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Summary of MACRA Proposed Rule

On April 27, 2016, the Centers for Medicare & Medicaid Services (CMS) released for public display a proposed rule to implement Section 101 of the Medicare Access and CHIP Reauthorization Act (MACRA)¹, which repealed the Sustainable Growth Rate (SGR) methodology for updates to the Medicare Physician Fee Schedule and replaced it with a new Merit-Based Incentive Program System for eligible physicians (Proposed Rule).² MACRA, which was signed into law in April 2015, made significant reforms to the Medicare physician payment system aimed at rewarding quality and value over volume.

Comments on the Proposed Rule will be accepted through <u>June 27, 2016</u>. Following is background information on Section 101 of MACRA and a section-by-section summary of the Proposed Rule.

I. Statutory Background

A. Adjustment to Physician Fee Schedule Rates

Section 101 of MACRA repealed the SGR formula and provided for a multi-year transition to a new Medicare physician payment system that is designed to reward the quality of care and not merely the volume of services and procedures. It extended through June 2015 the then-current Medicare Physician Fee Schedule (PFS) rates that were established in legislation in 2014 (Pub. L. 113-93), and for the remainder of 2015, it increased those rates by 0.5 percent. Beginning on January 1, 2016, the rates are to be increased annually by 0.5 percent, through 2019. For 2020 through 2025, MACRA calls for PFS payment rates to be frozen at 2019 levels, with payments adjusted to account for performance on certain quality metrics under the Merit-Based Incentive Payment System (MIPS) or participation in alternative payment models (APMs). For 2026 and subsequent years, qualified APM participants receive an annual 0.75 percent update on Medicare physician payment rates, while those not participating in APMs receive a 0.25 percent annual payment update, plus any applicable MIPS-based payment adjustments.

B. The Merit-Based Incentive Payment System

Under MIPS, payments to "eligible professionals" are to be adjusted based on performance on a new set of measures designed to consolidate the existing Physician Quality Reporting System (PQRS), the Value-Based Payment Modifier (VM), and the Electronic Health Records "Meaningful Use" incentive program. In conjunction with this consolidation and the establishment of MIPS, the legislation sunsets the existing reporting requirements and payment penalties required under the PQRS, VM, and Meaningful Use programs in 2018. However MACRA establishes a new system of payment bonuses and penalties that will be applied to MIPS-eligible professionals, beginning in 2019.

¹ Pub. L. 114-10.

Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models, 81 Fed. Reg. 28162 (May 9, 2016), available at https://www.gpo.gov/fdsys/pkg/FR-2016-05-09/pdf/2016-10032.pdf.

Initially, "eligible professionals" are physicians, dental surgeons, podiatrists, optometric physicians, chiropractors, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists (CRNAs). Beginning in 2021, certain other professionals paid under the PFS could be included in MIPS, if there are applicable performance measures. (These may include, for example, audiologists and speech language pathologists.) New Medicare-enrolled professionals would not be treated as "eligible professionals" under the system until the subsequent year after enrollment. Notably, practitioners participating in APMs are exempt from MIPS reporting and payment adjustment requirements, as are those who do not reach a low-volume Medicare threshold, to be established by CMS.

The legislation directs CMS to establish four performance categories for MIPS measures: (1) quality of care; (2) resource use; (3) clinical practice improvement activities (CPIA); and (4) meaningful use of EHR technology. MIPS-eligible professionals would have the option to report on these measures through an EHR, a physician specialty-society maintained clinical data registry, or another appropriate system that best fits their particular practice environments. They also would have the option of reporting and being assessed on performance as a group or as individuals. MIPS-eligible professionals would be assessed only on categories and activities that are applicable to their practices, and MIPS scoring weights would be adjusted accordingly.

For the quality of care category, CMS will be required to publish an annual list of quality measures that will be incorporated into MIPS reporting, after considering input from stakeholders. CMS must incorporate all of its VM measures into the resource use category of measures for MIPS. MIPS reporting also must allow for resource use measures to incorporate distinctions based on the type of service provided by the reporting professional (e.g., primary care service versus specialty service) and based on the type of condition for which the beneficiary is being treated (e.g., treatment for a chronic condition versus treatment for an acute care episode). Eligible professionals would satisfy the Meaningful Use measures category by demonstrating the use of certified EHR technology (CEHRT). Finally, the legislation provides that measurement of CPIAs will include expanded practice access activities, population management activities, and care coordination activities. MACRA allows provider organizations and other relevant stakeholders to suggest quality measures for consideration and to identify and submit updates to measures already on the list.

MIPS Category	Maximum Scoring Weight During First Two Years	Scoring Weight When Fully-Implemented
Quality of Care	50% (Year One)	30%
	45% (Year Two)	
Resource Use	10% (Year One)	30%
	15% (Year Two)	
EHR Meaningful Use	25%	25%
Clinical Improvement Activities	15%	15%

CMS will generate composite scores between zero and 100, based on the eligible professional's performance on MIPS measures two years prior to the adjustment year, and apply payment adjustments to base payment rates for each year, based on a the composite MIPS score relative to the mean. MACRA requires that CMS establish certain payment increases and penalties for MIPS-eligible professionals, based on the performance on

MIPS measures relative to the national average MIPS composite score, or "performance threshold." Maximum negative payment adjustments are capped at pre-determined levels for each year, while positive adjustments are provided in a budget-neutral manner from the amount of savings generated by the negative adjustments (although also subject to maximum positive adjustments), with eligible professionals with higher MIPS composite scores receiving higher payment adjustments. As an incentive to improve performance, eligible professionals would receive credit for improvement from one year to the next in determination of the quality and resource use performance scores. MACRA also establishes a system under which MIPS-eligible professionals would receive confidential feedback at least quarterly on their performance in the quality and resource use measures categories. MIPS-eligible professionals who fail to report on an applicable measure or activity will be treated as achieving the lowest potential score applicable to the measure or activity.

MIPS Composite Performance	<u>2019</u>	2020	<u>2021</u>	2022 & Subsequent Yrs
Less than ¼ of the MIPS Performance Threshold	4% Reduction (Maximum)	5% Reduction (Maximum)	7 % Reduction (Maximum)	9% Reduction (Maximum)
Between ¼ of MIPS Performance Threshold and Score Equal to MIPS Performance Threshold	Sliding Scale Negative Adjustment	Sliding Scale Negative Adjustment	Sliding Scale Negative Adjustment	Sliding Scale Negative Adjustment
Above MIPS Performance Threshold	Positive Adjustment (12% Maximum)	Positive Adjustment (15% Maximum)	Positive Adjustment (21% Maximum)	Positive Adjustment (27% Maximum)

MIPS-eligible professionals also could receive additional adjustments for exceptional performance, such that some professionals could receive positive payment adjustments even if all professionals score above the performance threshold. These additional payments would be capped at 10 percent per MIPS-eligible professional and at \$500 million per year in the aggregate from 2019 through 2024.

C. Alternative Payment Models

To encourage participation in APMs, MACRA provides for bonuses for physicians and other practitioners who receive a significant portion of Medicare revenue through such payment mechanisms. Medicare APMs include demonstration projects administered by the Center for Medicare and Medicaid Innovation (CMMI), the Medicare Shared Savings Program for Accountable Care Organizations (ACOs), bundled payment demonstrations, or other demonstrations required under federal law. For participation in APMs organized by other payors to count, they must have quality measures comparable to Medicare quality measures, require the use of CEHRT, and include downside financial risk for participants. Generally, physicians or other practitioners will be considered "qualified APM participants" if:

- in 2019 and 2020, at least 25 percent of all Medicare payments are attributable to services furnished through a qualifying APM;
- in 2021 and 2022, at least 50 percent of all Medicare payments are attributable to services furnished through a qualifying APM, or at least 50 percent of payments from all payors and at least 25 percent of Medicare payments are attributable to services furnished through a qualifying APM; and

• in 2023 and subsequent years, at least 75 percent of Medicare payments are attributable to services furnished through a qualifying APM, or at least 75 percent of payments from all payors and at least 25 percent of Medicare payments are attributable to services furnished through a qualifying APM.

For a covered professional service in a year in which a physician or other practitioner is a qualified APM participant, in addition to the amount of payment that otherwise would be made for such service, the physician or practitioner will receive a lump sum payment equal to five percent of the estimated aggregate payment amount, to be paid in the following year.

The legislation directs CMS to test APMs relevant to specialty professionals, professionals in small practices, and those that align with private and state-based payor initiatives. An 11-member Payment Model Technical Advisory Committee will be formed in order to establish criteria for physician-focused payment models, and stakeholders will be able to submit proposals to the committee for different kinds of models.

II. Provisions of the Proposed Rule

A. Establishing MIPS and the APM Incentive

Section 1848(q) of the Social Security Act (the "Act"), as added by Section 101 of MACRA, requires establishment of the MIPS and promotes the development of, and participation in, APMs for eligible clinicians.³ CMS said that "further information will be provided in future rulemaking," without giving details.

B. Program Principles and Goals

CMS states that MIPS promotes better care, healthier people, and smarter spending by evaluating MIPS eligible clinicians using a Composite Performance Score (CPS) that incorporates MIPS eligible clinicians' performance on quality, resource use, clinical practice improvement activities, and advancing care information. The agency also hopes to expand opportunities for and maximize participation in APMs, create clear and attainable standards for incentives, promote the continued flexibility in design of APMs, and support multi-payer initiatives across the health care market.

CMS says that its strategic goals in creating the Quality Payment Program (QPP) include: (1) design a patient-centered approach to program development that leads to better, smarter, and healthier care; (2) developing a program that is meaningful, understandable, and flexible for participating clinicians; (3) design incentives that drive delivery system reform principles and participation in APMs; and (4) ensure close attention to CMS's excellence in implementation, effective communication with stakeholders, and operational feasibility.

C. Changes to Existing Programs

<u>Sun-setting current payment adjustment programs</u></u>. Section 101 of MACRA calls for sun-setting the PQRS, VM, and Meaningful Use incentive program, but CMS will revise the regulations implementing those programs, rather than delete them in their entirety, because the final payment adjustments under these programs will not occur until the end of 2018.

While the legislation refers to them as "eligible professionals," CMS uses the term "eligible clinicians."

<u>CEHRT surveillance and information blocking attestations.</u> CMS is proposing to require eligible clinicians under both MIPS and APMs to attest that they have cooperated with the surveillance of CEHRT, as they have under the Medicare and Medicaid EHR incentive programs. Cooperation would include responding in a timely manner and in good faith to requests for information about the performance of the CEHRT capabilities in use by the provider in the field, and accommodating requests for access to the provider's CEHRT. An eligible clinician, Eligible Professional, eligible hospital, or Critical Access Hospital also would have to attest that it: (1) did not knowingly or willfully take action to limit or restrict the compatibility or interoperability of CEHRT; (2) implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure that the CEHRT was at all relevant times compliant with certain interoperability standards; and (3) responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information.

D. MIPS Program Details

1. MIPS Eligible Clinicians

Definition of MIPS eligible clinician. CMS proposes to define a "MIPS eligible clinician" as a physician (as defined in Sec. 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as defined in Sec. 1861(aa)(5) of the Act); a CRNA (as defined in Sec. 1861(bb)(2) of the Act); and a group that includes such professionals. CMS also proposes that the following would be excluded from the definition: Qualifying APM Participants (QPs), Partial Qualifying APM Participants (Partial QPs) who do not report data under MIPS, low-volume threshold eligible clinicians, and new Medicare-enrolled eligible clinicians.⁴ MACRA allows CMS to add other types of health care professionals to the list of "MIPS eligible clinicians" for the third and subsequent years that MIPA applies to payments (e.g., audiologists, speech language pathologists), and CMS plans to use its rulemaking authority to expand the definition in the future.

CMS also proposes to allow eligible clinicians who are not MIPS eligible clinicians to report measures and activities for MIPS voluntarily, not in order to receive incentive payments, but to gain experience with the program. CMS anticipates that certain types of professionals who have been reporting quality measures under the PQRS for years (e.g., physical therapists, occupational therapists, clinical social workers) will want to gain experience with MIPS, and the agency asks for comment on this proposal.

Non-patient-facing MIPS eligible clinicians. MACRA requires CMS, in specifying measures and activities for a performance category, to give consideration to the circumstances of professional types who typically furnish services that do not involve face-to-face interaction with a patient (*e.g.*, pathologists, radiologists, nuclear medicine physicians, anesthesiologists primarily providing oversight of CRNAs). The law also allows CMS to reweight MIPS performance categories if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician. CMS proposes to define a "non-patient-facing MIPS eligible clinician or group that bills 25 or fewer patient-facing encounters during a performance period. CMS proposes to publish a list of "patient-facing encounter" codes on a CMS website, similar to the way it publishes face-to-face encounter codes for PQRS currently.

⁴ The proposed definition reads: "an eligible clinician who first becomes a Medicare-enrolled eligible clinician within the Provider Enrollment, Chain and Ownership System (PECOS) during the performance period for a year and who had not previously submitted claims as a Medicare-enrolled eligible clinician either as an individual, an entity, or a part of a physician group or under a different billing number or tax identifier."

2. MIPS Eligible Clinician Identifier

To support MIPS eligible clinicians reporting to a single comprehensive and cohesive MIPS program, CMS needs to align the technical reporting requirements from PQRS, VM, and Meaningful Use into one and create a MIPS eligible clinician identifier. Based on comments it received previously, CMS is not proposing to create a new MIPS eligible clinician identifier; rather, it is proposing to use multiple identifiers that allow MIPS eligible clinicians to be measured as individuals or collectively through a group's performance. It also proposes that the same identifier would be used for all four MIPS performance categories: quality, resource use, clinical practice improvement activities, and advancing care information. It proposes to use a single identifier (TIN/NPI) for applying the payment adjustment.

Individual identifiers. CMS proposes to use a combination of TIN/NPI as the identifier to assess the performance of an individual MIPS eligible clinician. Each unique TIN/NPI combination would be considered a different MIPS eligible clinician, and MIPS performance would be assessed separately for each TIN under which an individual bills. (See Section II.D.4 of this memo for more information on how CMS proposes to proceed when the TIN/NPI changes during a performance period.)

Group identifiers for performance. For a MIPS eligible clinician who wishes to have performance assessed as part of a group, CMS proposes to use the group's billing TIN. CMS proposes to codify the definition of a "group" at 42 C.F.R. § 414.1305 as a group that consists of a single TIN with two or more MIPS eligible clinicians (as identified by their individual NPIs) who have reassigned their billing rights to the TIN. The agency requests comments on this approach.

APM group identifiers for performance. To identify a group to support APMs and to ensure that it has captured all of the eligible clinicians identified as participants in the APM, CMS proposes that each eligible clinician who is a participant of an APM Entity would be identified by a unique APM participant identifier. The identifier would be a combination of four identifiers: (1) APM identifier established by CMS; (2) APM Entity identifier established by CMS; (3) TIN(s); and (4) NPI. Thus, an APM identifier could be APM XXXXXXX, APM Entity AA0000111, TIN YYYYYYYYY, NPI ZZZZZZZZZZZ.

3. Exclusions

New Medicare-enrolled eligible clinician. Section 1848(q)(1)(C)(v) of the Act provides that in the case of a professional who becomes a Medicare-eligible clinician during the performance period for a year (and has not submitted claims to Medicare previously), the eligible clinician will not be treated as a MIPS eligible clinician until the subsequent year and performance period for that year. CMS proposes that a new Medicare-enrolled eligible clinician would be defined as a professional who first becomes a Medicare-enrolled eligible clinician within the PECOS during the performance period for a year and who has not submitted claims previously as a Medicare-enrolled eligible clinician either as an individual, an entity, or a part of a physician group or under a different billing number or tax identifier. As described further below, CMS is proposing that a MIPS performance period would be the calendar year two years prior to the year in which the MIPS adjustment is applied. This means that an eligible clinician who newly enrolls in Medicare within PECOS in 2017 would not be required to participate in MIPS in 2017 and would not receive a MIPS adjustment in 2019.

Qualifying APM participants and partial qualifying APM participants. Section 1848(q)(1)(C) (ii) of the Act provides that the definition of a MIPS eligible clinician does not include an eligible clinician who is a QP or Partial QP who does not report on the applicable measures and activities that are required under MIPS. (Detailed information on the determination of QPs and Partial QPs is in Section II.E.1 of this summary.) CMS plans to codify this definition in the regulations. Partial QPs will have the option to elect whether or not to report under MIPS, which determines whether or not they will be subject to MIPS adjustments.

Low-volume threshold. Per the statute, a MIPS eligible professional does not include MIPS eligible clinicians who are below the low-volume threshold elected by CMS for a given year. CMS proposes that a MIPs eligible clinician or group that does not exceed the low-volume threshold would be an individual or group who, during the performance period, has Medicare billing charges less than or equal to \$10,000 and provides care for 100 or fewer Part B-enrolled Medicare beneficiaries.

Group reporting. Section 1848(q)(1)(D) of the Act requires CMS to establish and apply a process that includes features of the PQRS group practice reporting option (GPRO) for MIPS eligible clinicians in a group for the purpose of assessing performance in the quality category and gives CMS the discretion to do so for the other performance categories. CMS proposes that in order to be assessed as a group, MIPS eligible clinicians must meet the definition of a group at all times during the performance year and aggregate their performance data across the TIN. Performance would be assessed as a group across all four performance categories. A group would have to register under an election process established by CMS.

Virtual groups. The statute allows for the use of voluntary "virtual groups" for certain assessment purposes, whereby a clinician or group consisting of no more than 10 MIPS eligible clinicians could elect to form a virtual group with at least one other such individual MIPS eligible clinician for a performance period. Because of technical and logistical barriers, CMS believes that this option is infeasible for the first performance period and plans to implement virtual groups for the 2018 calendar year performance period.

4. MIPS Performance Period

Performance period. CMS proposes that for 2019 and subsequent years, the performance period would be the calendar year two years prior to the year in which the MIPS performance adjustment is to be applied. For example, the performance period for the 2019 MIPS adjustment would be the full calendar year 2017 (January 1 through December 31). The agency proposes to use claims that are processed within 90 days after the end of the performance period for purposes of assessing performance.

Partial year data. For MIPS eligible clinicians with less than 12 months performance data to report, such as when a MIPS eligible clinician switches practices or goes on maternity leave, CMS proposes that the individual MIPS eligible clinician or group would be required to report all performance data available from the performance period. The agency says that under this approach, MIPS eligible clinicians with partial-year performance data could achieve a positive, neutral, or negative adjustment, and that it is doing this to "incentivize accountability for all performance during the performance year, and that any negative impact should be mitigated by the possibility of the eligible clinician not meeting the low-volume threshold or the requisite sample size for a given measure." It seeks comments on how to identify those with partial-year data and on alternative approaches for future years.

5. MIPS Category Measures and Activities

a) Performance Category Measures and Reporting

Submission mechanisms. CMS proposes that individual MIPS eligible clinicians and groups would be required to submit data on measures and activities for the quality, CPIA, and advancing care information performance categories, but not for the resource use performance category. (For the resource use performance category, an individual MIPS eligible clinician's and group's resource use performance would be calculated using administrative claims data; administrative claims data also would be used for a small subset of quality and CPIA measures.)

CMS is proposing multiple data submission mechanisms for MIPS to provide the flexibility for a MIPS eligible clinician or group to submit measures and activities in a manner that best accommodates the characteristic of the practice.

Proposed Data Submission Mechanisms for MIPS Eligible Clinicians Reporting Individually as TIN/NPI

Performance Category/Submission Combinations Accepted	Individual Reporting Data submission Mechanisms			
Quality	Claims QCDR Qualified registry EHR			
	Administrative claims (no submission required)			
Resource Use	Administrative claims (no submission required)			
Advancing Care Information	Attestation QCDR Qualified registry EHR			
CPIA	Attestation QCDR Qualified registry EHR Administrative claims (if technically feasible, no submission required)			

Proposed Data Submission Mechanisms for Groups

Performance Category/Submission	Group Practice Reporting			
Combinations Accepted	Data Submission Mechanisms			
Quality	QCDR			
	Qualified registry			
	EHR			
	CMS Web Interface (groups of 25 or more)			
	CMS-approved survey vendor for CAHPS for MIPS (must be reported in			
	conjunction with another data submission mechanism.)			
	and			
	Administrative claims (no submission required)			
Resource Use	Administrative claims (no submission required)			
Advancing Care Information	Attestation			
	OCDR			
	Qualified registry			
	EHR			
	CMS Web Interface (groups of 25 or more)			
CPIA	Attestation			
	QCDR			
	Qualified registry			
	EHR			
	CMS Web Interface (groups of 25 or more)			
	Administrative claims (if technically feasible, no submission required)			

Eligible clinicians and groups may elect to submit information via multiple mechanisms, but they must use the same identifier for all performance categories, and they may use only one submission mechanism per category. (While MIPS eligible clinicians and groups would have the flexibility to submit data for different performance categories via multiple submission categories, CMS encourages them to submit MIPS information for the CPIA and advancing care information performance categories through the same mechanism as the quality performance category to reduce the administrative burden and simplify the data submission process.)

The agency will encourage the use of QCDRs and CEHRT by awarding bonus points in the quality scoring section for measures gathered and reported electronically via the QCDR, qualified registry, Web Interface, or CEHRT submission mechanisms.

Submission deadlines. The proposed data submission deadline would be March 31 following the close of a performance period (data could be submitted at any time from January 2 through March 31 after a performance period). CMS is seeking input into whether there should be a shorter data submission period; whether it should have a submission period that would occur throughout the performance period, such as biannual or quarterly submissions; and whether January 1 also should be included in the data submission period.

b) Quality Performance Category

Contribution to Composite Performance Score. CMS proposes that for the 2019 MIPS adjustment year, the quality performance category would account for 50 percent of the CPS; in 2020, it would account for 45 percent; and in 2021 and subsequent years, it would account for 30 percent of the CPS.

Quality data submission criteria. MIPS eligible clinicians submitting data in a way other than the CMS Web Interface or CAHPS would be required to meet the following submission criteria: report at least six measures (including one cross-cutting measure, if patient-facing, and at least one outcome measure).⁵ If an applicable outcome measure is not available, the MIPS eligible clinician or group would be required to report one other "high priority" measure (defined at 42 C.F.R. § 414.1305 as an outcome, appropriate use, patient safety, efficiency, patient experience, or care coordination measure) in lieu of an outcome measure. If fewer than six measures apply to the individual MIPS eligible clinician or group, reporting would be on each measure that is applicable.

MIPS eligible clinicians and groups will select their measures either from the list of all measures or a set of specialty-specific measures (the specialty-specific measure also are included in the list of all measures). There are some special scenarios for those MIPS eligible clinicians who select their measures from a specialty-specific measure set at either the specialty or subspecialty level. Some of the specialty-specific measure sets have fewer than six measures. In these instances, patient-facing MIPS eligible clinicians would report on all of the available measures including an outcome measure or, if an outcome measure is unavailable, report another high priority measure (i.e., appropriate use, patient safety, efficiency, patient experience, and care coordination measures), within the set and a cross-cutting measure. If a measure set has more than six measures, reporting on at least six is required. Non-patient-facing eligible clinicians would not have to report any cross-cutting measures.

Proposed quality measures can be found starting at 81 Fed. Reg. 28399. The tables are as follows: Table A – Proposed Individual Quality Measures Available for MIPS Reporting in 2017 (81 Fed. Reg. 28399); Table B – Proposed Existing Quality Measures that are Calculated for 2017 MIPS Performance that Do Not Require Data Submission (81 Fed. Reg. 28447); Table C - Proposed Individual Quality Cross-Cutting Measures for the MIPS to Be Available to Meet the Reporting Criteria Via Claims, Registry, and EHR Beginning in 2017 (81 Fed. Reg. 28447); Table D – Proposed New Measures for MIPS Reporting in 2017 (81 Fed. Reg. 28450); Table E – Proposed MIPS Specialty Measure Sets (81 Fed. Reg. 28460); Table F - 2016 PQRS Measures Proposed for Removal for MIPS Reporting in 2017 (81 Fed. Reg. 28522); and Table G - Measures Proposed with Substantive Changes for MIPS Reporting in 2017 (81 Fed. Reg. 28531).

CMS plans to develop a validation process to review and validate a MIPS eligible clinicians' or group's ability to report on at least six quality measures, or a specialty-specific measure set, with a sufficient sample size, including at least one cross-cutting measure (if patient-facing) and either an available outcome measure or another high priority measure. CMS's proposal is a decrease from the 2016 PQRS requirement to report on at least nine measures, and, in response to comments received, the agency no longer will require reporting across multiple National Quality Strategy domains.

CMS proposes that for the submission of data on quality measures by registered groups of 25 or more MIPS eligible clinicians reporting via the CMS Web Interface, for the applicable 12-month performance period, the group would be required to report on all measures included in the CMS Web Interface completely, accurately, and timely by populating data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries. A group would be required to report on at least one measure for which there is Medicare patient data. Groups reporting via the CMS Web Interface are required to report on all of the measures in the set. Any measures not reported would be considered zero performance for that measure in our scoring algorithm.

Registered groups of two or more MIPS eligible clinicians could participate in the CAHPS for MIPS survey through an approved survey vendor, and quality data submission would be done through a different reporting mechanism.

Data Completeness Criteria. MIPS eligible clinicians and groups who do not meet the proposed reporting criteria in the table below would "fail the quality component of MIPS."

Summary of Proposed Quality Data Submission Criteria for MIPS via Part B Claims, QCDR, Qualified Registry, EHR, CMS Web Interface, and CAHPS for MIPS Survey

Performance Period	Measure Type	Submission Mechanism	Submission Criteria	Data Completeness
Jan I – Dec 31	Individual MIPS eligible clinicians	Part B Claims	Report at least six measures including one cross-cutting measure and at least one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. MIPS eligible clinicians and groups will have to select their measures from either the list of all MIPS Measures in Table A or a set of specialty specific measures in Table E.	80 percent of MIPS eligible clinician's patients
Jan 1 – Dec 31	Individual MIPS eligible clinicians or Groups	QCDR Qualified Registry EHR	Report at least six measures including one cross-cutting measure and at least one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. MIPS eligible clinicians and groups will have to select their measures from either the list of all MIPS Measures in Table A or a set of specialty specific measures in Table E.	90 percent of MIPS eligible clinician's or groups patients

Summary of Proposed Quality Data Submission Criteria for MIPS via Part B Claims, QCDR, Qualified Registry, EHR, CMS Web Interface, and CAHPS for MIPS Survey

Jan 1 – Dec 31	Individual MIPS eligible clinicians or Groups	QCDR Qualified Registry EHR	Report at least six measures including one cross-cutting measure and at least one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. MIPS eligible clinicians and groups will have to select their measures from either the list of all MIPS Measures in Table A or a set of specialty specific measures in Table E.	90 percent of MIPS eligible clinician's or groups patients
Jan 1 – Dec 31	Groups	CMS Web Interface	Report on all measures included in the CMS Web Interface; AND populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample for each module/measure. If the pool of eligible assigned	Sampling requirements for their Medicare Part B patients

c) Selection of Quality Measures for Individual MIPS Eligible Clinicians and Groups⁶

Annual list of quality measures available for MIPS assessment. For the first year of MIPS, CMS proposes to maintain a majority of previously-implemented PQRS measures.

Call for quality measures. CMS proposes to continue its annual "Call for Quality Measures" as a way to engage eligible clinician organizations and other stakeholders.

Requirements. The quality domains that CMS says it will address through measures are: (1) patient safety; (2) person and caregiver-centered experience and outcomes; (3) communication and care coordination; (4) effective clinical care; (5) community/population health; and (6) efficiency and cost-reduction.

Peer review. Section 1848(q)(2)(D)(iv) of the Act requires CMS to submit new measures for publication in applicable specialty-appropriate, peer-reviewed journals before including measures in an annual list of quality measures. CMS proposes to use the Call for Quality Measures process to gather information to draft the journal articles for submission. CMS seeks input on mechanisms that could be used to notify the public that this requirement has been met for a measure.

Exception for QCDR measures. Measures used by a QCDR are not required to be established through notice-and-comment rulemaking, published in the Federal Register, or be submitted for publication in a peer-reviewed journal. CMS must publish the list of quality measures used by QCDRs, and it plans to post them in the Spring of 2017 for the initial performance period and no later than January 1 for future performance periods. If a QCDR wants to use a non-MIPS measure for inclusion in the MIPS program, such measures would go through a "rigorous CMS approval process" during the QCDR self-nomination period. Once the measures are analyzed, the QCDR would be notified of which measures are approved for implementation.

On May 2, 2016, CMS posted on its website a final Quality Measure Development Plan, available here: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf. Section 102 of MACRA called for CMS to develop the plan to address how measures used by private payors and integrated delivery systems could be incorporated under Medicare, describe how coordination will occur between organizations developing such measures, and take into account how clinical best practice quidelines should be used in the development of quality measures.

Cross-cutting measures for 2017 and beyond. Under MIPS, CMS is proposing fewer cross-cutting measures than those available for reporting under PQRS, but the agency believes that the list contains measures for which all patient-facing MIPS eligible clinicians should be able to report, because the measures include "commonplace health improvement activities" such as checking blood pressure and medication management. (Proposed cross-cutting measures are found in Table C of the Appendix, beginning at 81 Fed. Reg. 28447.)

d) Resource Use Performance Category

Weighting in the Composite Performance Score. MACRA directs that the resource use performance score is to make up no more than 10 percent of the CPS for the first MIPS payment year (CY 2019) and no more than 15 in the second payment year, and those are the percentage CMS is proposing for each of those years. For the third payment year and beyond, resource use performance would comprise 30 percent of the CPS.

Resource Use Criteria. Performance in this category would be assessed through administrative Medicare claims data, and CMS is not proposing any additional data submissions for this category. MIPS eligible clinicians and groups will be assessed based on resource use for Medicare patients only, and only for patients that are attributed to them. Those without enough attributed cases would not be have their resource use performance assessed. CMS proposes to utilize the total per capita cost measure,⁷ the Medicare spending per beneficiary (MSPB) measure,⁸ and several episode-based measures.⁹

Non-patient-facing eligible clinicians or groups. CMS is not proposing any alternative measures for non-patient-facing MIPS eligible clinicians and groups. Such clinicians/groups may not have sufficient measures and activities to report and would not be scored on the resource use performance category under MIPS.

Part D drug costs. In the future, CMS intends to consider how best to incorporate Part D drugs costs into the resource use performance category, and it seeks input from the public on this issue.

e) Clinical Practice Improvement Activity (CPIA) Category

A CPIA is an activity that relevant eligible clinician organizations and stakeholders identify as improving clinical practice or care delivery and that CMS determines is likely to result in improved outcomes.

Contribution to Composite Performance Score. CMS proposes that the CPIA performance category will account for 15 percent of the CPS. Section 1848(q)(5)(C)(i) of the Act specifies that if a MIPS eligible clinician is certified as a patient-centered medical home or comparable specialty practice, ¹⁰ it must be given the highest potential score for the CPIA performance category for the performance period.

⁷ This is a global measure of all Part A and Part B resource use during the performance period. The total per capita cost measure has been in the VM since 2015 and feedback has been reported to groups since 2014.

⁸ CMS proposes to use attribution logic that is similar to what is used in the VM, with technical adjustments. For more information on the MSPB measure, see 78 Fed. Reg. 74774 through 74780, and 80 Fed, Reg, 71295 through 71296.

⁹ For proposed episode-based measures, please see Table 4 of the Proposed Rule, beginning at 81 Fed. Reg. 28202.

A patient-centered medical home will be recognized if it is a nationally-recognized accredited patient-centered medical home, a Medicaid Medical Home Model, or a Medical Home Model. Also, the National Committee for Quality Assurance Patient-Centered Specialty Recognition will qualify as a comparable specialty practice.

CPIA data submission criteria. MIPS eligible clinicians and groups would select activities from the CPIA inventory (included in Table H of the Appendix) and submit data using a QCDR, qualified registry, EHR, or CMS Web Interface, and CMS will supplement these data with administrative claims data, if possible. For the first year only, CMS proposes that all MIPS eligible clinicians and groups, or third party entities submitting data on their behalf, must designate a yes/no response for activities on the CPIA inventory. CPIA activities would be weighted as "high" (20 points) or "medium" (10 points); a perfect CPIA score would require an eligible clinician or group to submit a combination of high and medium measures adding up to 60 points. An activity would have to be performed for a minimum of 90 days before a MIPS eligible clinician or group could get credit for it. CMS anticipates that in future years, longer periods of CPIA activities will be required.

Application of CPIA to non-patient-facing MIPS eligible clinicians and groups. Non-patient-facing groups would have to report on a minimum of one activity to receive partial credit or two activities, irrespective of weighting, to receive full credit to meet the CPIA submission criteria.

Special consideration for small, rural, or HPSA practices. These types of practices would receive partial or full credit for submitting two activities of any type of weighting (e.g., two medium-weighted activities will qualify for full credit).

CPIA subcategories. CMS groups these activities into the following subcategories: (1)_ expanded practice access; (2)population management; (3) care coordination; (4) beneficiary engagement; (5) patient safety; (6) achieving health equity; (7) emergency preparedness and response; and (8) integrated behavioral and mental health.¹¹ CMS seeks input on the following subcategories, as well: promoting health equity and community, and social and community involvement. CMS plans to develop a Call for Measures so that stakeholders can propose additions to the CPIA Inventory. As part of the process, MIPS eligible clinicians or groups would be able to nominate additional activities that we could consider adding to the CPIA Inventory. The MIPS eligible clinician or group or relevant stakeholder would be able to provide an explanation of how the activity meets all the criteria we have identified. This nomination and acceptance process would, to the best extent possible, parallel the annual call for measures process already conducted by CMS for quality measures. The final CPIA Inventory for the performance year would be published in accordance with the overall MIPS rulemaking timeline and program. In addition, in future years CMS anticipates developing a process and establishing criteria to remove or add new activities to CPIA.

f) Advancing Care Information Performance Category

Section 1848(q)(2)(A) of the Act includes the Meaningful Use of certified EHR technology as a performance category under the MIPS, referred to in the Proposed Rule as the "advancing care information performance category." MIPS eligible clinicians who were not eligible for Meaningful Use incentive payments or subject to payment adjustments will report data for this performance category; these include physician assistants, nurse practitioners, clinical nurse specialists, CRNAs, and hospital based eligible professionals. A "meaningful EHR user" under MIPS would be defined as a MIPS eligible clinician who possesses CEHRT, uses the functionality of CEHRT, and reports on applicable objectives and measures specified for the advancing care information performance category for a performance period in the form and manner specified by CMS.

More information on the proposed CPIA measures can be found in Table H of the Appendix of the Proposed Rule, beginning at 81 Fed. Reg. 28570.

Performance period. CMS proposes to align the performance period for the advancing care information performance category with the MIPS performance period of one full calendar year.

Certified EHR technology. For the first performance period in 2017, a MIPS eligible clinician or group would be able to use EHR technology certified to either the 2014 or 2015 Edition ONC Certification Criteria; beginning with the 2018 performance period, only the 2015 Edition would be acceptable.

Method of data submission. CMS proposes to allow for MIPS eligible clinicians to submit advancing care information performance category data through a qualified registry, QCDR, EHR, attestation, and CMS Web Interface submission methods. It also proposes that this performance category's objectives and measures would be assessed and reported at the group level, as opposed to the individual MIPS eligible clinician level. The data submission criteria would be the same when submitted at the group level as when submitted at the individual level, but the data submitted would be aggregated for all MIPS eligible clinicians within a group practice.

Reporting requirements and scoring methodology. Performance in the advancing care information performance category would comprise 25 percent of a MIPS eligible clinician's CPS for payment year 2019 and subsequent years. The score will be comprised of a score for participation and reporting ("base score") and a score for performance at varying levels above the base score requirements ("performance score"). To earn points toward the base score, a MIPS eligible clinician must report the numerator and denominator of certain measures specified for the advancing care information performance category (based on the measures adopted in the Stage 3 Meaningful Use final rule in 2015), to account for 50 percent of the total performance category score.

To earn points toward the performance score, a MIPS eligible clinician must earn additional points above the base score for performance in the objectives and measures for patient electronic access, coordination of care through patient engagement, and health information exchange. A MIPS eligible clinician would have to meet the "Protect Patient Health Information" objective from the Stage 3 Meaningful Use rule to earn any score within the entire advancing care information performance category; failure to meet the objective would result in a base score of zero and a performance score of zero. Under the proposal, it would be possible to score more than 100 points in this performance category, and those who do would receive a score of 100 percent for the advancing care information performance category.

Advancing care information performance category objectives and measures specifications. The objectives and measures summarized in this section of the Proposed Rule were adapted from the Stage 3 Meaningful Use 2015 final rule and from the modified Stage 2 Meaningful Use objective and measures, also included in that 2015 final rule. CMS sets forth the proposed objectives and their numerators and denominators. The measures include: (1) security risk analysis, (2) e-prescribing, (3) clinical decision support interventions, (4) drug interaction and drug-allergy checks, (5) medication orders, (6) laboratory orders, (7) diagnostic imaging orders, (8) patient access, (9) patient-specific education, (10) view-download-transmit, (11) patient-generated health data, (12) request/accept patient care record, (13) clinical information reconciliation, and (14) immunization registry reporting. It also includes optional measures: syndromic surveillance reporting, electronic case reporting, public health registry reporting, and clinical data registry reporting.

Exclusions. Because it proposes to exclude from MIPS those clinicians who do not exceed the low-volume threshold (Medicare billing charges less than or equal to \$10,000 and provide care for 100 or fewer Part B-enrolled Medicare beneficiaries), CMS does not believe that exclusions for most of the individual advancing care information are necessary.

Reweighting the advancing care information performance category for MIPS eligible clinicians without sufficient measures applicable and available. CMS proposes to assign a weight of zero to the advancing care information performance category for hospital-based MIPS eligible clinicians and MIPS eligible clinicians facing a significant hardship.¹² For at least the first performance period, CMS also proposes to assign a weight of zero to the advancing care information performance category for nurse practitioners, physician assistants, clinical nurse specialists, and CRNAs if there are not sufficient measures applicable and available to them; these practitioners have not been eligible for Meaningful Use incentives and adjustments and may not have the requisite experience with the program.

g) APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

QPs and Partial QPs are not MIPS eligible clinicians, but other eligible clinicians participating in APMs are MIPS eligible clinicians and are subject to the MIPS requirements, including reporting requirements and payment adjustments. CMS proposes to establish a scoring standard for MIPS eligible clinicians participating in certain types of APMs to reduce the participant reporting burden by eliminating the need for such clinicians to submit data both for MIPS and their respective APMs. CMS also proposes to assess the performance of a group of MIPS eligible clinicians in an APM entity that participates in certain types of APMs based on their collective performance. The criteria for identification of MIPS APMs are independent of the criteria for Advanced APM determinations, discussed below in Section II.E.

APM scoring standard performance period. The performance period for MIPS eligible clinicians participating in MIPS APMs would be the same performance period as for other MIPS eligible clinicians.

How the APM scoring standard differs from the assessment of groups and individual MIPS eligible clinicians using MIPS. The APM scoring standard would differ in one or more of the following ways: (1) depending on the terms and conditions of the MIPS APM, an APM Entity could be comprised of a sole MIPS eligible clinician (for example, a physician practice with only one eligible clinician could be considered an APM Entity); (2) the APM Entity could include more than one unique TIN, as long as the MIPS eligible clinicians are identified as participants in the APM by their unique APM participant identifiers; and (3) the composition of the APM Entity group could include APM participant identifiers with TIN/NPI combinations such that some MIPS eligible clinicians in a TIN are APM participants and other MIPS eligible clinicians in that same TIN are not APM participants. In contrast, assessment as a group under MIPS requires a group to be comprised of at least two MIPS eligible clinicians who have assigned their billing rights to a TIN. It also requires that all MIPS eligible clinicians in the group to use the same TIN. The weights assigned to the MIPS performance categories also may be different; CMS proposes that for certain MIPS APMs, the resource use category weight would be zero, and weights of other categories would be redistributed.

A "hospital based MIPS eligible clinician" would be defined as a MIPS eligible clinician who furnishes 90 percent or more of his or her covered professional services in sites of services identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the MIPS payment year. The "significant hardships" would include insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over the availability of CEHRT, and lack of face-to-face interaction with patients; a MIPS eligible clinician would apply to CMS for reweighting based on one of these hardships.

APM participant identifier and participant database. CMS plans to maintain an APM participant database that will include all of the MIPS eligible clinicians who are part of the APM Entity. Only an MIPS eligible clinicians who is listed as a participant in an APM Entity on December 31 (the last day of the performance period) would be considered part of an APM Entity group for purposes of the APM scoring standard.

APM Entity group scoring for the MIPS performance categories. CMS proposes to calculate one CPS that is applied to the billing TIN/NPI combination of each MIPS eligible clinician in the APM Entity group, and there would be one score for each of the four performance categories for the group. The CPS would be used to develop the MIPS payment adjustment that is applicable for each MIPS eligible clinician in the group.

Shared Savings Program – quality performance category scoring under the APM scoring standard. Beginning with the first performance period all Shared Savings Program ACOs would submit their quality measures to MIPS using the CMS Web Interface through the same process they use to report to the Shared Savings Program and be scored as they normally would under that program's rules. The quality measure data would be submitted only once but used for two purposes: to calculate the MIPS quality performance category score at the APM Entity group level, and for the Shared Savings Program.

Shared Savings Program – resource use performance category scoring under the APM scoring standard. For the first MIPS performance period, CMS proposes it will not assess MIPS eligible clinicians participating in the Shared Savings Program under the resource use performance category because they already are subject to cost and utilization performance assessments under the APM and because the beneficiary attribution methods for measuring resource use under the two programs differ. As a result, CMS proposes to redistribute the 10 percent weight of the resources use performance category evenly between the CPIA and advancing care information performance categories (which would be 20 percent and 30 percent, respectively).

Shared Savings Program – CPIA and advancing care information performance category scoring under the APM scoring standard. CMS proposes that MIPS eligible clinicians participating in the Shared Savings Program would submit data for the MIPS CPIA and advancing care information performance categories through their respective ACO participant billing TINs, independent of the Shared Savings Program ACO. The scores from all of the ACO participant billing TINs would be averaged to a weighted mean MIPS APM Entity group level score, and all MIPS eligible physicians in the APM Entity group, as identified by their APM identifiers, would receive that APM Entity score.

Next Generation ACO Model – **quality performance category scoring under the APM scoring standard.**Beginning with the first performance period, all Next Generation ACO Model ACOs would submit their ACO quality measures to MIPS using the CMS Web Interface through the same process as they currently use and be scored as they normally would under Next Generation ACO Model rules. This information would be used to calculate the MIPS APM quality performance score.

Next Generation ACO Model - resource use performance category scoring under the APM scoring standard. For the first MIPS performance period, CMS proposes it will not assess MIPS eligible clinicians participating in the Next Generation ACO Model under the resource use performance category because they already are subject to cost and utilization performance assessments under the APM and because the beneficiary attribution methods for measuring resource use under the two programs differ. As a result, CMS proposes to redistribute the 10 percent weight of the resources use performance category evenly between the CPIA and advancing care information performance categories (which would be 20 percent and 30 percent, respectively).

Next Generation ACO Model – CPIA and advancing care information performance category scoring under the APM scoring standard. CMS proposes that MIPS eligible clinicians participating in the Next Generation ACO Model would submit data for the MIPS CPIA and advancing care information performance categories through their respective ACO participant billing TINs, independent of the Shared Savings Program ACO. The scores from all of the ACO participant billing TINs would be averaged to a weighted mean MIPS APM entity group level score, and all MIPS eligible physicians in the APM entity group, as identified by their APM identifiers, would receive that APM entity score.

MIPS APMs other than the Shared Savings Program and Next Generation ACO model – quality and resource use performance category scoring under the APM scoring standard. For MIPS APMs other than the Shared Savings Program and Next Generation ACO Model, MIPS eligible clinicians would submit APM quality measures under their respective MIPS APMs as usual and not under MIPS. Because of operational and logistical difficulties, for the first scoring period only, CMS will reduce the quality performance category to zero for these APMs. For the same reason that CMS proposes to reduce the resource use performance category weight to zero for the other APMs, for the first scoring period, CMS will reduce the resource use performance category to zero for these APMs, as well. CMS proposes to redistribute the weight of the quality and resource use categories for MIPS eligible clinicians in these APMs to the CPIA performance category (25 percent) and the advancing care information category (75 percent).

MIPS APMs other than the Shared Savings Program and Next Generation ACO model - CPIA and advancing care information performance category scoring under the APM scoring standard. CMS proposes that MIPS eligible clinicians participating in the these APMs would submit data for the MIPS CPIA and advancing care information performance categories as individual MIPS eligible clinicians. A MIPS eligible clinician in an APM Entity group that meets the definition of a patient-centered medical home or comparable specialty practice will receive the highest potential score for the CPIA performance category.

6. MIPS Composite Performance Score Methodology

Under MACRA, CMS is required to:

- develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards for a performance period for a year;
- using the methodology, provide a composite performance score for each MIPS eligible clinician for each performance period; and
- use the CPS of the MIPS eligible clinician for a performance period to determine and apply a MIPS adjustment factor (and, as applicable, an additional MIPS adjustment factor) to the MIPS eligible clinician for the MIPS payment year.

As discussed in detail below, pursuant to MACRA, CMS proposes a methodology for assessing and scoring MIPS eligible clinician performance for each of the four performance categories. Under the proposal, MIPS eligible clinicians would be scored based on their performance on measures and activities in four performance categories and would receive a CPS, composed of their scores on individual measures and activities. CMS proposes that the baseline period will be two years prior to the performance period for the MIPS payment year.

Thus, although MIPS has four different performance categories, CMS proposes a unified scoring system that the agency believes would enable MIPS eligible clinicians, beneficiaries, and stakeholders to understand what is required for a strong performance in MIPS while being consistent with statutory requirements.

7. MIPS Payment Adjustments

Under the proposal, MIPS eligible clinicians would receive payment adjustments based on their CPS. As discussed above, CMS proposes to allow MIPS eligible clinicians to measure performance as an individual, as a group defined by TIN, or as an APM Entity group using the APM scoring standard. However, for purposes of applying the MIPS payment adjustments, CMS proposes to use a single identifier, TIN/NPI, for all MIPS eligible clinicians – regardless of whether the TIN/NPI was measured as an individual, group or APM Entity group. In other words, a TIN/NPI may receive a CPS based on individual, group, or APM Entity group performance, but the payment adjustment would be applied at the TIN/NPI level.

For each year of the MIPS, CMS proposes to compute a performance threshold (*i.e.*, the level of performance that is established for a performance period) with respect to which the CPS of MIPS eligible clinicians are compared to determine the MIPS adjustment factors for a year. CPSs above the performance threshold would receive a positive MIPS adjustment factor and CPSs below the performance threshold would receive a negative MIPS adjustment factor. CPSs that are equal to or greater than zero, but not greater than one-fourth of the performance threshold would receive the maximum negative MIPS adjustment factor for the MIPS payment year. CPSs at the performance threshold would receive a neutral MIPS adjustment factor. CMS proposes to set the performance for the 2019 MIPS payment year at a level where approximately half of MIPS eligible clinicians would fall below the threshold and approximately half would be above it. To achieve budget neutrality, as required under the statute, CMS proposes to scale the positive adjustments up or down, meaning that the maximum positive adjustments could be lower or higher than four percent in 2019. As required by MACRA, both positive and negative adjustments would increase over time.

Additionally, in the first five payment years of the program, the law allows for \$500 million in an additional performance bonuses (exempt from budget neutrality) for exceptional performance. CMS proposes to establish the additional performance threshold at the 25th percentile of the range of possible CPS above the performance threshold. For example, if the performance threshold is 60, then the range of possible CPS above the performance threshold would be 61-100. The 25th percentile of those possible values would be 70. CMS intends to publish the exceptional performance threshold with the performance threshold prior to the performance period. This exceptional performance bonus will provide high performers a gradually increasing adjustment based on their MIPS score that can be no higher than an additional 10 percent.

As specified under the statute, negative adjustments would increase over time and positive adjustments would correspond. The maximum negative adjustments for each year are:

2019	2020	2021	2022 and after
4%	5%	7%	9%

For MIPS eligible clinicians, CMS proposes to provide performance feedback on an annual basis since the first performance feedback, required on July 1, 2017, would be based on historic data sets. As the program evolves, and CMS can operationally assess/analyze the MIPS data, CMS may consider providing performance feedback on a more frequent basis, such as quarterly.

For APM Entities, CMS proposes that MIPS eligible clinicians who participate in APM Entities would receive performance feedback, as technically feasible.

8. Review and Correction of MIPS Composite Performance Score

Targeted review. CMS proposes that a MIPS eligible clinician or group may request a targeted review of the calculation of the MIPS adjustment factor and the additional MIPS adjustment factor for a performance year. CMS notes that the review would be limited to the calculation of the MIPS adjustment factor and, as applicable, the additional MIPS adjustment factor for which the agency may find it necessary to review data related to measures and activities and the calculation of the CPS according to the defined methodology. CMS outlines the process for targeted reviews as:

- A MIPS eligible clinician may submit his or her election to request a targeted review to CMS within 60 days (or a longer period specified by CMS) after the close of the data submission period. All requests for targeted review must be submitted by July 31 after the close of the data submission period or by a later specified date.
- A response on whether or not a targeted review is warranted will be provided by CMS.
- There will not be a hearing or evidence submission process, although the MIPS eligible clinician may submit information to assist in the review.
- All decisions based on the targeted review will be final.
- There will be no further review or appeal.

CMS adds that there is no administrative or judicial review of:

- The methodology used to determine the amount of the MIPS adjustment factor and the amount of the additional MIPS adjustment factor and the determination of such amounts;
- The establishment of the performance standards and the performance period;
- The identification of measures and activities specified for a MIPS performance category and information made public or posted on a CMS public website; or
- The methodology developed that is used to calculate performance scores and the calculation of such scores, including the weighting of measures and activities under such methodology.

Data validation and auditing. CMS proposes to audit MIPS eligible clinicians selectively on a yearly basis. If a MIPS eligible clinician or group is selected for audit, the MIPS eligible clinician or group would be required to: (1) comply with data sharing requests, providing all data requested by CMS (all data must be shared within 10 business days or an alternate agreed upon timeframe); and (2) provide substantive, primary source documents as requested.

9. Third Party Data Submission

Under the proposal, CMS would allow MIPS data to be submitted by third party intermediaries on behalf of a MIPS eligible clinician or group by: a qualified registry; a QCDR; a health IT vendor that obtains data from a MIPS eligible clinician's CEHRT; or a CMS-approved survey vendor. These third party intermediaries would be allowed to submit data on measures, activities, or objectives for any of the following MIPS performance categories: quality, CPIA, or advancing care information (if the MIPS eligible clinician or group is using CEHRT). CMS-approved survey vendors would be allowed to submit data for the CAHPS for MIPS survey under the quality performance category.

Third party intermediaries would be required to meet all the requirements designated by CMS as a condition of their qualification or approval to participate in MIPS as third party intermediaries, including: (1) indicating the data source for measures, activities, and objectives under the quality, advancing care information, and CPIA performance categories; and (2) submitting all data in the form and manner specified by CMS.

Qualified clinical data registry. CMS proposes to define a QCDR as a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. An entity interested in becoming a QCDR for MIPS must go through a qualification process, including meeting the requirements below.

- (1) QCDR Self-Nomination Requirements. CMS would require QCDRs to self-nominate, for the 2017 performance period, from November 15, 2016 until January 15, 2017. For future years of the program, starting with the 2018 performance period, QCDRs would be required to self-nominate from September 1 of the prior year until November 1 of the prior year. An entity that wants to qualify as a QCDR for a given performance period would need to self-nominate for that year and provide all information requested by CMS at the time of self-nomination. CMS notes that having qualified as a QCDR does not automatically qualify an entity to participate in subsequent MIPS performance periods.
- (2) Establishment of a QCDR Entity. For an entity to qualify for a given performance period as a QCDR, the entity would be required to: (a) have been in existence as of January 1 of the performance period for which the entity seeks to become a QCDR; and (b) have at least 25 participants by January 1 of the performance period.

Collaboration of Entities to Become a QCDR. An entity that may not meet the requirements of a QCDR solely on its own, but can do so in conjunction with another entity, can meet the QCDR definition in situations where the entity uses an external organization for purposes of data collection, calculation, or transmission and has a signed written agreement that details the relationship and responsibilities of the external organization effective September 1 the year prior to the year the entity seeks to become a QCDR.

Identifying Non-MIPS Quality Measures. For purposes of QCDRs submitting data for the MIPS quality performance category, CMS would consider the following types of quality measures to be non-MIPS quality measures: (a) a measure that is not contained in the annual list of MIPS quality measures for the applicable performance period; (b) a measure that may be in the annual list of MIPS quality measures but has substantive differences, as determined by the Secretary, in the manner it is reported by the QCDR; and (c) CAHPS for MIPS survey.

QCDR Measure Specifications Requirements. CMS would require a QCDR to provide specifications for each measure, activity, or objective the QCDR intends to submit to CMS. The QCDR must provide CMS narrative specifications for each measure, activity, or objective no later than January 15 of the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (CPIA and advancing care information) data. In future years, starting with the 2018 performance period, CMS would require those specifications to be provided no later than November 1 prior to the applicable performance period.

For non-MIPS quality measures, CMS would require that the quality measure specifications include the following for each measure: name/title of measures; National Quality Forum (NQF) number (if NQF-endorsed); descriptions of the denominator, numerator, and when applicable, denominator exceptions; denominator exclusions; risk adjustment variables; and risk adjustment algorithms. CMS indicates that the agency would consider all non-MIPS quality measures submitted by the QCDR, but the measures must address a gap in care and outcome measures or other high priority measures are preferred. CMS also notes that measures that have very high performance rates already or address extremely rare gaps in care (thereby allowing for little or no quality distinction between eligible clinicians) would be unlikely to be approved for inclusion. For MIPS quality measures, the QCDR would only need to submit the MIPS measure numbers and/or specialty-specific measure sets (if applicable). The QCDR would be required to publicly post the measure specifications (no later than 15 days following CMS approval of the measure specifications) for each non-MIPS quality measure it intends to submit.

Qualified registry. CMS proposes to define a qualified registry as a medical registry or a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification requirements specified by CMS for that performance period. CMS would require that the registry have the requisite legal authority to submit MIPS data (as specified by CMS) on behalf of a MIPS eligible clinician or group to CMS.

Qualified Registry Self-Nomination Requirements. Qualified registries would be required to self-nominate, for the 2017 performance period from November 15, 2016 until January 15, 2017. For future years, starting with the 2018 performance period, the qualified registry would be required to self-nominate from September 1 until November 1 of the prior year and provide all requested information to CMS at the time of self-nomination. CMS notes that having qualified as a qualified registry does not automatically qualify the entity to participate in subsequent MIPS performance periods.

Establishment of a Qualified Registry Entity. To become qualified for a given performance period as a qualified registry, CMS proposes that the entity must: (a) be in existence as of January 1 the performance period for which the entity seeks to become a qualified registry; and (b) have at least 25 participants by January 1 of the performance period.

<u>Health IT vendors</u>. CMS proposes to allow health IT vendors to submit data, on behalf of a MIPS eligible clinician or group, on measures, activities, or objectives for the quality, CPIA, or advancing care information MIPS performance categories. Health IT vendors submitting data would be required to obtain data from the MIPS eligible clinician's CEHRT. CMS notes that this approach would permit a single health IT vendor to report on quality, advancing care information, and CPIA performance category requirements for MIPS and should mitigate the risks, costs, and burden of MIPS eligible clinicians having to report multiple times to

meet the requirements of MIPS. CMS proposes that health IT vendors that obtain data from a MIPS eligible clinician's CEHRT, like other third party intermediaries, would have to meet all requirements designated by CMS as a condition of their qualification or approval to participate in MIPS as a third party intermediary (*i.e.*, data source reporting, and form and manner requirements – as discussed above). CMS anticipates providing further subregulatory guidance that would identify the CERT data formats that providers must submit.

CMS-approved survey vendor application requirements. CMS proposes to define a CMS-approved vendor as a survey vendor that is approved by CMS for a particular performance period to administer the CAHPS for MIPS survey and to transmit survey measures data to CMS. CMS would require vendors to undergo the CMS approval process for each year in which the survey vendor seeks to transmit survey measures data to CMS. All CMS-approved survey vendor applications and materials would be due by April 30 of the performance period.

<u>Auditing of entities submitting MIPS data</u>. CMS would require that any third party intermediary (that is, a QCDR, health IT vendor, qualified registry, or CMS-approved survey vendor) must comply with the following requirements as a condition of its qualification or approval to participate in MIPS as a third party intermediary: (a) the entity must make available to CMS the contact information of each MIPS eligible clinician or group on behalf of whom it submits data; and (b) the entity must retain all data submitted to CMS for MIPS for a minimum of 10 years.

Probation and disqualification of a third-party intermediary. Under the proposal, if at any time CMS determines that a third party intermediary has not met all of the applicable requirements for qualification, CMS may place the third party intermediary on probation for the current performance period and/or the following performance period. CMS would require a corrective action plan from the third party intermediary to address any deficiencies or issues and prevent them from recurring. The corrective action plan must be received and accepted by CMS within 14 days of the CMS notification to the third party intermediary of the deficiency or probation. CMS proposes to disqualify from the MIPS program (for the subsequent performance period) any third party intermediary who fails to comply with this requirement. Under the proposal, probation means that, for the applicable performance period, the third party intermediary would not be allowed to miss any meetings or deadlines and would need to submit a corrective action plan for remediation or correction of any deficiencies identified by CMS that resulted in the probation.

If the third party intermediary has data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies affecting in excess of three percent (but less than five percent) of the total number of MIPS eligible clinicians or groups submitted by the third party intermediary, CMS would annotate on the CMS qualified posting that the entity furnished data of poor quality and would place the third party intermediary on probation for the subsequent MIPS performance period with the opportunity to go on probation for a year to correct deficiencies.

If the third party intermediary does not reduce its data error rate below three percent for the subsequent performance period, the third party intermediary would continue to be on probation and have its listing on the CMS website continue to note the poor quality of the data it is submitting for MIPS for one additional year. After two years on probation, the third party intermediary would be disqualified for the subsequent performance period.

In placing the third party intermediary on probation, CMS proposes to notify the third party intermediary of the identified issues, at the time of discovery of such issues. CMS notes that data errors affecting in excess of five percent of the MIPS eligible clinicians or groups submitted by the third party intermediary could lead to the disqualification of the third party intermediary from participation in MIPS for the following performance period. If the third party intermediary does not submit an acceptable corrective action plan within 14 days of notification of deficiencies—and correct the deficiencies within 30 days or before the submission deadline—whichever is sooner, CMS could disqualify the third party intermediary from participating in MIPS for the current performance period and/or the following performance period, as applicable.

10. Public Reporting on Physician Compare

CMS proposes to report publicly on Physician Compare for the MIPS, APM and other information required by MACRA. Specifically, CMS proposes to post publicly on Physician Compare the composite score for each MIPS eligible clinician and performance of each MIPS eligible clinician for each performance category, and periodically to post aggregate information on the MIPS, including the range of composite scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category. Additionally, CMS proposes to make all measures under the MIPS quality and resource use performance categories, and all activities under the MIPS CPIA performance category, available for public reporting on Physician Compare. CMS proposes to include an indicator on Physician Compare for any eligible clinician or group who successfully meets the advancing care information performance category.

CMS proposes that in advance of publication of any data on Physician Compare, MIPS eligible clinicians would have the opportunity to review the information 30 days prior to publication. CMS notes that all data available for public reporting – measure rates, scores, and/or attestations – would be available for review and correction during the targeted review process. CMS notes that the technical details of the review, appeal, and correction process will be communicated directly to affected MIPS eligible clinicians and groups and detailed outside of rulemaking.

E. Incentive Payments for Participating in Advanced APMs

MACRA requires that CMS provide incentive payments and offer other flexibilities for physicians and other professionals that achieve QP or Partial QP status via their participation in eligible APMs (or so-called "Advanced APMs" under the Proposed Rule). These incentives and other flexibilities include bonus payments, higher conversion factor updates to PFS payment rates, and an exemption from required participation and payment adjustments in the MIPS. Specifically, MACRA provides the following incentives for participation in Advanced APMs:

- Beginning in 2019, if an eligible clinician participates in an Advanced APM, he or she may become a QP. QPs
 are excluded from the MIPS. Partial QPs have an opportunity to decide whether they wish to be subject
 to a MIPS payment adjustment.
- For years from 2019 through 2024, QPs receive a lump sum incentive payment equal to five percent of their prior year's payments for Medicare Part B covered professional services.
- For 2026 and future years, QPs receive a higher conversion factor update (0.75 percent) under the MPFS than non-QPs (0.25 percent).

Under MACRA, to qualify as an APM, the payment model must be: (1) tested at CMMI (except for Innovation Award models); (2) an ACO under the Medicare Shared Savings Program¹³ (MSSP); (3) a Health Care Quality Demonstration model; or (4) another model tested via a demonstration required by federal law.

MACRA provides that for 2019 and 2020, eligible clinicians may become QPs only through participation in Advanced APMs. For 2021 and later, eligible clinicians may become QPs through a combination of participation in Advanced APMs and participation in APMs with other payers ("Other Payer Advanced APMs"). When determining whether a clinician meets the standards for being a QP or a Partial QP, MACRA requires that CMS examine the percentage of the clinician's Medicare Part B payment payments for professional services (or the percentage of all-payer payments for the professional in later years) that are attributable to services furnished through an Advanced APM Entity. An Advanced APM Entity would be an entity that participates in an APM that: (1) requires the use of CEHRT; and (2) provides payment based on quality measures comparable to MIPS quality measures. In addition, in order to qualify as an Advanced APM Entity, the entity must: (1) bear financial risk for monetary losses under the APM that are in excess of a nominal amount; or (2) be a Medical Home Model expanded through CMMI's expansion authority under section 1115A(c) of the Act.

1. Procedures and Timing for Determining QP Status

CMS proposes that a QP determination would be made based on the following process:

- CMS determines whether the design of an APM meets three specified criteria for it to be deemed an Advanced APM;
- An entity (the Advanced APM Entity) with a group of individual eligible clinicians participates in the Advanced APM;
- CMS determines whether, during a performance period (the "QP Performance Period"), the eligible clinicians in the Advanced APM Entity collectively have at least a specified percentage of their aggregate Medicare Part B payments for covered professional services (or patients who received covered professional services) through the Advanced APM; and
- All of the eligible clinicians in the Advanced APM Entity are designated QPs for the payment year associated with that QP Performance Period.

Those QPs would receive the five percent lump-sum APM Incentive Payments mentioned above for the payment year. This QP determination process would occur each year following the QP Performance Period, with the first payment year being 2019. Under the Proposed Rule, the QP Performance Period would be the calendar year two years prior to the payment year. For example, for 2019 APM payment incentives, the performance year would be 2017.

Under the Proposed Rule, only Track Two and Track Three ACOs would qualify as "Advanced APMs," due to the lack financial risk associated with Track One ACOs. See Table 32 at 81 Fed. Reg. 28312.

Exhibit A of this summary includes a listing of current CMS/CMMI models, with details on whether entities participating in the models would qualify as Advanced APM Entities.

The Proposed Rule establishes a similar approach for determining QP status based on the "All-Payer Combination Option" approach, where the determination is made through assessing a clinician's combined participation in an Advanced APM (*i.e.* under Medicare Part B) and additional "Other Payer Advanced APMs," which incorporate Medicare Advantage (MA), Medicaid, and private health insurance payment model participation. The first QP Performance Period for this option would be 2019, for 2021 APM payment incentives.

2. Medical Home Model Definition

In the Proposed Rule, CMS notes that MACRA does not provide a specific definition for what constitutes a "Medical Home Model" that is expanded by CMMI. CMS proposes to require that a Medical Home Model must have the following elements at a minimum: (1) the model participants include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services; and (2) empanelment of each patient to a primary clinician. In addition, the Proposed Rule would require that a Medical Home Model must have at least four of the following seven elements: (1) planned coordination of chronic and preventive care; (2) patient access and continuity of care; (3) risk-stratified care management; (4) coordination of care across the medical neighborhood; (5) patient and caregiver engagement; (6) shared decision-making; and (7) payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings, population-based payments).

For the purposes of determining whether the model has a primary care focus, CMS also proposes that a Medical Home Model would have to involve specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant.

Medical Home Model standard for risk assumption. CMS proposes that for a Medical Home Model to be an Advanced APM, it must include provisions that potentially:

- withhold payment for services to the APM Entity and/or the APM Entity's eligible clinicians;
- reduce payment rates to the APM Entity and/or the APM Entity's eligible clinicians;
- require the APM Entity to owe payment(s) to CMS; or
- lose the right to all or part of an otherwise guaranteed payment or payments, if either: (1) actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified performance period; or (2) APM Entity performance on specified performance measures does not meet or exceed expected performance on such measures for a specified performance period.

Standard for minimum levels of financial risk for Medical Home Models. CMS proposes that for Medical Home Models, the total annual amount that an Advanced APM Entity potentially owes CMS or foregoes under the Medical Home Model must be at least the following amounts in a given performance year:

- In 2017, 2.5 percent of the APM Entity's total Medicare Parts A and B revenue
- In 2018, 3 percent of the APM Entity's total Medicare Parts A and B revenue

- In 2019, 4 percent of the APM Entity's total Medicare Parts A and B revenue
- In 2020 and later, 5 percent of the APM Entity's total Medicare Parts A and B revenue

Interaction with Medical Home Model "expansion". In the Proposed Rule, CMS clarifies that an APM both would have to be determined to be a Medical Home Model as defined in this rulemaking and in fact be expanded using the CMMI expansion authority before it could qualify as an Advanced APM for the purposes of the payment incentives and MIPS exemption. Under this statutory authority for model expansion, CMMI may expand the scope and extend the duration of a model tested at the Innovation Center, provided that the model meets the following criteria:

- The Secretary determines that such expansion is expected to reduce spending without reducing the quality of care, or improve the quality of patient care without increasing spending;
- CMS's Chief Actuary certifies that such expansion would reduce (or would not result in any increase in) net program spending; and
- The Secretary determines that such expansion would not deny or limit the coverage or provision of benefits for applicable individuals. In determining which models or demonstration projects to expand, the Secretary shall focus on models and demonstration projects that improve the quality of patient care and reduce spending

3. Advanced APMs

CMS proposes a number of policies that provide a definitional and programmatic framework for making Advanced APM and Advanced APM Entity determinations. In addition, the Proposed Rule provides details on how CMS will assess whether an APM and APM Entity meet the multi-part criteria for qualifying as an Advanced APM.

a) Definitional Framework

Demonstration required by Federal law. CMS proposes that in order to be an APM as a "demonstration required by Federal law," the demonstration must meet the following three criteria: (1) the demonstration must be compulsory under the statute, *i.e.* not just a provision of statute that gives the agency authority, but one that requires the agency to undertake a demonstration; (2) there must be some "demonstration" thesis that is being evaluated; and (3) the demonstration must require that there are entities participating in the demonstration under an agreement with CMS or under a statute or regulation.

APM Entity & Advanced APM Entity. CMS proposes that that an "APM Entity" is the participating entity in an APM that is primarily responsible for the cost and quality of care provided to beneficiaries under the terms of a direct agreement with CMS. Meanwhile, CMS proposes that an "Advanced APM Entity" is an APM Entity that participates in an Advanced APM that, through terms of a Participation Agreement with CMS or through Federal law or regulation, meets the criteria proposed in this rule. Under the proposed rule, each unit—APM, APM Entity, and eligible clinician—would be clearly identified in CMS systems by a unique combination of APM identifier/APM Entity identifier/TIN/NPI to be considered for possible determination as an Advanced APM, Advanced APM Entity, or QP, respectively.

"Track" issues. For instances where a model offers multiple tracks or options (e.g. different risk-sharing "tracks" for MSSP ACOs), and one track meets the criteria as an Advanced APM, but another track does not meet all criteria, CMS proposes that the agency would distinguish that the APM is only an Advanced APM for specific options or tracks.

Group collective assessment for QP determinations. CMS proposes that an eligible clinician's QP status for a given payment year would be based on a collective evaluation of a group consisting of all eligible clinicians participating in an Advanced APM Entity. Specifically, to attain QP status, an eligible clinician would have to be listed on December 31 of the QP Performance Period as part of an Advanced APM Entity that, through the collective calculation of all its eligible clinicians, meets the QP Payment Amount Threshold or the QP Patient Count Threshold (as discussed below).

b) Advanced APM Determination Process and Advanced APM Criteria

In the Proposed Rule, CMS indicates that it will post an advance notification on the CMS website concerning the APMs (including specific APM tracks or options) that would be considered Advanced APMs for a QP Performance Period, prior to the start of the first Performance Period (*i.e.* 2017) and update the list on a rolling basis. CMS would make determinations for Other Payer Advanced APMs during the third QP Performance Period (*i.e.* 2019).

APM participant use of CEHRT. CMS proposes that for the 2017 QP Performance Period, an Advanced APM must require at least 50 percent of eligible clinicians who are enrolled in Medicare (or each hospital if hospitals are the APM participants) use the certified health IT functions outlined in the proposed definition of CEHRT to document and communicate clinical care with patients and other health care professionals. Under the Proposed Rule, CMS would increase the minimum CEHRT use threshold from 50 percent to 75 percent for the 2018 QP Performance Period and future years. CMS also proposes to adopt for Advanced APMs and Other Payer Advanced APMs, the definition of CEHRT that is proposed for MIPS.

Separate CEHRT requirement for MSSP ACOs. CMS also proposes an alternative criterion for determining whether an APM meets the CEHRT requirement, exclusively applicable for the MSSP, to allow MSSP ACOs to meet the CEHRT requirement through continued reporting of existing MSSP quality measures on EHR use by the ACO participants.

APM payment based on quality measures comparable to MIPS. MACRA requires that payments to Advanced APM Entities must provide for payment for covered professional services based on quality measures comparable to quality measures in the MIPS. CMS proposes that the quality measures upon which the Advanced APM bases payment must include at least one of the following types of measures (provided that they have an evidence-based focus and are reliable and valid):

- any of the quality measures included on the proposed annual list of MIPS quality measures;
- quality measures that are endorsed by a consensus-based entity;
- quality measures developed under the PQRS;
- quality measures submitted in response to the MIPS Call for Quality Measures; or
- any other quality measures that CMS determines to have an evidence-based focus and be reliable and valid.

Financial risk assumption standard for Advanced APMs. CMS proposes that the generally applicable financial risk standard for Advanced APMs would be that an APM must include provisions to require that, if actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified performance period, CMS can:

- Withhold payment for services to the APM Entity and/or the APM Entity's eligible clinicians;
- Reduce payment rates to the APM Entity and/or the APM Entity's eligible clinicians; or
- Require the APM Entity to owe payment(s) to CMS.

Standard for minimum levels of financial risk for Advanced APMs. CMS proposes that the "financial risk beyond a nominal amount" standard requires that Advanced APM Entities must bear financial risk for monetary "losses" that could be incurred through either direct repayments to CMS or reductions in payments for services. CMS's interpretation of MACRA's provisions would not allow for models and their participating entities to demonstrate "financial risk" via expenditures allocated for investment in care process changes and infrastructure needed to operate in the APM. Specifically, CMS proposes that for an APM to meet the nominal amount standard:

- the specific level of Marginal Risk must be at least 30 percent of losses in excess of expected expenditures;
- the Minimum Loss Rate (MLR), to the extent applicable, must be no greater than four percent of expected expenditures;¹⁶ and
- Total Potential Risk must be at least four percent of expected expenditures.

Application of financial risk criteria for capitation arrangements. CMS proposes that full capitation risk arrangements would meet the Advanced APM financial risk criterion. The proposed rule provides that a capitation risk arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made to an APM Entity for all items and services furnished to a population of beneficiaries, and no settlement is performed for the purpose of reconciling or sharing losses incurred or savings earned by the APM Entity. In the Proposed Rule, CMS reiterates that MA plans and other private plans paid to act as insurers on the Medicare program's behalf are not Advanced APMs, although capitation arrangements between clinicians and MA plans or other private payers could be counted towards the All-Payer Combination Option threshold for QP status, beginning in 2021.

4. QP and Partial QP Determination Process

In the Proposed Rule, CMS reiterates that for 2019 and 2020 payment incentives, only the "Medicare Option" will be available for clinicians seeking to achieve QP or Partial QP status through demonstration of a sufficient percentage of Medicare Part B professional services that are attributable to services furnished through an Advanced APM Entity during the QP Performance Period (i.e. 2017 for the 2019 payment incentive, and 2018 for the 2020 payment incentive). For payment incentives in 2021 and future years, clinicians will be able to achieve QP or Partial QP status through the Medicare Option or through the All-Payer Combination Option.

¹⁵ CMS proposes to define Marginal Risk as the ratio of financial risk to the amount that actual expenditures exceed expected expenditures.

¹⁶ CMS proposes to define MLR as the percentage by which actual expenditures may exceed expected expenditures under the APM without triggering financial risk.

¹⁷ CMS proposes to define Total Potential Risk as the maximum potential payment for which the APM Entity could be liable under the APM.

a) Medicare Option

The percentage of Part B professional services that must be attributable to services furnished through an Advanced APM Entity in order to achieve QP status is referred to as the "QP Threshold." The lower percentage of Part B professional services that must be attributable to services furnished through an Advanced APM Entity in order to achieve Partial QP status is referred to as the "Partial QP Threshold."

CMS proposes to use its authority under MACRA to allow for "patient counts" as an alternative to "payment counts" for the purpose of meeting the QP or Partial QP Thresholds. When determining whether to use the payment amounts or patient counts method to calculate the QP Threshold status, CMS proposes to use both methods in tandem for each Advanced APM Entity group of eligible clinicians. CMS proposes that after QP and Partial QP Threshold calculations have been completed, the agency will use whichever QP Threshold method is more favorable to the Advanced APM Entity clinician group.

The proposed QP Thresholds and Partial QP Thresholds for both the Payment Amount Count and Patient Count methods for the Medicare Option for each year are as follows:

TABLE 33: QP Payment Amount Thresholds – Medicare Option

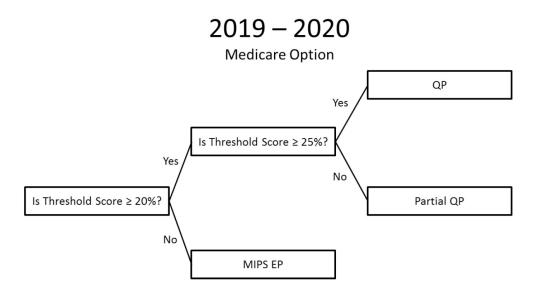
Medicare Option - Payment Amount Method						
Payment Year	2019	2020	2021	2022	2023	2024 and later
QP Payment Amount Threshold	25%	25%	50%	50%	75%	75%
Partial QP Payment Amount Threshold	20%	20%	40%	40%	50%	50%

TABLE 35: QP Patient Count Thresholds - Medicare Option

Payment Year	2019	2020	2021	2022	2023	2024 and later
QP Patient Count Threshold	20%	20%	35%	35%	50%	50%
Partial QP Patient Count Threshold	10%	10%	25%	25%	35%	35%

For the 2019 and 2020 payment incentives, CMS proposes to use the following "decision tree" to determine whether an eligible clinician group meets the QP Threshold or Partial QP Threshold:

FIGURE E: QP Determination Tree, Payment Years 2019-2020



QP Performance Period. CMS proposes to use the following QP Performance Period for determining eligibility for 2019 payment incentives:

FIGURE H: Proposed QP Performance Period

2017	2018	2019	
Proposed QP Timeline		QP Performance Period 3	
1	QP Performance Period 2	Incentive Payment Base Period 2	
QP Performance Period 1	Incentive Payment Base Period 1	QP Incentive Payment 1	
Proposed MIPS Timeline	2	MIPS Performance Period 3	
23	MIPS Performance Period 2	MIPS Submission and Analysis 2	
MIPS Performance Period 1	MIPS Submission and Analysis 1	MIPS Payment Adjustments 1	

Under this proposal, the determination of whether a clinician group has met the QP Thresholds for 2019 payment incentives would be based on its Payment Amount Counts and Patient Counts for 2017. However, for a clinician who successfully achieves QP status based on 2017 performance for 2019 payment incentives, the five percent lump sum bonus payment incentive in 2019 would be based on five percent of the clinician's Medicare Part B professional services payments in 2018, i.e. the "Incentive Payment Base Period." CMS proposes that a QP Performance Period would be a full year.

Making QP determinations at the group level. CMS proposes to make QP determinations at the clinician group level, rather than an individual level. If that eligible clinician group's collective Threshold Score meets the relevant QP Threshold, all eligible clinicians in that group would receive the same QP determination for the relevant year. The one exception to this is when none of the Advanced APM Entities in which the eligible clinician participates meet the QP Threshold, CMS proposes to assess the eligible clinician individually, using combined information for services associated with that individual's NPI and furnished through all such eligible clinician's Advanced APM Entities during the QP Performance Period. For group QP determinations, CMS proposes identify the eligible clinician group for each Advanced APM Entity on December 31st of each QP Performance Period via a Participation List that the Advanced APM Entity would provide to CMS. CMS then would provide notice to clinicians of QP determinations during the summer of the following year.

Beneficiary attribution for QP Threshold determinations. CMS proposes to assess the number of "Attributed Beneficiaries" of a clinician group relative to the number of "Attribution-Eligible Beneficiaries" for the purpose of determining the QP Threshold. Attributed Beneficiaries would be defined as beneficiaries attributed to the Advanced APM Entity on the latest available list of attributed beneficiaries during the QP Performance Period, based on each APM's respective attribution rules. CMS proposes to define an Attribution-Eligible Beneficiary as a beneficiary who:

- Is not enrolled in Medicare Advantage or a Medicare cost plan;
- Does not have Medicare as a secondary payer;
- Is enrolled in both Medicare Parts A and B;
- Is at least 18 years of age;
- Is a United States resident;
- Has a minimum of one claim for evaluation and management services by an eligible clinician or group of eligible clinicians within an APM Entity for any period during the QP Performance Period.

Mechanics of the Payment Amount Method. For the Payment Amount Method calculation, CMS proposes to measure: (1) the aggregate of all payments for Medicare Part B covered professional services furnished by the eligible clinicians in the Advanced APM Entity to Attributed Beneficiaries during the QP Performance Period; relative to: (2) the aggregate of all payments for Medicare Part B covered professional services furnished by the eligible clinicians in the Advanced APM Entity to Attribution-Eligible Beneficiaries during the OP Performance Period.

Mechanics of the Patient Count Method. For the Patient Count Method calculation, CMS proposes to measure: (1) the number of unique Attributed Beneficiaries to whom eligible clinicians in the Advanced APM Entity furnish Medicare Part B covered professional services during the QP Performance Period; relative to: (2) the number of Attribution-Eligible Beneficiaries to whom eligible clinicians in the Advanced APM Entity furnish covered professional services during the QP Performance Period. The following table provides an example of the Patient Count Method for determining achievement of the QP Threshold:

TABLE 37: Example of Threshold Score Calculation

	(A) # of Attributed Beneficiaries	(B) # of Attribution- Advanced Beneficiaries	Threshold Score (A/B)
Advanced APM Entity 1	500	1,000	50%
Advanced APM Entity 2	300	1,200	25%

Partial QP "election" on MIPS. CMS proposes to require that each Advanced APM Entity must make an election each year on behalf of all of its identified participating eligible clinicians on whether to report under MIPS in the event that the eligible clinicians participating in the Advanced APM Entity are determined as a group to be Partial QPs for a year. An example of the Partial QP election timing is detailed in the table below:

FIGURE I: Partial QP Election Timeframe

		QP Performance Period 3
	QP Performance Period 2	Incentive Payment Base Period 2
QP Performance Period 1	Incentive Payment Base Period 1	QP Incentive Payment 1
Partial QP Election Period 1	Partial QP Election Period 2	Partial QP Election Period 3
Eligible APM Entity may change election at any point during this period.		

Under this proposal, the Advanced APM Entity could change its election for a year at any time during the QP Performance Period, but the election becomes permanent at the close of the QP Performance Period.

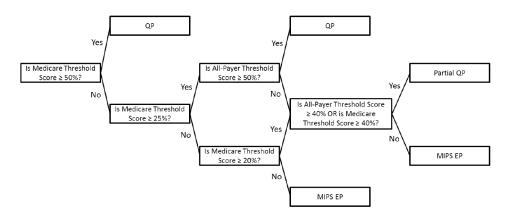
b) All-Payer Combination Option

CMS proposes to establish criteria for Other Payer Advanced APMs, through which clinician groups could achieve QP or Partial QP status through the All-Payer Combination Option, if those groups are unable to achieve QP or Partial QP status through the Medicare Option. CMS also proposes to establish a similar Patient Count Method and Payment Amount Method for making QP determinations under the All-Payer Combination Method.

Process for achieving QP/Partial QP status via participation in Other Payer Advanced APMs. CMS proposes that eligible clinicians may become QPs if the following steps occur: (1) the eligible clinician submits to CMS sufficient information on all relevant payment arrangements with other payers; (2) CMS determines that an Other Payer APM is an Other Payer Advanced APM; and (3) the eligible clinician meets the relevant QP Thresholds by having sufficient payments or patients attributed to a combination of participation in Advanced APMs and Other Payer Advanced APMs.

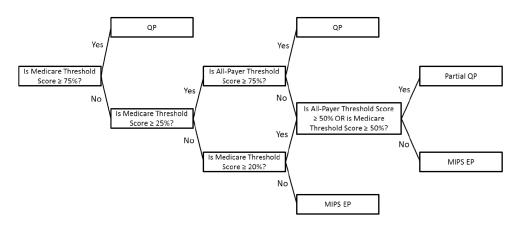
Details on the process for making QP determinations though the All-Payer Combination Option are provided in the flow charts below:

2021 - 2022 All-Payer Combination Option



2023 and later

All-Payer Combination Option



Information submission requirements for Other Payer Advanced APMs. CMS proposes that in order to be considered under the All-Payer Combination Option, APM Entities or individual eligible clinicians must submit by a date and in a manner determined by CMS: (1) payment arrangement information necessary to assess whether each Other Payer APM is an Other Payer Advanced APM, including information on financial risk arrangements, use of CEHRT, and payment tied to quality measures; and (2) for each Other Payer APM, the amounts of revenues for services furnished through the arrangement, the total revenues from the payer, the numbers of patients furnished any service through the arrangement (that is, patients for whom the eligible clinician is at risk if actual expenditures exceed projected expenditures), and the total numbers of patients furnished any service through the payer.

Quality measure requirements for Other Payer Advanced APMs. CMS proposes that the quality measures upon which the Other Payer Advanced APM bases payment must include at least one of the following types of measures (provided that they have an evidence-based focus and are reliable and valid):

· Any of the quality measures included on the proposed annual list of MIPS quality measures;

- Quality measures that are endorsed by a consensus-based entity;
- · Quality measures developed under the PQRS;
- Quality measures submitted in response to the MIPS Call for Quality Measures; or
- Any other quality measures that CMS determines to have an evidence-based focus and be reliable and valid.

CEHRT requirements for Other Payer Advanced APMs. CMS proposes that Other Payer APMs would meet the CEHRT requirement for Other Payer Advanced APMs by requiring participants to use CEHRT, as defined for MIPS and Advanced APMs.

Financial risk requirements for Other Payer Advanced APMs. CMS proposes to require that Other Payer Advanced APMs must involve a payment arrangement requiring that if an APM Entity's actual aggregate expenditures exceed expected aggregate expenditures during a specified performance period, the payer may withhold payment for services to the APM Entity and/or the APM Entity's eligible clinicians; reduce payment rates to the APM Entity and/or the APM Entity's eligible clinicians; or require direct payments by the APM Entity to the payer. CMS would apply a similar minimum nominal risk amount standard as that which would be applied for Advanced APMs. CMS proposes to require that for an Other Payer APM to meet the nominal amount standard: the specific level of Marginal Risk must be at least 30 percent of losses in excess of the expected expenditures; and Total Potential Risk must be at least four percent of the expected expenditures. In addition, CMS would put in place a standard MLR of four percent and also would establish an exception process for smaller Other Payer APMs, through which the agency could determine that a risk arrangement with an MLR higher than four percent could meet the nominal amount standard, provided that the other portions of the nominal risk standard are met.

Capitation and Medicare Advantage. CMS proposes that full capitation risk arrangements would meet the Other Payer Advanced APM financial risk criterion. A capitation risk arrangement refers to a payment arrangement in which a per capita or otherwise predetermined payment is made to an APM Entity for services furnished to a population of beneficiaries, and no settlement is performed for the purpose of reconciling or sharing losses incurred or savings earned by the APM Entity. CMS also proposes that under the All-Payer Combination Option for QP determinations, eligible clinicians and Advanced APM Entities can meet the QP Threshold based in part on payment amounts or patients counts associated with Medicare Advantage plans and other payers, provided that such arrangements meet the criteria to be considered Other Payer Advanced APMs.

Medical Medical Home Model Elements. CMS proposes to define a Medicaid Medical Home Model as a Medical Home Model that is operated under a State Medicaid program and not through a CMMI demonstration. As a result of not being operated through a CMMI demonstration, the Medicaid Medical Home Model would be ineligible for model expansion by CMMI, and therefore would be required to meet the financial risk requirements. CMS proposes financial risk standards and nominal risk amount standards for Medicaid Medical Home Models that are consistent with the standards proposed for the Medical Home Model for Advanced APMs (see above).

Determination of QP status via Payment Amount Method. CMS proposes that for the Payment Amount Method in the QP determination in the All-Payer Combination Option, the numerator would be the aggregate of all payments from all other payers (except those excluded, see below) to the Advanced APM Entity's eligible clinicians under the terms of all Other Payer Advanced APMs during the QP Performance Period. CMS proposes that the denominator for the Payment Amount Method would equal the aggregate of all payments from all other payers (except those excluded) to the Advanced APM Entity's eligible clinicians during the QP Performance Period. The applicable QP Threshold under the Payment Amount Method is detailed below:

All-Payer Combination Option – Payment Amount Method										
Payment Year	2019	2020	1	2021	2	2022	2023		2024 and later	
QP Payment Amount Threshold	N/A	N/A	50%	25%	50%	25%	75%	25%	75%	25%
Partial QP Payment Amount Threshold	N/A	N/A	40%	20%	40%	20%	50%	20%	50%	20%
	•		Total	Medicare	Total	Medicare	Total	Medicare	Total	Medicare

TABLE 38: QP Payment Amount Thresholds - All-Payer Combination Option

Determination of QP status via Patient Count Method. CMS proposes that for the Patient Count Method in the QP determination in the All-Payer Combination Option, the numerator would be the number of unique patients to whom eligible clinicians in the Advanced APM Entity furnish services that are included in the measures of aggregate expenditures used under the terms of all of their Other Payer Advanced APMs during the QP Performance Period, plus the patient count numerator for Advanced APMs. CMS proposes that the denominator for the Patient Count Method would equal the number of unique patients to whom eligible clinicians in the Advanced APM Entity furnish services under all non-excluded payers during the QP Performance Period. The applicable QP Threshold under the Patient Count Method is detailed below:

All-Payer Combination Option - Patient Count Method 2019 2024 and later **Payment Year** 2020 2021 2022 2023 QP Patient Count N/A N/A 35% 20% 35% 20% 50% 35% 50% 35% Threshold Partial QP Patient N/A N/A 25% 10% 25% 10% 35% 25% 35% 25% Count Threshold Total Total Total Medicare Total Medicare Medicare

TABLE 39: QP Patient Count Thresholds - All-Payer Combination Option

Excluded payments and patients. CMS proposes to exclude, from the numerator and the denominator for the All-Payer Combination Option QP determination, payments and patients under: (1) the Department of Defense health care programs; (2) the Department of Veterans Affairs health care programs; and (3) State Medicaid programs where there is no Medicaid Medical Home Model or APM currently available under the State plan.

5. APM Incentive Payments

Exclusion of 2018 payment adjustments from base calculation for 2019 APM incentive. The 2019 APM payment incentive would equal five percent of the clinicians' 2018 aggregate payments for Medicare Part B covered professional services. 2018 is also the final year in which payment adjustments will be made under PQRS, EHR Meaningful Use, and the VM programs. CMS proposes to exclude PQRS, Meaningful Use, and VM payment adjustments from the base amount of 2018 payment upon which the five percent lump sum payment for 2019 is derived.

Exclusion of other payments from the case Calculation for the APM bonus. CMS also would exclude shared savings payments and certain Per-Beneficiary Per-Month (PBPM) payments from the Medicare Part B base amount that is used to determine the five percent bonus.

Exclusion of APM bonus from spending benchmarks for APM Entity. CMS proposes that the APM incentive payment shall not be taken into account for purposes of determining actual expenditures under an APM and for purposes of determining or rebasing any benchmarks (*e.g.* ACO spending benchmarks) used under the APM.

Timing for distribution of APM Incentive Payment. CMS proposes that the lump-sum bonuses must be distributed within one year after the end of the Incentive Payment Base Period. For example, for 2019 APM incentive payments, CMS would be required to distribute the lump-sum payments by December 31, 2019, since the Incentive Payment Base Period ends on December 31, 2018. However, CMS indicated that the agency generally anticipates being able to distribute the lump-sum payments within six months after the end of the Incentive Payment Base Period.

6. Physician-Focused Payment Models

MACRA establishes the Physician-Focused Payment Model Technical Advisory Committee ("PTAC") to advise CMS on the development and implementation of physician-focused payment models (PFPMs) that could qualify as Advanced APMs. The PTAC's members have been appointed by the U.S. Comptroller General, and the Committee convened its inaugural meeting in February 2016. CMS is required post detailed responses to PTAC public comments on CMS/CMMI-proposed PFPMs. However, CMS is not required to implement models that are endorsed or proposed by the PTAC, although the proposed rule indicates that the agency will give "serious consideration" to proposed PFPMs recommended by the PTAC.

PFPM Definition. CMS proposes to define a PFPM as a an Alternative Payment Model wherein Medicare is a payer, which includes physician group practices or individual physicians as APM Entities and targets the quality and costs of physician services.

PFPM Criteria. CMS proposes that in carrying out its review of PFPMs, the PTAC shall assess whether the PFPM meets the following criteria: (1) the model has incentives to pay for high-value care; (2) the model promotes better care coordination, protects patient safety, and encourages patient engagement; and (3) the model improves the availability of information to guide decision-making, via the use of health information technology to inform care.

EXHIBIT A CMS PRELIMINARY APM QUALIFICATION FINDINGS

APM and Abbreviation	Qualifies as a MIPS APM for APM Scoring Standard?	Medical Home Model?	Use of CEHRT Criterion?	Quality Measures Criterion?	Financial Risk Criterion?	Advanced APM?
Bundled Payment for Care Improvement Model 2	No	No	No	No	Yes	No
Bundled Payment for Care Improvement Model 3	No	No	No	No	Yes	No
Bundled Payment for Care Improvement Model 4	No	No	No	No	Yes	No
Comprehensive Care for Joint Replacement	No	No	No	Yes	Yes	No
Comprehensive ESRD Care (LDO arrangement)	Yes	No	Yes	Yes	Yes	Yes
Comprehensive ESRD Care (non-LDO)	Yes	No	Yes	Yes	No	No
Comprehensive Primary Care Plus	Yes	Yes	Yes	Yes	Yes	Yes
Frontier Community Health Integration Program	No	No	No	No	No	No
Health Plan Innovation – MA Value-Based Insurance Design Model	No	No	No	No	No	No
Health Plan Innovation – Part D Enhanced Medication Therapy Management Model	No	No	No	No	No	No
Home Health Value-Based Purchasing Model	No	No	No	No	No	No
Independence at Home Demonstration	No	Yes	No	Yes	No	No
Initiative to Reduce Preventable Hospitalizations Among Nursing Facility Residents – Phase 2	No	No	No	No	No	No

APM and Abbreviation	Qualifies as a MIPS APM for APM Scoring Standard?	Medical Home Model?	Use of CEHRT Criterion?	Quality Measures Criterion?	Financial Risk Criterion?	Advanced APM?
Intravenous Immune Globulin Demonstration	No	No	No	No	No	No
Maryland All-Payer Hospital Model	No	No	No	No	No	No
Medicare Part B Drugs Payment Model	No	No	No	No	No	No
Medicare Care Choices Model	No	No	No	No	No	No
Medicare Shared Savings Program – Track 1	Yes	No	Yes	Yes	No	No
Medicare Shared Savings Program – Track 2	Yes	No	Yes	Yes	Yes	Yes
Medicare Shared Savings Program – Track 3	Yes	No	Yes	Yes	Yes	Yes
Million Hearts – Cardiovascular Risk Reduction Model	No	No	No	No	No	No
Next Generation ACO Model	Yes	No	Yes	Yes	Yes	Yes
Oncology Care Model, One-Sided Risk Arrangement	Yes	No	Yes	Yes	No	No
Oncology Care Model, Two-sided Risk Arrangement	Yes	No	Yes	Yes	Yes	Yes