criteria for MIPS quality measures in the 2019 PFS final rule. All previously approved QCDR measures and new QCDR measures would be reviewed on an annual basis (as a part of the QCDR measure review process that occurs after the self-nomination period closes on September 1st) to determine whether they are appropriate for the program.

Comments were concerned about process measures versus outcome measures, particularly for clinicians that do not have face-to-face interactions with physicians. CMS' general preference is to have more outcome measures in the program but it understands a need for process measures for non-patient facing clinicians. Specialties are encouraged to develop measures that address a high priority area when it is not feasible to develop outcome measures. If QCDRs are able to demonstrate a gap in practice for their process measure, that information will be considered as a part of the QCDR measure approval process.

Some commenters were concerned that when a measure is not directly attributable to the clinician, the clinician should not be held responsible for the quality of care. CMS supports care coordination but also believes it is important that clinicians and groups are not inadvertently

penalized for actions that are outside of their control. After the QCDR measure self-nomination period, CMS reviews clinician attribution criteria as it reviews measures. For measures that do not have a clear clinician attribution, CMS encourages QCDRs to submit a short explanation.

Some commenters opposed removing topped-out QCDR measures because it will limit the number of specialty-specific measures available in the MIPS program. There were also comments asking for a grace period to phase out measures. Other comments asked CMS to allow measure developers to re-tool measures removed from the program into specialty or procedure-specific measures. CMS responded that it is not consistent with the Meaningful Measures Initiative to retain topped out QCDR measures in the program when there are other relevant measures available for a given specialty.

CMS is finalizing its policy as proposed.

QCDR Measure Review Process. Currently, QCDR measure approvals are year-to-year. CMS proposed to implement, at its discretion, 2-year approval of QCDR measures. However, the second-year approval could subsequently be revoked if the measure is topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; requires harmonization with another measure; or the QCDR is no longer in good standing.

Comments generally supported CMS' proposal. Some comments requested that QCDR measures should be approved for 2 years without being subject to CMS discretion as long as the measure satisfies QCDR measure requirements. CMS responded that 2-year approval should be left to its discretion, because many considerations must be given: the QCDR's ability to comply with program requirements, considerations about other QCDR measures with more robust quality actions, future changes to program requirements, and future transitions to MVPs.

CMS is finalizing its policy as proposed.

Participation Plan for Existing QCDR Measures that have Failed to Reach Benchmarking Thresholds. CMS proposed that a low-reported QCDR measure not meeting benchmarking thresholds that is important and relevant to a specialist's practice could be retained if the QCDR submits a QCDR measure participation plan to CMS. This QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program. Implementation of a participation plan would not guarantee that a QCDR measure would be approved for a future performance period. CMS will consider many factors in deciding whether to approve QCDR measures.

Commenters supported the proposal. One commenter requested that CMS specify in the final rule when notice of low-reporting volume will be given so that QCDRs may have ample time to develop and implement the participation plan. CMS disagreed saying that QCDRs should be monitoring the reporting of their QCDR measures throughout the year and be able to identify when their measures are low-reported.

CMS is finalizing its policy as proposed.

(4) Qualified Registries

Requirement for Qualified Registries to Support all Three Performance Categories. The proposed requirement for qualified registries to support all three performance categories is the same as for QCDRs. Comments and responses paralleled those for QCDRs. Commenters requested that CMS provide additional guidance and descriptions of what data would be necessary to validate that an individual MIPS eligible clinician or group could appropriately attest to a specific activity. CMS referred readers to the 2017 Quality Payment Program final rule (81 FR 77368 through 77369) and (81 FR 77384 through 77385). QCDRs and qualified registries are required to provide information on their sampling methodology.

CMS is finalizing its proposal with technical modifications for clarity and consistency between related regulations.

Enhanced Performance Feedback Requirement. Qualified Registries and QCDRs are currently required to provide timely performance feedback at least 4 times a year on all of MIPS performance categories that the qualified registry or QCDR reports to CMS. CMS proposed that beginning with the 2023 MIPS payment year, it would require the feedback (still required 4 times a year) would be required to include information on how participants compare to other clinicians within the qualified registry of QCDR cohort who have submitted data on a given measure. CMS proposed that if the qualified registry does not receive the data from their clinician until the end of the performance period, this would preclude the qualified registry form providing feedback 4 times a year, and the qualified registry would be exempted from this requirement.

Comments expressed concern that a single registry does not represent a participant's entire peer cohort making it difficult to provide comparative performance feedback. As an alternative, the comments requested comparison to a published benchmark. CMS responded that performance feedback allows for comparison of peers who have submitted data on a given MIPS quality measure. CMS believes that it is important to provide meaningful data to clinicians to understand and identify areas for improvement.

CMS is finalizing its policy as proposed.

(5) Remedial Action and Termination of Third-Party Intermediaries

CMS expressed concern that certain third-party intermediaries may not fully appreciate their current regulatory obligations or the implications of selectively submitting data that are unrepresentative of MIPS performance. The proposed rule clarified that: 1) remedial action and termination are triggered if a third-party intermediary submits a false certification and 2) CMS authority to bring remedial actions or terminate a third-party intermediary for submitting data that is inaccurate, unusable or otherwise compromised extends beyond the specific examples set forth in the regulations. Third-party intermediaries may face liability under the federal False Claims Act if they submit or cause the submission of false MIPS data.

Several commenters requested that CMS clearly define that a registry's responsibility is limited to the data it has access to, controls and manages. Third-party intermediaries do not have the capacity to tell whether a group has specifically submitted false or incomplete data. These commenters believe it is the responsibility of the MIPS eligible clinician or group to demonstrate to CMS that their data are accurate and complete using documentation as described by CMS in this rule. If selective data submission is found by CMS, these commenters believed the audit should be sent to the MIPS eligible clinician or group, and not the third-party intermediary.

A few commenters requested clarification on whether specific scenarios involved data inaccuracies that would trigger remedial action. There were also comments requesting CMS to distinguish between errors and criteria that may disqualify a third-party intermediary from participation. One commenter encouraged CMS to release additional instructions for individual clinicians and groups.

CMS responded to the comments for additional instructions by providing links to resources to:

- The 2020 Self-Nomination Tool Kit for QCDR and qualified registries: Nomination%20Toolkit%20for%20QCDRs%20%26%20Qualified%20Registries.zip.
- The MIPS Data Validation Execution Report (DVER) template and the self-nomination factsheet; https://qpp.cms.gov/about/resource-library.

In addition, CMS holds monthly mandatory support calls where approved QCDRs and qualified registries are reminded of CMS' expectations for the data validation execution report and the methodology for calculating error rates.

CMS indicated that it is the responsibility of the third-party intermediary to validate data prior to submission to CMS and to ensure that the data is true, accurate, and complete to the best of its knowledge. It is a joint responsibility of the eligible clinician and the third-party intermediary to ensure that data submitted to CMS is true and reflective of their scope of practice, while avoiding selection bias. If a third-party intermediary knows data are not true, accurate or complete, it should not submit those data. Remedial action or termination of a third-party intermediary for submitting a false certification or data that are inaccurate, unusable or otherwise compromised will depend on the particular facts and circumstances.

CMS is finalizing its policy as proposed.

h. Public Reporting on Physician Compare

Background. For background on Physician Compare, CMS refers readers to the 2016 PFS final rule (80 FR 71116 through 71123), the 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the 2019 PFS final rule (83 FR 59910 through 59915), and the Physician Compare Initiative Website at https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/.

Data Available. CMS finalizes without change the addition of new paragraphs in §414.1395(a) that more completely describe and add to the data that CMS will make available for public reporting on Physician Compare. It received no comments on the addition of the paragraphs.

- In new §414.1395(a)(1) CMS states that, as part of public reporting, CMS will post on Physician Compare information regarding the performance of MIPS eligible clinicians, including, but not limited to, final scores and performance category scores for each MIPS eligible clinician; and the names of eligible clinicians in Advanced APMs and to the extent feasible, the names and performance of such advanced APMs. (Italicized language is new.)
- In new §414.1395(a)(2), CMS will periodically post aggregate information on the MIPS including the range of final scores and range of performance for each performance category.
- New §414.1395(a)(3) states that publicized information made available will indicate, where appropriate, that the information may not be representative of a clinician's entire patient population, services provided, or health conditions treated.

Final Score, Performance Categories, and Aggregate Information. CMS states that although it previously finalized a policy to periodically post aggregate information on the MIPS, it has not to date established a timeframe for doing so. Now that CMS has experience with the data, it plans to post aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS-eligible clinicians, beginning with Year 2 (2018 data, available starting in late 2019).

CMS sought comment on any other aggregate information that stakeholders would find useful for future public reporting on Physician Compare. Commenters raised concerns about the ability of Medicare patients and their caregivers to understand the aggregated data and the accuracy of the data. CMS notes in response that it will use statistical and user testing, will consult with the Physician Compare Technical Expert Panel to best ensure these data are able to be understood, and will work to ensure that the language on the Web site and in outreach and education is clear. To help ensure that data publicly reported on Physician Compare is accurate, CMS will make it available for the public to review and correct (as specified §414.1385). Finally, CMS clarifies that aggregate data will reflect MIPS eligible clinicians and groups collectively and will not be specialty-specific.

Quality. CMS did not propose changes to reporting on quality performance category information, but sought comment on adding patient narratives to the Physician Compare website. It states that consumers have consistently expressed interest in seeing narrative reviews, quotes and testimonials as well as a single overall "value indicator" on the Physician Compare website. Comments were sought on the value and considerations for publicly reporting such information. CMS notes that in section III.K.3.c.(1)(c)(i) of the final rule, CMS discusses a solicitation for comments regarding adding narrative reviews into the CAHPS for MIPS group surveys in future rulemaking.

To add such information to Physician Compare, the data would need to meet public reporting standards (in §414.1395(b)) and be reviewed in consultation with the Physician Compare Technical Expert Panel. CMS sought comment on the value of collecting and publicly reporting

information from narrative questions, as well as publishing a single "value indicator" reflective of cost, quality and patient experience and satisfaction with care for each MIPS eligible clinician and group, on the Physician Compare website. CMS received comments but does not summarize or respond to them in the preamble to the final rule. They may, however, be taken into account as CMS develops future policies for public reporting on Physician Compare.

Promoting Interoperability. CMS did not propose changes regarding publicly reporting promoting interoperability category information, but referred readers to the Interoperability and Patient Access proposed rule (84 FR 7646 through 7647) where CMS describes a proposal to include an indicator on Physician Compare for the eligible clinicians and groups that submit a "no" response to any of three prevention of information blocking attestation statements. To report successfully in this category, a MIPS eligible clinician must attest to "yes" responses for each of those statements which are intended to verify that the clinician has not taken any actions to limit or restrict the compatibility or interoperability of CEHRT. Readers are referred to the 2017 Quality Payment Program final rule for additional information on these attestation statements (81 FR 77028 through 77035).

Facility-based Clinician Indicator. CMS informs readers that it has determined how it will display facility-based MIPS-eligible clinician quality and cost information on Physician Compare. It considered two options for public reporting: (a) displaying hospital-based measure-level performance information on Physician Compare profile pages, including scores for specific measures and the hospital overall rating; or (b) including an indicator showing that the clinician or group was scored using the facility-based scoring option with a link from the clinician's Physician Compare profile page to the relevant hospital's measure-level performance information on Hospital Compare.

In the final rule CMS repeats its conclusion that a link from the clinician's Physician Compare profile page to the relevant hospital's performance information on Hospital Compare is preferable and provides its reasoning. Consistent with that conclusion, CMS proposed to make available for public reporting an indicator on the Physician Compare profile page or downloadable database that displays if a MIPS-eligible clinician is scored using facility-based measurement. In addition, CMS proposed to provide a link to facility-based measure-level information for such MIPS-eligible clinicians on Hospital Compare, as technically feasible; and to post this indicator on Physician Compare with the linkage to Hospital Compare beginning with CY 2019 performance period data available for public reporting starting in late CY 2020 and for all future years, as technically feasible.

CMS received some comments in support of these proposals. Other commenters expressed concern about the ability of patients and their caregivers to understand the facility-based indicator and recommended that CMS provide explanatory text to clarify that the facility-level measures are indicators of care provided at a facility level and not at a single clinician or group level.

CMS finalizes the proposals without change and assures commenters that all non-mandatory data included on Physician Compare must meet public reporting standards and that CMS will use

statistical and user testing as well as consultation with the Physician Compare Technical Expert Panel to ensure data are best reported and to provide the appropriate context and explanation.

4. Overview of the Alternative Payment Model (APM) Incentive

a. Background of the APM Incentive Pathway of the QPP

CMS begins its discussion of the APM pathway for payment of eligible clinicians as proposed for 2020 by highlighting some facets of the APM Incentive program.

- For payment years 2019 and 2020, eligible clinicians can become Qualifying APM Participants (QPs), and thereby be excluded from MIPS, based only upon their extent of Advanced APM participation (i.e. payments or patient counts, through the "Medicare Option"). All "Advanced APMs" are sponsored by CMS.
- For payment years 2021 and later, QP status also can be reached by combining Advanced APM participation with "Other Payer Advanced APM" participation (i.e., through the "All-Payer Combination Option"). Payment arrangements that may qualify as Other Payer Advanced APMs include those between eligible clinicians and Medicare Health Plans, Medicaid programs, CMS Multi-Payer Models, and what CMS terms "Remaining Other Payers". Determinations of whether an APM sponsored by a payer other than Medicare ("Other Payer") meets criteria to be treated as an Other Payer Advanced APM are made by CMS using the Payer Initiated or Eligible Clinician Initiated process.
- A clinician reaching QP status for any payment year from 2019 through 2024, will receive a lump sum incentive payment for that year, equal to 5 percent of their immediately preceding year's estimated aggregate payments for Part B covered professional services. No lump sum incentives will be paid after 2024. Beginning with payment year 2026, QPs will receive a higher annual PFS update than non-QPs.²⁵

CMS reviews the criteria that must be satisfied for a payment arrangement to be considered an Advanced APM. The criteria are set in statute and all must be met.

- Participants are required to use CEHRT.
 - All APM Entities within an Advanced APM must require at least 75 percent of their eligible clinicians to use CEHRT in clinical care delivery.
- Payment for covered professional services must be based at least in part on quality measures comparable to those of the MIPS Quality performance category.
 - o Beginning with performance year 2020, at least one of the measures must be finalized on the MIPS final list of measures; endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid. At least one of the measures also must be an outcome measure, if available.

Participating APM Entities must be able to bear risk for more than nominal monetary losses. CMS approaches this criterion as having two parts: 1) describing ways to bear risk (e.g.,

²⁵ 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.

repayment, forfeiture of future payment; the "financial standard") and 2) what constitutes more than nominal monetary losses (e.g., percentage of revenues, actual loss amount; "the nominal amount standard"). Other than for Medical Home Models, the applicable revenue-based nominal amount standard will remain at 8 percent through the 2024 QP Performance Period. ²⁶ For models not expressing risk in terms of revenues, the total expenditure-based nominal amount standard will remain indefinitely at 3 percent.

Medical Home Exception

Any Medicare-sponsored APM that 1) meets the CEHRT and Quality criteria; 2) is a Medical Home Model (defined at §414.1305); <u>and 3</u>) has been expanded under section 1115A(c) of the Act, is considered to be an Advanced APM.²⁷ Absent expansion, a modified nominal amount standard with a more gradual risk percentage progression (described at §414.1415(c)(4)) is applied to APMs meeting the Medical Home Model definition.

CMS expects that the following 11 APMs will satisfy the requirements to be Advanced APMs for the 2020 MIPS performance period. The final determinations will be announced via the QPP website.

- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track)
- Comprehensive ESRD Care Model (Two-Sided Risk Arrangement)
- Comprehensive Primary Care Plus Model (all Tracks)
- Next Generation ACO Model
- Oncology Care Model (Two-Sided Risk Arrangement)
- Medicare Shared Savings Program (Track 2, Basic Track Level E, and the Enhanced Track)
- Medicare ACO Track 1+ Model
- Bundled Payments for Care Improvement (BPCI) Advanced
- Maryland Total Cost of Care Model (Maryland Care Redesign Program, Maryland Primary Care Program)
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative)

b. Aligned Other Payer Medical Home Model

CMS finalizes its proposal to add the term Aligned Other Payer Medical Home Model, to be defined as a payment arrangement with the following features:

- Is operated by a payer other than Medicare or Medicaid;
- Formally partners with CMS in a CMS Multi-Payer Model that also is a Medical Home Model;
 - The partnership is described by a written expression of alignment and cooperation, such as a memorandum of understanding (MOU).
- Has a primary care focus (i.e., the practice must include primary care practitioners and offer primary care services) and empanels each patient to a primary clinician; and

²⁶ The QP Performance Period is defined as extending from January 1 through August 31 of the calendar year that is 2 years prior to the related payment year.

²⁷ As yet, no medical home models have been expanded under section 1115A(c) of the Act.

• Demonstrates at least 4 of the following: planned coordination of chronic and preventive care; patient access and continuity of care; risk-stratified care management; coordination of care across the medical neighborhood; patient and caregiver engagement; shared decision-making; and/or payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

CMS notes that this definition is purposefully structured to parallel existing language that defines a Medical Home Model (applicable under Medicare) and a Medicaid Medical Home Model. CMS, however, emphasizes that the three medical home models (Medicare, Medicaid, and Aligned Other Payer), though similarly defined, are distinct from one another. Further, CMS proposed to limit the term Aligned Other Payer Medical Home Model specifically to other payers' payment arrangements that are aligned with CMS Multi-Payer Models that are themselves Medical Home Models. CMS cites recent experience showing that aligned medical home model participants typically resemble Medicaid medical home model participants in size, revenues, and limited ability to bear risk. That said, CMS also emphasizes that participants in the various medical home models do vary in their risk-bearing abilities regardless of payer, so that the existing 50-clinician limit applies to the proposed Aligned Medical Home model. (When a medical home model participant has more than 50 clinicians, the generally applicable standards apply rather than the medical home financial and nominal amount standards. For full details see §414.1415(c)(7).)

Support from commenters was mixed. Some were concerned about the narrowness of the definition and recommended removing the requirement that the Aligned Other Payer Medical Home Model simultaneously be a participant in a CMS multipayer model that is a medical home model, and stated that uptake of the new model would be constrained thereby. CMS remains concerned about the potential for gaming within models that it does not directly sponsor.

c. Bearing Risk: Defining Excess Expenditures

Context

When assessing whether a model meets the Advanced APM Financial criterion, CMS first examines how risk-bearing is described (e.g., in terms of returning payment received or of future payment withholding), termed the financial standard. Second, CMS determines if the actual amount at risk (potential monetary losses by the APM) exceeds the nominal amount threshold, termed the nominal amount standard. Both standards (financial and nominal amount) differ for medical home models from those for other models; the former are referred to as "medical home standards" and the latter as "generally applicable" standards. The current generally applicable nominal standards are 8 percent for models with risk expressed in terms of revenue (revenue-based) and 3 percent total risk for other models. (The remainder of this section will focus on the generally applicable standards, since the medical home standard does not depend upon expected expenditures; see §414.1415(c)(2).)

Since the QPP's inception, CMS has acquired extensive experience with the design and evaluation of APM financial structures. For QPP Year 1, CMS proposed 3 dimensions of risk

²⁸ The Comprehensive Primary Care Plus model (CPC+) is an example of a CMS Multi-Payer Model that also is a Medical Home Model that has not yet been expanded.

for use when assessing if a model's design meets the generally applicable nominal risk standard: 1) marginal risk, the percentage of (actual – expected) expenditures for which an APM Entity would be liable; 2) minimum loss rate, or MLR, the percentage by which actual expenditures may exceed expected expenditures without triggering financial risk for the APM Entity; and 3) total potential risk, the maximum potential payment for which an APM Entity could be held liable. For simplicity, CMS finalized only the total potential risk parameter for Medicare-sponsored Advanced APMs, anticipating that their model designs always would incorporate appropriately strong risk levels. (For use in assessing risk under Other Payer Advanced APMs, CMS retained all 3 risk dimensions.) CMS states an expectation that the participants within a model meeting the nominal amount standard should face: 1) the potential for financial losses based on expenditures in excess of the model's benchmark or episode target price, and 2) a meaningful possibility that a participating APM entity might exceed the benchmark or episode target price.

CMS voiced concern in the proposed rule that a model's risk-bearing and nominal monetary loss parameters can satisfy current regulations but may be structured in a way that actually limits risk-bearing to inappropriately low levels. CMS links insufficient risk-bearing to the definition of expected expenditures, a number that is part of virtually all calculations of amounts for which APMs might be at risk. CMS offers the example that an APM could have a sufficient total risk to meet the benchmark-based nominal amount standard and a sharing rate that results in an adequate marginal risk rate if actual expenditures exceed expected expenditures. However, that same APM's level of expected expenditures, reflected in its benchmark or episode target price. could be set in a way that substantially reduces the loss that the APM Entity would reasonably expect to incur. High expected expenditures increase the likelihood that a participant's actual expenditures will be near or less than the benchmark or episode target price, resulting in small or no monetary loss by the participant. High expected expenditures can result from factors such as using non-representative baseline data for benchmarking (e.g., data only from high cost regions or too old to reflect current medical practice), or basing adjustments that are made to benchmarks in order to account for possible expenditure increases that may be viewed as desirable, on flawed assumptions (e.g., rates of patient compliance with behavioral interventions). CMS states that increased costs due to proper patient risk-adjustment are not considered excess expenditures.

Given the foregoing, for 2020 and thereafter, CMS finalizes its proposal to revise the definition of expected expenditures (at §414.1415(c)(5)), when used for assessing risk-bearing, to exclude excess expenditures. CMS will require that the expected expenditures under the terms of the APM not exceed the Medicare Part A and B expenditures for a participant in the absence of the APM. If the expected expenditures do exceed those that would occur in the model's absence, the excess expenditures will not be counted towards meeting the nominal amount standard.

A few commenters expressed concern that the application of the proposed definition of expected expenditures could potentially cause some current Advanced APMs to no longer meet the generally applicable nominal amount standard. Others supported the exclusion of risk adjustment when considering what constitutes excess expenditures. In response, CMS notes that it is possible that the application of the amended definition could result in an Advanced APM not meeting the standard. CMS agrees with commenters on the exclusion of risk adjustment and states that it will not consider risk adjustments to be excess expenditures.

d. Request for Comment: Excluded Items and Services under Full Capitation Arrangements

CMS has previously established that a full capitation arrangement meets the Advanced APM financial risk criterion. A full capitation arrangement is one in which: 1) a predetermined payment (e.g., per capita) is made through the APM to cover all items and services furnished to a beneficiary population during a fixed time period; and 2) no settlement or reconciliation with CMS is performed. (Arrangements between CMS and MA organizations are not considered capitation arrangements under the QPP.²⁹) More recently, CMS has become aware that other payers' capitation arrangements contain lists of services excluded from the capitation rate, such as hospice care, organ transplants, and out-of-network emergency services. CMS sought comment upon the following questions to assess whether CMS should allow capitation arrangements to be judged as "full" capitation if they categorically exclude specified items or services from payment through the capitation rate:

- Are there common industry practices to exclude certain categories of items and services from capitated payment rates?
 - o If so, are there are common principles or reasons for excluding those categories?
- What percentage of the total cost of care do such exclusions typically account for under what is intended to be a "full" global capitation arrangement?
- How do non-Medicare payers define service categories that are excluded from global capitation payment arrangements?

For Other Payer Advanced APMs, CMS has similarly defined a full capitation arrangement that meets the Other Payer Advanced APM financial risk criterion. CMS also asked for comment on the above questions as part of considering whether other payers' arrangements that exclude specified services from the capitation rate should be determined by CMS to satisfy the Other Payer Advanced APM financial risk criterion.

CMS received only supportive comments. The commenters identified specific items and services such as hospice care, emergency care, or specific high cost pharmaceuticals as items and services to be excluded from the definition of full capitation arrangements for the purposes of the advanced APM financial risk criterion. CMS states that it will take these comments into consideration for a possible proposal in future rulemaking.

e. QP and Partial QP Determinations

Application of Partial QP Status

Clinicians (each identified by an NPI) may belong to more than one group (identified by a TIN) and may reassign their billing rights across different groups, so that multiple TIN/NPI combinations are associated with a single clinician. When an individual reaches QP status through participation in one group, CMS has considered the individual to be a QP for all of his or her TIN/NPI combinations when calculating the APM incentive bonus payment. Currently, CMS applies this approach in a similar way to individuals reaching Partial QP status: the

²⁹ The Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration, an Innovation Center initiative, was designed to test options for counting MA participation towards the QP threshold. Announced on July 12, 2018, the MAQI demonstration was discontinued on August 1, 2019 due to low participation rates.

election of a partial QP to be exempt from MIPS reporting and payment adjustment is applied to all of his or her TIN/NPI combinations. Since Partial QP status is not linked to additional payment, a clinician who might qualify for a positive MIPS adjustment through one TIN/NPI combination could be precluded from receiving that adjustment by reaching Partial QP status under another TIN/NPI combination and electing MIPS exemption under the latter TIN/NPI.

CMS has recently considered in detail the scenario of the clinician with multiple TIN/NPI combinations who does not independently reach Partial QP status for each TIN/NPI arrangement. CMS expresses concern that the potential loss of the positive MIPS adjustment by a Partial QP clinician under this scenario could discourage participation in Advanced APMs. CMS, therefore, proposed that beginning with the 2020 QP performance period, Partial QP status would apply only to the TIN/NPI combination(s) through which an individual attains Partial QP status, if the clinician elects MIPS exemption.

However, after exploring the system requirements that would need to be met in order to implement the proposed policy, CMS concluded it would not be able to modify its system to implement the policy for the 2020 performance period. CMS, therefore does not finalize the proposed policy for Partial QP status, but may revisit this issue in future rulemaking.

APM Entity Termination

Current regulations are designed to ensure that APM Entities and their member clinicians face more than nominal financial risk for at least the full QP performance period of a year in which they attain QP or Partial QP status. Nevertheless, CMS expresses concern about scenarios in which an APM Entity terminates (voluntarily or not) from an Advanced APM at a date on which the entity would not yet have incurred financial accountability under the terms of the APM. Such scenarios could arise because terms of the agreements between Advanced APMs and CMS can vary, giving flexibility that is intended to foster innovation. Currently, the QP or Partial QP status of the entity's clinicians would not be affected by "early termination", even though they would have reached their status through an Advanced APM that in fact did not satisfy the Advanced APM financial risk criterion.

CMS finalizes its proposal to eliminate such scenarios for performance year 2020 and subsequent years. Specifically, revised regulatory language will state that an eligible clinician is not a QP or Partial QP for the year if an APM Entity were to terminate before incurring financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs.

A few commenters opposed this proposal; they were concerned that there would not be sufficient time between the termination from the Advanced APM and the reporting deadlines required for reporting to MIPS. CMS was not sympathetic to these concerns and states that it has consistently maintained that participants in Advanced APMs may be considered MIPS eligible clinicians and that they may need to report to MIPS, depending on whether they attain QP or Partial QP status.

f. All-Payer Combination Option and Other Payer Advanced APMs

Context

The All-Payer Combination became available to clinicians starting with the 2019 QP Performance Period, and 2021 will be the first payment year under this option. Through the All-Payer option, groups and individual clinicians may achieve QP or Partial QP status by reaching pre-defined levels (thresholds) of participation in both (Medicare-sponsored) Advanced APMs and those sponsored by other payers. A minimum level of Advanced APM participation is required; that is, QP status cannot be reached based solely on participation in Other Payer Advanced APMs. Tables 64A and 64B, reproduced below from the rule, show the thresholds; the material in these tables has been previously finalized and has appeared in prior rules. When determining if a clinician, a TIN, or an APM Entity is a QP, CMS actually makes a series of determinations so that the Medicare Option is applied first (using the payment and patient count thresholds) followed by the All-Payer option (using both thresholds); the most favorable result from the series of determinations is applied to the clinician, TIN, or entity.

TABLE 64A: QP Payment Amount Thresholds – All-Payer Combination Option

Payment Year	2019	2020	2021	2022	2023 and later
QP Payment Count Thresh	old				
Medicare Minimum	N/A	N/A	25%	25%	25%
Total			50%	50%	75%
Partial QP Payment Count	Threshold			·	·
Medicare Minimum	N/A	N/A	20%	20%	20%
Total			40%	40%	50%

TABLE 64B: QP Patient Count Thresholds – All-Payer Combination Option

Payment Year	2019	2020	2021	2022	2023 and later
QP Patient Count Threshol	d				
Medicare Minimum	N/A	N/A	20%	20%	20%
Total			35%	35%	50%
Partial QP Patient Count T	hreshold			·	·
Medicare Minimum	N/A	N/A	10%	10%	10%
Total			25%	25%	35%

Payment arrangements that may qualify as Other Payer Advanced APMs include those between clinicians and Medicare Health Plans, Medicaid programs, and what CMS terms "Remaining Other Payers". All of the information necessary to make an Advanced APM determination is maintained by CMS, and the agency automatically performs determinations annually, releasing

³⁰ Figures 2 and 3 of the rule depict the QP determination decision trees for both the Medicare and All-Payer Combination options.

an Advanced APM list thereafter. CMS lacks the corresponding information about APMs sponsored by others, and determinations of Other Payer Advanced APM status are performed by CMS upon request. Requests may originate from payers (Payer Initiated process), and from clinicians or APM entities (Eligible Clinician Initiated process). CMS maintains a list of Other Payer Advanced APMs.³¹

Other Payer Advanced APM Criteria

CMS has previously finalized the criteria by which it makes "Advanced" status determinations for APMs sponsored by others. The Other Payer Advanced APM criteria are designed to parallel the Advanced APM criteria but are not identical; all must be met to earn Advanced status.

- Participants are required to use CEHRT.
 - All APM Entities within an Other Payer Advanced APM must require at least 75 percent of their eligible clinicians to use CEHRT in clinical care delivery beginning in 2020 (up from 50 percent in 2019).
- Payment for covered professional services must be conditioned at least in part on quality measures comparable to those of the MIPS Quality performance category.
 - O Beginning with performance year 2020, at least one of the measures must be finalized on the MIPS final list of measures; endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid. At least one of the measures also must be an outcome measure, if available. The 2020 change is not retroactive; models determined to be Other Payer Advanced APMs for prior performance years would not be affected.
- Participating Other Payer APM Entities must be able to bear risk for more than nominal monetary losses. CMS again approaches this criterion as having two parts: 1) describing ways to bear risk (e.g., repayment to payer), and 2) what constitutes more than nominal monetary losses (e.g., percentage of expenditures). The generally applicable nominal risk standard for Other Payer Advanced APMs is as follows:
 - The applicable revenue-based nominal amount standard remains at 8 percent through the 2024 QP Performance Period;
 - The total potential risk has been set previously at 4 percent;
 - o The terms of an Other Payer Advanced APM agreement must require a marginal risk rate of at least 30 percent; and
 - The terms of an Other Payer Advanced APM agreement must require an MLR of no more than 4 percent.

Medicaid-sponsored Advanced APM Exception

APMs sponsored by Medicaid are considered one type of Other Payer APM, and they must meet all of the Other Payer Advanced APM criteria described above. An exception is provided for Medicaid-sponsored medical home models. A modified nominal amount standard with a more gradual risk percentage progression is applied to APMs meeting the Medicaid Medical Home Model definition (model defined at §414.1305, risk progression found at §414.1415(c)(2)). This exception is analogous to that provided to Medicare-sponsored Medical Home Models.

³¹ The current list is available at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/395/2019%20MHP%20OP%20APM%20Determination%20List.pdf.

g. Aligned Other Payer Medical Home Models Advanced Status Determinations

CMS refers to the definition of an Aligned Other Payer Medical Home Model (section III.K.1.b.(3)(a) of the rule and section III.K.4.b. of this summary). CMS proposed that a payment arrangement structured as an Aligned Other Payer Medical Home Model would be required to meet the Other Payer Advanced APM CEHRT and Quality criteria. CMS also proposed that the financial risk and nominal amount standards for Medicaid-sponsored medical homes would be extended to apply to Aligned Other Payer medical homes. Additionally, CMS proposed that under the terms of either a Medicaid or Aligned Other Payer Medical Home Model, any required payments from the APM Entity (e.g., for failure to meet the model's cost metrics) would be made directly by the entity to the payer (the Medicaid agency or the Other Payer, respectively).

CMS proposed that requests by payers for Advanced Other Payer APM status determinations for their aligned medical homes would be submitted beginning in 2020 through the Payer-Initiated Process already established for Remaining Other Payers (i.e., not Medicaid or Medicare Health Plans). Similarly, CMS proposed that eligible clinicians and APM Entities would submit their requests for determinations through the Eligible Clinician Initiated process.

CMS received no comments on its proposals, and finalizes them without modification.

h. Generally Applicable Other Payer Advanced APM Nominal Amount Standard

Marginal Risk

The Other Payer Advanced APM generally applicable nominal amount standard includes a requirement that the terms of the model agreement specify a marginal risk rate of at least 30 percent, with marginal risk representing the percentage of actual minus expected expenditures for which an APM Entity would be liable. Some model agreements incorporate a sliding scale for marginal risk, so that the marginal risk rate percentage varies with the magnitude of the loss (e.g., a smaller percentage as the loss amount increases). When assessing model agreements having variable marginal risk rates, CMS has required the model to apply at least a 30 percent marginal risk rate percentage at all levels of loss, so that the 30 percent rate serves as a floor or minimum standard for all levels of total loss. CMS proposed that for models with a variable marginal risk rate, it would require that the average marginal risk rate across the entire range of potential losses would be used to assess compliance with the 30 percent marginal risk rate. CMS notes that the exceptions for large losses and small losses specified at §414.1420(d)(5)(ii) and (iii), respectively, would not change. CMS also described an example calculation of average marginal risk rate in the rule (Table 65 in final rule). CMS anticipates that changing the approach to calculating marginal risk would help to protect other payer APM entities from potentially catastrophic losses. CMS believes that its proposed approach represents an alternative way of expressing risk than an inappropriate lowering of risk-bearing.

CMS received very few comments on its proposal, and all were supportive. CMS finalizes its proposal, without modification.

Expected Expenditures

Section III.K.4.c.(2)(b) of the rule (see section III.K.4.c of this summary) addresses the definition of Expected Expenditures in the context of ensuring appropriately robust levels of risk under Medicare-sponsored Advanced APM model agreements. CMS repeats much of that discussion in this section, as it also applies to assessing the extent of financial risk to be borne under Other Payer Advanced APM model agreements. CMS reaches the conclusion that a flawed definition of Expected Expenditures could allow an Other Payer Advanced APM to meet the relevant nominal risk standard but actually bear low levels of risk. Therefore, CMS finalizes its proposal, without modification, to amend the definition of Expected Expenditures for use when making Other Payer Advanced APM determinations in a manner similar to its finalized application to Medicare-sponsored Advanced APMs.

5. QPP Technical Revisions

CMS proposed several technical revisions to the QPP regulations. In general, these were designed to accomplish the following:

- To clarify (e.g., that a regulation applies beginning with a performance year and to subsequent years rather than applying only to a single year);
- To correct inadvertent errors made in dates (e.g., one month errors in the dates for releasing guidance related to the Other Payer Advanced APM determination timeline);
- To correct erroneous citations embedded in otherwise correctly-written regulations;
- To correct omissions in making conforming changes; and
- To correct inadvertent terminology errors.

CMS did not receive any comments and finalizes the technical revisions.

CMS also proposed to revise Table 59 of the 2019 PFS final rule (which summarized the proposed processes and timelines for submitting requests for Other Payer Advanced APM determinations for QP Performance Period 2020) to modify certain dates (from September 2020 to August 2020) to align that table with what was originally finalized in the 2018 PFS final rule. Table 66 in the 2020 PFS final rule is included as the corrected Table 59 from the 2019 PFS final rule. CMS finalizes the technical change. Table 66 is reproduced below.

TABLE 66: Proposed Other Payer Advanced APM Determination Process for Medicaid, Medicare Health Plans, and Remaining Other Payers for QP Performance Period 2020 (Corrected Table 59 from the CY 2020 PFS proposed rule)³²

	Payer Initiated Process	Date	Eligible Clinician (EC) Initiated Process*	Date
Medicaid Title XIX	Guidance sent to STATES Submission Opens STATES	Jan 2019	Guidance to ECs Submission Opens ECs	Sept 2019
	Submission Closes STATES	April 2019	Submission Closes ECs	Nov 2019
	CMS Notifies STATES CMS Posts OP AAPM List	Sept 2019	CMS Notifies STATES & ECs CMS Posts OP AAPM List	Dec 2019
Medicare Health Plans (MHP)	Guidance available for MHP Submission Opens MHP	April 2019	Guidance available to ECs Submission Opens ECs	Aug 2020
	Submission Closes MHP	June 2019	Submission Closes ECs	Nov 2020
	CMS Notifies MHP CMS Posts OP AAPM List	Sept 2019	CMS Notifies ECs CMS Posts OP AAPM List	Dec 2020
Remaining Other Payers (ROP)	Guidance available to ROP Submission Opens ROP	Jan 2019	Guidance available to ECs Submission Opens ECs	Aug 2020
	Submission Closes ROP	June 2019	Submission Closes ECs	Nov 2020
	CMS Notifies ROP CMS Posts OP AAPM List	Sept 2019	CMS Notifies ECs & ROP CMS Posts OP AAPM List	Dec 2020

^{*}Note that APM entities or eligible clinicians may use the Eligible Clinician Initiated Process.

IV. Regulatory Impact Analysis: Quality Payment Program

CMS estimates that approximately 59 percent of the nearly 1.5 million clinicians billing to Part B (879,966) will be assigned a MIPS score for 2022 because others will be ineligible for or excluded from MIPS. Table 122, reproduced below, provides the details of clinicians' MIPS eligibility status for 2022 MIPS payment year (2020 MIPS performance year). CMS notes it is

³² Note: The parenthetical material in the heading for Table 66 differs from the explanation of the technical change in the preamble of the 2020 PFS final rule.

difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the finalized policies; CMS assumes 33 percent of the clinicians who exceed at least one but not all low-volume threshold criteria and submitted data to 2018 MIPS performance period would elect to opt-in to the MIPS program.

TABLE 122: Description of MIPS Eligibility Status for CY 2022 MIPS Payment Year Using the 2020 PFS Assumptions***				
Eligibility Status	Predicted Participation Status in MIPS Among Clinicians*	Number of Clinicians	PFS allowed charges (\$ in mil)***	
Required eligibility	Participate in MIPS	201,708	\$48,349	
(always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Do not participate in MIPS	18,610	\$4,147	
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	639,004	\$15,426	
Opt-In eligibility (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	20,644	\$1,019	
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges			68,941	
Not MIPS Eligible				
Potentially MIPS eligible (not subject to payment adjustment for non- participation; could be eligible for one of two reasons: 1) meet group eligibility or 2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	380,352	\$9,069	
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	81,982	\$444	
Excluded for other reasons (Non-eligible clinician type, newly- enrolled, QP)	Not applicable	265,982	\$10,980	
Total Number of Clinicians Not MIPS Eligible	728,316	20,493		
Total Number of Clinicians (MIPS and Not MIPS I	1,608,282	89,434		

^{*}Estimated MIPS Eligible Population

In the aggregate, CMS estimates that for the 2022 payment year, it would redistribute about \$433 million in payment adjustments on a budget neutral basis. The maximum positive payment adjustments are 6.2 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. CMS estimates that 92.5 percent of

^{**} This table also does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 20,000 clinicians and \$1,672 million in PFS allowed charges).

^{***} Allowed charges estimated using 2017 and 2018 dollars. Low volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

eligible clinicians are expected to have a positive or neutral payment adjustment and 7.5 percent will have a negative payment adjustment.

Table 123, reproduced below, shows the impact of payments by practice size and based on whether clinicians are expected to submit data to MIPS. CMS estimates that clinicians in small practices (1-15 clinicians) participating in MIPS would not perform as well as larger sized practices. For example, almost 19 percent of clinicians in small practices (1-15 clinicians) are expected to receive a negative payment adjustment compared with about 3.5 percent for clinicians in very large practices (100+). CMS notes that it is using 2018 MIPS performance data and that it is likely there will be changes that it cannot account for at this time, because the performance thresholds increased for the 2020 MIPS performance period to avoid a negative payment adjustment.

Table 1	Table 123: MIPS Estimated Payment Year 2022 Impact on Total Estimated Paid Amount								
by Participation Status and Practice Size*									
Practice Size*	Number of MIPS eligible clinicians	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount**				
Among t	Among those submitting data***								
1) 1-15	140,825	81.1%	36.2%	18.9%	1.0%				
2) 16-24	43,304	87.4%	40.0%	12.6%	1.3%				
3) 25-99	199,829	92.0%	40.7%	8.0%	1.4%				
4) 100+	477,991	96.5%	50.3%	3.5%	1.8%				
Overall	861,949	92.5%	45.3%	7.5%	1.4%				
Among t	hose not sub	mitting data							
1) 1-15	15,993	0.0%	0.0%	100.0%	-8.6%				
2) 16-24	663	0.0%	0.0%	100.0%	-8.6%				
3) 25-99	904	0.0%	0.0%	100.0%	-8.8%				
4) 100+	457	0.0%	0.0%	100.0%	-8.7%				
Overall	18,017	0.0%	0.0%	100.0%	-8.6%				

^{*}Practice size is the total number of TIN/NPIs in a TIN.

^{** 2018} data used to estimate 2020 performance period payment adjustments. Payment estimated using 2018 dollars trended to 2022.

^{***}Includes facility-based clinicians whose quality data is submitted through hospital programs.

CMS estimates that approximately 210,000 to 270,000 eligible clinicians will become QPs for the 2022 payment year and a total of \$535 to \$685 million in APM incentive payments will be made.

<u>Limitations of CMS Analysis</u>

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 2019 predictive APM Participation List, 2018 QPP Year 2 data and CAHPS for ACOs. The scoring model results assume that 2018 QPP Year 2 data submissions and performance are representative of 2020 QPP data submissions and performance. In particular, CMS anticipates that clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment. In addition, because CMS used historic data, it assumes that participation in the three performance categories in MIPS Year 2 would be similar to MIPS Year 4 performance. CMS states that given these limitations and others, there is considerable uncertainty around its estimates.

Summary of Annual Quality Payment Program Burden Estimates

CMS estimates the QPP policies finalized for the 2020 performance year will reduce the total annual burden associated with the QPP as 2,171,152 hours with a reduction of total costs of \$166,778,034.

Table 114 in the final rule summarizes the final rule's burden estimates for the QPP requirements. CMS estimates a burden estimate of 2,932,925 hours at a cost of \$279,573,747. The burden estimate for the 2019 performance year was 5,103,801 hours.

Table 115 summarizes the 2020 finalized policies that contribute to changes in the estimated information collection burden.