

Executive Summary

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 414 and 495

[CMS-5517-FC]

RIN 0938-AS69

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repeals the Medicare Sustainable Growth Rate (SGR) methodology for updates to the Physician Fee Schedule (PFS) and replaces it with a new approach to payment called the Quality Payment Program that rewards the delivery of high-quality patient care through two avenues: Advanced Alternative Payment Models (Advanced APMs) and the Merit-based Incentive Payment System (MIPS) for eligible clinicians or groups under the PFS. This final rule with comment period establishes incentives for participation in certain Alternative Payment Models (APMs) and includes the criteria for use by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) in making comments and recommendations on physician-focused payment models (PFPMs). Alternative Payment Models are payment approaches, developed in partnership with the clinician community, that provide added incentives to deliver high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population. This final rule with comment period also establishes the MIPS, a new program for certain Medicare-enrolled practitioners. MIPS will consolidate components of three existing programs, the Physician Quality Reporting System (PQRS), the Physician Value-based Payment Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for Eligible Professionals (EPs), and will continue the focus on quality, cost, and use of certified EHR technology (CEHRT) in a cohesive program that avoids redundancies. In this final rule with comment period we have rebranded key terminology based on

feedback from stakeholders, with the goal of selecting terms that will be more easily identified and understood by our stakeholders.

DATES: Effective date: The provisions of this final rule with comment period are effective on January 1, 2017.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m., 60 days after the date of filing for public inspection.

ADDRESSES: In commenting, please refer to file code CMS-5517-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-5517-FC,
P.O. Box 8013,
Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-5517-FC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a) For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b) For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786 7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Molly MacHarris, (410) 786-4461, for inquiries related to MIPS.

James P. Sharp, (410) 786-7388, for inquiries related to APMs.

1. Overview

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114 10, enacted April 16, 2015), amended title XVIII of the Social Security Act (the Act) to repeal the Medicare Sustainable Growth Rate, to reauthorize the Children's Health Insurance Program, and to strengthen Medicare access by improving physician and other clinician payments and making other improvements. This rule finalizes policies to improve physician and other clinician payments by changing the way Medicare incorporates quality measurement into payments and by developing new policies to address and incentivize participation in Alternative Payment Models (APMs). These unified policies to promote greater value within the healthcare system are referred to as the Quality Payment Program.

The MACRA, landmark bipartisan legislation, advances a forward-looking, coordinated framework for health care providers to successfully take part in the CMS Quality Payment Program that rewards value and outcomes in one of two ways:

- Advanced Alternative Payment Models (Advanced APMs).
- Merit-based Incentive Payment System (MIPS).

The MACRA marks a milestone in efforts to improve and reform the health care system. Building off of the successful coverage expansions and improvements to access under the Patient Protection and Affordable Care Act (Affordable Care Act), the MACRA puts an increased focus on the quality and value of care delivered. By implementing MACRA to promote participation in certain APMs, such as the Shared Savings Program, Medical Home Models, and innovative episode payment models for cardiac and joint care, and by paying eligible clinicians for quality and value under MIPS, we support the nation's progress toward achieving a patient-centered health care system that delivers better care, smarter spending, and healthier people and communities. By driving significant changes in how care is delivered to make the health care system more responsive to patients and families, we believe the Quality Payment Program supports eligible clinicians in improving the health of their patients, including encouraging interested eligible clinicians in their successful transition into APMs. To implement this vision, we are finalizing a program that emphasizes high-quality care and patient outcomes while minimizing burden on eligible clinicians and that is flexible, highly transparent, and improves over time with input from clinical practices. To aid in this process, we have sought feedback from the health care community through various public avenues and solicited comment through the proposed rule. As we establish policies for effective implementation of the MACRA, we do so with the explicit understanding that technology, infrastructure, physician support systems, and clinical practices will change over the next few years. In addition, we are aware of the diversity of clinician practices in their experience with quality-based payments. As a result of these factors, we expect the Quality Payment Program to evolve over multiple years in order to achieve our national goals. In the early years of the program, we will begin by laying the groundwork for expansion towards an innovative, outcome-focused, patient-centered, resource-effective health system. Through a staged approach, we can develop policies that are operationally feasible and made in consideration of system capabilities and our core strategies to drive progress and reform efforts.

Thus, due to this staged approach, we are finalizing the rule with a comment period. We commit to continue iterating on these policies.

The Quality Payment Program aims to do the following: (1) support care improvement by focusing on better outcomes for patients, decreased provider burden, and preservation of independent clinical practice; (2) promote adoption of Alternative Payment Models that align incentives across healthcare stakeholders; and (3) advance existing efforts of Delivery System Reform, including ensuring a smooth transition to a new system that promotes high-quality, efficient care through unification of CMS legacy programs.

This final rule with comment period establishes the Quality Payment Program and its two interrelated pathways: Advanced APMs and the MIPS. This final rule with comment period establishes incentives for participation in Advanced APMs, supporting the Administration's goals of transitioning from fee-for-service (FFS) payments to payments for quality and value, including approaches that focus on better care, smarter spending, and healthier people. This final rule with comment period also includes definitions of Qualifying APM Participants (QPs) in Advanced APMs and outlines the criteria for use by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) in making comments and recommendations to the Secretary on physician-focused payment models (PFPMs).

MIPS is a new program for certain Medicare-participating eligible clinicians that will make payment adjustments based on performance on quality, cost and other measures, and will consolidate components of three existing programs—the Physician Quality Reporting System (PQRS), the Physician Value-based Payment Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for eligible professionals (EPs). As prescribed by Congress, MIPS will focus on: quality – both a set of evidence-based, specialty-specific standards as well as practice-based improvement activities; cost; and use of certified electronic health record (EHR) technology (CEHRT) to support interoperability and advanced quality objectives in a single, cohesive program that avoids redundancies. Many features of MIPS are intended to simplify and integrate further during the second and third years.

2. Quality Payment Program Strategic Objectives

We solicited and reviewed over 4000 comments and had over 100,000 physicians and other stakeholders attend our outreach sessions. Through this outreach, we created six strategic objectives to drive continued progress and improvement.

These objectives guided our final policies and will guide our future rulemaking in order to design, implement and evolve a Quality Payment Program that aims to improve health outcomes, promote smarter spending, minimize burden of participation, and provide fairness and transparency in operations. These strategic objectives are as follows: (1) to improve beneficiary outcomes and engage patients through patient-centered Advanced APM and MIPS policies; (2) to enhance clinician experience through flexible and transparent program design and interactions with easy-to-use program tools; (3) to increase the availability and adoption of robust Advanced APMs; (4) to promote program understanding

and maximize participation through customized communication, education, outreach and support that meet the needs of the diversity of physician practices and patients, especially the unique needs of small practices; (5) to improve data and information sharing to provide accurate, timely, and actionable feedback to clinicians and other stakeholders; and (6) to ensure operational excellence in program implementation and ongoing development. More information on these objectives and the Quality Payment Program can be found at QualityPaymentProgram.cms.gov.

With these objectives we recognize that the Quality Payment Program provides new opportunities to improve care delivery by supporting and rewarding clinicians as they find new ways to engage patients, families and caregivers and to improve care coordination and population health management. In addition, we recognize that by developing a program that is flexible instead of one-size-fits-all, clinicians will be able to choose to participate in a way that is best for them, their practice, and their patients. For clinicians interested in APMs, we believe that by setting ambitious yet achievable goals, eligible clinicians will move with greater certainty toward these new approaches of delivering care. To these ends, and to ensure this program works for all stakeholders, we further recognize that we must provide ongoing education, support, and technical assistance so that clinicians can understand program requirements, use available tools to enhance their practices, and improve quality and progress toward participation in Alternative Payment Models if that is the best choice for their practice. Finally, we understand that we must achieve excellence in program management, focusing on customer needs, promoting problem-solving, teamwork, and leadership to provide continuous improvements in the Quality Payment Program.

3. One Quality Payment Program

Clinicians have told us that they do not separate their patient care into domains, and that the Quality Payment Program needs to reflect typical clinical workflows in order to achieve its goals of better patient care. Advanced APMs, the focus of one pathway of the Quality Payment Program, contribute to better care and smarter spending by allowing physicians and other clinicians to deliver coordinated, customized, high-quality care to their patients within a streamlined payment system. Within MIPS, the second pathway of the Quality Payment Program, we believe that the unification into one Quality Payment Program can best be accomplished by making connections across the four pillars of the MIPS payment structure identified in the MACRA legislation – quality, clinical practice improvement activities (referred to as “improvement activities”), meaningful use of CEHRT (referred to as “advancing care information”), and resource use (referred to as “cost”) – and by emphasizing that the Quality Payment Program is at its core about improving the quality of patient care. Indeed, the bedrock of the Quality Payment Program is high-quality, patient-centered care followed by useful feedback, in a continuous cycle of improvement. The principal way MIPS measures quality of care is through evidence-based clinical quality measures which MIPS eligible clinicians can select, the vast majority of which are created by or supported by clinical leaders and endorsed by a consensus-based process. Over time, the portfolio of quality measures will grow and develop, driving towards outcomes that are of the greatest importance to patients and clinicians. Through MIPS, we have the opportunity to measure quality not only through

clinician-proposed measures, but to take it a step further by also accounting for activities that physicians themselves identify: namely, practice-driven quality improvement. The MACRA requires us to measure whether technology is used meaningfully. Based on significant feedback, this area is simplified into supporting the exchange of patient information and how technology specifically supports the quality goals selected by the practice. The cost performance category has also been simplified and weighted at zero percent of the final score for the transition year of CY 2017. Given the primary focus on quality, we have accordingly indicated our intention to align these measures fully to the quality measures over time in the scoring system (see section II.E.6.a. for further details). In this vein, we are establishing special policies for the first year of the Quality Payment Program, which we refer to as the “transition year” throughout this final rule with comment period; this transition year corresponds to the first performance period of the program, calendar year (CY) 2017, and the first payment year, CY 2019. We envision that it will take a few years to reach a steady state in the program, and we therefore anticipate a ramp-up process and gradual transition with less financial risk for clinicians in at least the first 2 years. In the transition year in 2017, we will test this performance category alignment, for example by allowing certain improvement activities that are completed using CEHRT to achieve a bonus score in the advancing care information performance category with the intent of analyzing adoption, and in future years, potentially adding activities that reinforce integration of the program. Our hope is for the program to evolve to the point where all the clinical activities captured in MIPS across the four performance categories reflect the single, unified goal of quality improvement.

4. Summary of the Major Provisions

a. Transition Year and Iterative Learning and Development Period

We recognize, as described through many insightful comments, that many eligible clinicians face challenges in understanding the requirements and being prepared to participate in the Quality Payment Program in 2017. As a result, we have decided to finalize transitional policies throughout this final rule with comment period, which will focus the program in its initial years on encouraging participation and educating clinicians, all with the primary goal of placing the patient at the center of the healthcare system. At the same time, we will also increase opportunities to join Advanced APMs, allowing eligible clinicians who chose to do so an opportunity to participate.

Given the wide diversity of clinical practices, the initial development period of the Quality Payment Program implementation would allow physicians to pick their pace of participation for the first performance period that begins January 1, 2017. Eligible clinicians will have three flexible options to submit data to MIPS and a fourth option to join Advanced APMs in order to become QPs, which would ensure they do not receive a negative payment adjustment in 2019.

In the transition year CY 2017 of the program, this rule finalizes a period during which clinicians and CMS will build capabilities to report and gain experience with the program. Clinicians can choose their course of participation in this year with four options.

(1) Clinicians can choose to report to MIPS for a full 90-day period or, ideally, the full year, and maximize the MIPS eligible clinician's chances to qualify for a positive adjustment. In addition, MIPS eligible clinicians who are exceptional performers in MIPS, as shown by the practice information that they submit, are eligible for an additional positive adjustment for each year of the first 6 years of the program.

(2) Clinicians can choose to report to MIPS for a period of time less than the full year performance period 2017 but for a full 90-day period at a minimum and report more than one quality measure, more than one improvement activity, or more than the required measures in the advancing care information performance category in order to avoid a negative MIPS payment adjustment and to possibly receive a positive MIPS payment adjustment.

(3) Clinicians can choose to report one measure in the quality performance category; one activity in the improvement activities performance category; or report the required measures of the advancing care information performance category and avoid a negative MIPS payment adjustment. Alternatively, if MIPS eligible clinicians choose to not report even one measure or activity, they will receive the full negative 4 percent adjustment.

(4) MIPS eligible clinicians can participate in Advanced APMs, and if they receive a sufficient portion of their Medicare payments or see a sufficient portion of their Medicare patients through the Advanced APM, they will qualify for a 5 percent bonus incentive payment in 2019.

We are finalizing the 2017 performance period for the 2019 MIPS payment year to be a transition year as part of the development period in the program. For this transition year, for MIPS, the performance threshold will be lowered to a threshold of 3 points. Clinicians who achieve a final score of 70 or higher will be eligible for the exceptional performance adjustment, funded from a pool of \$500 million.

For full participation in MIPS and in order to achieve the highest possible final scores, MIPS eligible clinicians are encouraged to submit measures and activities in all three integrated performance categories: quality, improvement activities, and advancing care information. To address public comments on the cost performance category, the weighting of the cost performance category has been lowered to 0 percent for the transition year. For full participation in the quality performance category, clinicians will report on six quality measures, or one specialty-specific or subspecialty-specific measure set. For full participation in the advancing care information performance category, MIPS eligible clinicians will report on five required measures. For full participation in the improvement activities performance category, clinicians can engage in up to four activities, rather than the proposed six activities, to earn the highest possible score of 40.

For the transition year CY 2017, for quality, clinicians who submit one out of at least six quality measures will meet the MIPS performance threshold of 3; however, more measures are required for groups who submit measures using the CMS Web Interface. For the transition year CY 2017, for quality, higher measure points may be awarded based on achieving higher performance in the measure. For improvement activities, attesting to at least one improvement activity will also be sufficient to meet the

MIPS performance threshold in the transition year CY 2017. For advancing care information, clinicians reporting on the required measures in that category will meet the performance threshold in the transition year. These transition year policies for CY 2017 will encourage participation by clinicians and will provide a ramp up period for clinicians to prepare for higher performance thresholds in the second year of the program.

Historical evidence has shown that clinical practices of all sizes can successfully submit data, including over 110,000 solo and small practices with 15 or fewer clinicians who participated in PQRS in 2015. The transition year and development period approach gives clinicians structured, practical choices that can best suit their practices. Resources will be made available to assist clinicians and practices through this transition. The hope is that by lowering the barriers to participation at the outset, we can set the foundation for a program that supports long-term, high-quality patient care through feedback and open communication between CMS and other stakeholders.

We anticipate that the iterative learning and development period will last longer than the first year, CY 2017, of the program as we move towards a steady state; therefore, we envision CY 2018 to also be transitional in nature to provide a ramp-up of the program and of the performance thresholds. We anticipate making proposals on the parameters of this second transition year through rule-making in 2017.

b. Legacy Quality Reporting Programs

This final rule with comment period will sunset payment adjustments under the current Medicare EHR Incentive Program for eligible professionals (section 1848(o) of the Act), the PQRS (section 1848(k) and (m)) of the Act, and the VM (section 1848(p) of the Act) programs after CY2018. Components of these three programs will be carried forward into MIPS. This final rule with comment period establishes new subpart O of our regulations at 42 CFR 414.1300 to implement the new MIPS program as required by the MACRA.

c. Significant Changes from Proposed Rule

In developing this final rule with comment period, we sought feedback from stakeholders throughout the process, including through Requests for Information in October 2015 and through the comment process for the proposed rule from April to June 2016. We received thousands of comments from a broad range of sources including professional associations and societies, physician practices, hospitals, patient groups, and health IT vendors, and we thank our many commenters and acknowledge their valued input throughout the proposed rule process.

In response to comments to the proposed rule, we have made significant changes in this final rule with comment period, including (1) bolstering support for small and independent practices; (2) strengthening the movement towards Advanced Alternative Payment Models by offering potential new opportunities such as the Medicare ACO Track 1+, (3) securing a strong start to the program with a flexible, pick-your-own-pace approach to the initial years of the program; and (4) connecting the statutory domains into one

unified program that supports clinician-driven quality improvement. These themes are illustrated in the following specific policy changes: (1) the creation of a transition year and iterative learning and development period in the beginning of the program; (2) the adjustment of the MIPS low-volume threshold; (3) the establishment of an Advanced APM financial risk standard that promotes participation in robust, high-quality models; (4) the simplification of prior “all-or-nothing” requirements in the use of certified EHR technology; and (5) the establishment of Medical Home Model standards that promote care coordination.

We intend to continue open communication with stakeholders, including consultation with tribes and tribal officials, on an ongoing basis as we develop the Quality Payment Program in future years.

d. Small Practices

As outlined above, protection of small, independent practices is an important thematic objective for this final rule with comment. For 2017, many small practices will be excluded from new requirements due to the low-volume threshold, which has been set at less than or equal to \$30,000 in Medicare Part B allowed charges or less than or equal to 100 Medicare patients, representing 32.5 percent of pre-exclusion Medicare clinicians but only 5 percent of Medicare Part B spending. Stakeholder comments suggested setting a higher low-volume threshold for exclusion from MIPS but allowing clinicians that would be excluded by the threshold to opt in to the program if they wished to report to MIPS and receive a MIPS payment adjustment for the year. We considered this option but determined that it was inconsistent with the statutory MIPS exclusion based on the low-volume threshold. We anticipate that more clinicians will be determined to be eligible to participate in the program in future years.

MACRA also provides that solo and small practices may join “virtual groups” and combine their MIPS reporting. Many commenters suggested that we allow groups with more than 10 clinicians to participate as virtual groups. As noted, the statute limits the virtual group option to individuals and groups of no more than 10 clinicians. We are not implementing virtual groups in the transition year 2017 of the program; however, through the policies of the transition year and development period, we believe we have addressed some of the concerns expressed by clinicians hesitant to participate in the Quality Payment Program. CMS wants to make sure the virtual group technology is meaningful and simple to use for clinicians, and we look forward to stakeholder engagement on how to structure and implement virtual groups in future years of the program.

In keeping with the objectives of providing education about the program and maximizing participation, and as mandated by the MACRA, \$100 million in technical assistance will be available to MIPS eligible clinicians in small practices, rural areas, and practices located in geographic health professional shortage areas (HPSAs), including IHS, tribal, and urban Indian clinics, through contracts with quality improvement organizations, regional health collaboratives, and others to offer guidance and assistance to MIPS eligible clinicians in practices of 15 or fewer MIPS eligible clinicians. Priority will be given to practices located in rural areas, defined as clinicians in zip codes designated as rural, using the most recent Health Resources

and Services Administration (HRSA) Area Health Resource File data set available; medically underserved areas (MUAs); and practices with low MIPS final scores or in transition to APM participation.

The MACRA also includes provisions requiring an examination of the pooling of financial risk for physician practices, in particular for small practices. Specifically, Section 101(c)(2)(C) of MACRA requires the Government Accountability Office (GAO) to submit a report to Congress, not later than January 1, 2017, examining whether entities that pool financial risk for physician practices, such as independent risk managers, can play a role in supporting physician practices, particularly small physician practices, in assuming financial risk for the treatment of patients. We have been closely engaged with the GAO throughout their study to better understand the unique needs and challenges faced by clinicians in small practices and practices in rural or health professional shortage areas. We have provided information to the GAO, and the GAO has shared some of their initial findings regarding these challenges. We look forward to further engagement with the GAO on this topic and to the release of GAO's final report. Using the knowledge obtained from small practices, other stakeholders, and the public, as well as from GAO, we continue to work to improve the flexibility and support available to small, underserved, and rural practices. Throughout the evolution of the Quality Payment Program that will unfold over the years to come, CMS is committed to working together with stakeholders to address the unique challenges these practices encounter.

Using updated policies for the transition year and development period, we performed an updated regulatory impact analysis, including for small and solo practices. With the extensive changes to policy and increased flexibility, we believe that estimating impacts of this final rule with comment period using only historic 2015 quality submission data significantly overestimates the impact on small and solo practices. Although small and solo practices have historically been less likely to engage in PQRS and quality reporting, we believe that small and solo practices will respond to MIPS by participating at a rate close to that of other practice sizes. In order to quantify the impact of the rule on MIPS eligible clinicians, including small and solo practices, we have prepared two sets of analyses that assume the participation rates for some categories of small practices will be similar to those of other practice size categories. Specifically, our primary analysis assumes that each practice size grouping will achieve at least 90 percent participation rate and our alternative assumption is that each practice size grouping will achieve at least an 80 percent participation rate. In both sets of analyses, we estimate that over 90 percent of MIPS eligible clinicians will receive a positive or neutral MIPS payment adjustment in the transition year, and that at least 80 percent of clinicians in small and solo practices with 1-9 clinicians will receive a positive or neutral MIPS payment adjustment.

e. Advanced Alternative Payment Models (Advanced APMs)

In this rule, we finalize requirements we will use for the purposes of the incentives for participation in Advanced APMs, and the following is a summary of our finalized policies. The MACRA defines APM for the purposes of the incentive as a model under section 1115A of the Act (excluding a health care innovation

award), the Shared Savings Program under section 1899 of the Act, a demonstration under section 1866C of the Act, or a demonstration required by federal law.

APMs represent an important step forward in the Administration's efforts to move our healthcare system from volume-based to value-based care. APMs that meet the criteria to be Advanced APMs provide the pathway through which eligible clinicians, who would otherwise participate in MIPS, can become Qualifying APM Participants (QPs), and therefore, earn incentive payments for their Advanced APM participation. In the proposed rule, we estimated that 30,000 to 90,000 clinicians would be QPs in 2017. With new Advanced APMs expected to become available for participation in 2017 and 2018, including the Medicare ACO Track 1 Plus (1+), and anticipated amendments to reopen applications to modify current APMs, such as the Maryland All-Payer Model and Comprehensive Care for Joint Replacement (CJR) model, we anticipate higher numbers of QPs—approximately 70,000 to 120,000 in 2017 and 125,000 to 250,000 in 2018.

As discussed in section II.F.4.b. of this final rule period, we are exploring development of the Medicare ACO Track 1+ Model to begin in 2018. The model would be voluntary for ACOs currently participating in Track 1 of the Shared Savings Program or ACOs seeking to participate in the Shared Savings Program for the first time. It would test a payment model that incorporates more limited downside risk than is currently present in Tracks 2 or 3 of the Shared Savings Program but sufficient financial risk in order to be an Advanced APM. We will announce additional information about the model in the future.

This rule finalizes two types of Advanced APMs: Advanced APMs and Other Payer Advanced APMs. To be considered an Advanced APM, an APM must meet all three of the following criteria, as required under section 1833(z)(3)(D) of the Act: (1) The APM must require participants to use CEHRT; (2) The APM must provide for payment for covered professional services based on quality measures comparable to those in the quality performance category under MIPS and; (3) The APM must either require that participating APM Entities bear risk for monetary losses of a more than nominal amount under the APM, or be a Medical Home Model expanded under section 1115A(c) of the Act. In this rule, we finalize proposals pertaining to all of these criteria.

To be an Other Payer Advanced APM, as set forth in section 1833(z)(2) of the Act, a payment arrangement with a payer (for example, Medicaid or a commercial payer) must meet all three of the following criteria: (1) The payment arrangement must require participants to use CEHRT; (2) The payment arrangement must provide for payment for covered professional services based on quality measures comparable to those in the quality performance category under MIPS and; (3) The payment arrangement must require participants to either bear more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures; or be a Medicaid Medical Home Model that meets criteria comparable to Medical Home Models expanded under section 1115A(c) of the Act.

We are completing an initial set of Advanced APM determinations that we will release as soon as possible but no later than January 1, 2017. For new APMs that are announced after the initial determination, we

will include Advanced APM determinations in conjunction with the first public notice of the APM, such as the Request for Applications (RFA) or final rule. All determinations of Advanced APMs will be posted on our website and updated on an ad hoc basis, but no less frequently than annually, as new APMs become available and others end or change.

An important avenue for the creation of innovative payment models is the Physician-Focused Payment Model Technical Advisory Committee (PTAC), created by the MACRA. The PTAC is an 11-member independent federal advisory committee to the HHS Secretary. The PTAC will review stakeholders' proposed physician-focused payment models (PFPMs), and make comments and recommendations to the Secretary regarding whether the PFPMs meet criteria established by the Secretary. PTAC comments and recommendations will be reviewed by the CMS Innovation Center and the Secretary, and we will post a detailed response to them on the CMS website.

(i) QP Determination

QPs are eligible clinicians in an Advanced APM who have a certain percentage of their patients or payments through an Advanced APM. QPs are excluded from MIPS and receive a 5 percent incentive payment for a year beginning in 2019 through 2024. We finalize our proposal that professional services furnished at Critical Access Hospitals (CAHs), Rural Health Clinics (RHCs), and Federally Qualified Health Centers (FQHCs) that meet certain criteria be counted towards the QP determination using the patient count method.

We finalize definitions of Medical Home Model and Medicaid Medical Home Model and the unique standards by which Medical Home Models may meet the financial risk criterion to be an Advanced APM.

The statute sets thresholds for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, is applicable beginning in the payment year 2019. The All-Payer Combination Option, which utilizes the Medicare Option as well as an eligible clinician's participation in Other Payer Advanced APMs, is applicable beginning in the payment year 2021. For eligible clinicians to become QPs through the All-Payer Combination Option, an Advanced APM Entity or eligible clinician must participate in an Advanced APM under Medicare and also submit information to CMS so that we can determine whether payment arrangements with non-Medicare payers are an Other Payer Advanced APMs and whether an eligible clinician meets the requisite QP threshold of participation. We are finalizing our methodologies to evaluate eligible clinicians using the Medicare and All-Payer Combination Options.

We are finalizing the two methods by which we will calculate Threshold Scores to compare to the QP thresholds and make QP determinations for eligible clinicians. The payment amount method assesses the amount of payments for Part B covered professional services that are furnished through an Advanced APM. The patient count method assesses the amount of patients furnished Part B covered professional services through an Advanced APM.

We are finalizing our proposal to identify individual eligible clinicians by a unique APM participant identifier using the individuals' APM, APM Entity, and TIN/NPI combinations, and to assess as an APM Entity group all individual eligible clinicians listed as participating in an Advanced APM Entity to determine their QP status for a year. We are finalizing that if an individual eligible clinician who participates in multiple Advanced APM Entities does not achieve QP status through participation in any single APM Entity, we will assess the eligible clinician individually to determine QP status based on combined participation in Advanced APMs.

We are finalizing the method to calculate and disburse the lump-sum APM Incentive Payments to QPs, and we are finalizing a specific approach for calculating the APM Incentive Payment when a QP also receives non-fee-for-service payments or has received payment adjustments through the Medicare EHR Incentive Program, PQRS, VM, or MIPS during the prior period used for determining the APM Incentive Payment.

We are finalizing a modified policy such that, following a final determination that an Advanced APM Entity group or eligible clinician is determined to be a Partial Qualifying APM Participant (Partial QP), the Advanced APM Entity—or eligible clinician in the case of an individual determination—will make an election on behalf of all of its eligible clinicians in the group of whether to report to MIPS, thus making all eligible clinicians in the Advanced APM Entity group subject to MIPS payment adjustments; or not report to MIPS, thus excluding all eligible clinicians in the APM Entity group from MIPS adjustments. We finalize our proposals to vet and monitor APM Entities, Advanced APM Entities, and eligible clinicians participating in those entities. We are finalizing a definition for PFPs and criteria for use by the PTAC in fulfilling its responsibility to evaluate proposals for PFPs.

We are finalizing an accelerated timeline for making QP determinations, and will notify eligible clinicians of their QP status as soon as possible, in advance of the end of the MIPS performance period so that QPs will know whether they are excluded from MIPS prior to having to submit information to CMS for purposes of MIPS.

We are finalizing the requirement that MIPS eligible clinicians, as well as EPs, eligible hospitals, and critical access hospitals (CAHs) under the existing Medicare and Medicaid EHR Incentive Programs demonstrate cooperation with certain provisions concerning blocking the sharing of information under section 106(b)(2) of the MACRA and, separately, to demonstrate engagement with activities that support health care providers with the performance of their CEHRT such as cooperation with ONC direct review of certified health information technologies.

f. Merit-based Incentive Payment System (MIPS)

In establishing MIPS, this final rule with comment period will define MIPS participants as “MIPS eligible clinicians” rather than “MIPS EPs” as that term is defined at section 1848(q)(1)(C) and used throughout section 1848(q) of the Act. MIPS eligible clinicians will include physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and groups that include

such clinicians who bill under Medicare Part B. The rule finalizes definitions and requirements for groups. In addition to finalizing definitions for MIPS eligible clinicians, the rule also finalizes rules for the specific Medicare-enrolled clinicians that will be excluded from MIPS, including newly Medicare-enrolled MIPS eligible clinicians, QPs, certain Partial QPs, and clinicians that fall under the finalized low-volume threshold.

For the 2017 performance period, we estimate that more than half of clinicians – approximately 738,000 to 780,000 – billing under the Medicare PFS will be excluded from MIPS due to several factors, including the MACRA itself. We estimate that nearly 200,000 clinicians, or approximately 14.4 percent, are not one of the eligible types of clinicians for the transition year CY 2017 of MIPS under section 1848(q)(1)(C). The largest cohort of clinicians excluded from MIPS is low-volume clinicians, defined as those clinicians with less than or equal to \$30,000 in allowed charges or less than or equal to 100 Medicare patients, representing approximately 32.5 percent of all clinicians billing Medicare Part B services or over 380,000 clinicians. Additionally, between 70,000 and 120,000 clinicians (approximately 5-8 percent of all clinicians billing under the Medicare Part B) will be excluded from MIPS due to being QPs based on participation in Advanced APMs. In aggregate, the eligible clinicians excluded from MIPS represent only 22 to 27 percent of total Part B allowed charges.

This rule finalizes MIPS performance standards and a minimum MIPS performance period of any 90 continuous days during the 2017 calendar year (January 1 through December 31) for all measures and activities applicable to the integrated performance categories. After consideration of public comments, this rule finalizes a shorter than annual performance period in 2017 to allow flexible participation options for MIPS eligible clinicians as the program begins and evolves over time. For performance periods occurring in 2017, MIPS eligible clinicians will be able to pick a pace of participation that best suits their practices, including submitting data, in special circumstances as discussed in section II.E.5. of this rule, for a period of less than 90 days, to avoid a negative MIPS payment adjustment. Further, we are finalizing our proposal to use performance in 2017 as the performance period for the 2019 payment adjustment. Therefore, the first performance period will start in 2017 and consist of a minimum period of any 90 continuous days during the calendar year in order for clinicians to be eligible for payment adjustment above neutral. Performance in that period of 2017 will be used to determine the 2019 payment adjustment. This timeframe is needed to allow data and claims to be submitted and data analysis to occur in the initial years. In subsequent years, we intend to explore ways to shorten the period between the performance period and the payment year, and ongoing performance feedback will be provided more frequently. The final policies for CY 2017 provide flexibilities to ensure clinicians have ample participation opportunities.

As directed by the MACRA, this rule finalizes measures, activities, reporting, and data submission standards across four integrated performance categories: quality, cost, improvement activities, and advancing care information, each linked by the same overriding mission of supporting care improvement

under the vision of one Quality Payment Program. Consideration will be given to the application of measures and activities to non-patient facing MIPS eligible clinicians.

Under the requirements finalized in this rule, there will be options for reporting as an individual MIPS eligible clinician or as part of a group. Some data may be submitted via relevant third party intermediaries, such as qualified clinical data registries (QCDRs), health IT vendors¹, qualified registries, and CMS-approved survey vendors.

Within each performance category, we are finalizing specific requirements for full participation in MIPS which involves submitting data on quality measures, improvement activities, and use of certified EHR technology on a minimum of any continuous 90 days up to the full calendar year in 2017 in order to be eligible for a positive MIPS payment adjustment. It is at the MIPS eligible clinician's discretion whether to submit data for the same 90-day period for the various measures and activities or for different time periods for different measures and activities. Note that during the 2017 transition year, MIPS eligible clinicians may choose to report a minimum of a single measure in the quality performance category, a single activity in the improvement activities performance category or the required measures in the advancing care information performance category, in order to avoid a negative payment adjustment. For full participation in MIPS, the specific requirements are as follows:

(i) Quality

Quality measures will be selected annually through a call for quality measures process, and a final list of quality measures will be published in the Federal Register by November 1 of each year. For MIPS eligible clinicians choosing full participation in MIPS and the potential for a higher payment adjustment, we note that for a minimum of a continuous 90-day performance period, the MIPS eligible clinician or group will report at least six measures including at least one outcome measure if available. If fewer than six measures apply to the individual MIPS eligible clinician or group, then the MIPS eligible clinician or group will only be required to report on each measure that is applicable.

¹ We also note that throughout this final rule, as in the proposed rule, we use the terms "EHR Vendor" and "Health IT Vendor." First, the use of the term "health IT" and "EHR" are based on the common terminology within the specified program (see 80 FR 62604; and the advancing care information performance category in this rule). Second, we recognize that a "health IT vendor" may or may not also be a "health IT developer" and, in some cases, the developer and the vendor of a single product may be different entities. Under the ONC Health IT Certification Program (Program), a health IT developer constitutes a vendor, self-developer, or other entity that presents health IT for certification or has health IT certified under the Program. Therefore, for purposes of this final rule, we clarify that the term "vendor" shall also include developers who create or develop health IT. Throughout this final rule, we use the term "health IT vendor" or "EHR vendor" to refer to entities that support the health IT requirements of a MIPS eligible clinician participating in the proposed Quality Payment Program. This use is consistent with prior CMS rules, see for example the 2014 CEHRT Flexibility final rule (79 FR 52915).

Alternatively, for a minimum of a continuous 90-day period, the MIPS eligible clinician or group can report one specialty-specific measure set, or the measure set defined at the subspecialty level, if applicable. If the measure set contains fewer than six measures, MIPS eligible clinicians will be required to report all available measures within the set. If the measure set contains six or more measures, MIPS eligible clinicians can choose six or more measures to report within the set. Regardless of the number of measures that are contained in the measure set, MIPS eligible clinicians reporting on a measure set will be required to report at least one outcome measure or, if no outcome measures are available in the measure set, report another high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures) within the measure set in lieu of an outcome measure.

(ii) Improvement Activities

Improvement activities are those that support broad aims within healthcare delivery, including care coordination, beneficiary engagement, population management, and health equity. In response to comments from experts and stakeholders across the healthcare system, improvement activities were given relative weights of high and medium. We are reducing the number of activities required to achieve full credit from six medium-weighted or three high-weighted activities to four medium-weighted or two high-weighted activities to receive full credit in this performance category in CY 2017. For small practices, rural practices, or practices located in geographic health professional shortage areas (HPSAs), and non-patient facing MIPS eligible clinicians, we will reduce the requirement to only one high-weighted or two medium-weighted activities. We also expand our definition of how CMS will recognize a MIPS eligible clinician or group as being a certified patient-centered medical home or comparable specialty practice to include certification from a national program, regional or state program, private payer or other body that administers patient-centered medical home accreditation. As previously mentioned, in recognition of improvement activities as supporting the central mission of a unified Quality Payment Program, we will include a designation in the inventory of improvement activities of which activities also qualify for the advancing care information bonus score, consistent with our desire to recognize that EHR technology is often deployed to improve care in ways that our programs should recognize.

(iii) Advancing Care Information Performance Category

Measures and objectives in the advancing care information performance category focus on the secure exchange of health information and the use of certified electronic health record technology (CEHRT) to support patient engagement and improved healthcare quality. We are maintaining alignment of the advancing care information performance category with the other integrated performance categories for MIPS. We are reducing the total number of required measures from eleven in the proposed rule to only five in our final policy. All other measures would be optional for reporting. Reporting on all five of the required measures would earn the MIPS eligible clinician 50 percent. Reporting on the optional measures would allow a clinician to earn a higher score. For the transition year, we will award a bonus score for improvement activities that utilize CEHRT and for reporting to public health or clinical data registries.

Public commenters requested that the advancing care information performance category allow for reporting on “use cases” such as the use of CEHRT to manage referrals and consultations (“closing the referral loop”) and other practice-based activities for which CEHRT is used as part of the typical workflow. This is an area we intend to explore in future rulemaking, but we did not finalize any such policies in this rule. However, for the 2017 transition year, we will award bonus points for improvement activities that utilize CEHRT and for reporting to a public health or clinical data registry, reflecting the belief that the advancing care information performance category should align with the other performance categories to achieve the unified goal of quality improvement.

(iv) Cost

For the transition year, we are finalizing a weight of zero percent for the cost performance category in the final score, and MIPS scoring in 2017 will be determined based on the other three integrated MIPS performance categories. Cost measures do not require reporting of any data by MIPS eligible clinicians to CMS. Although cost measures will not be used to determine the final score in the transition year, we intend to calculate performance on certain cost measures and give this information in performance feedback to clinicians. We intend to calculate measures of total per capita costs for all attributed beneficiaries and a Medicare Spending per Beneficiary (MSPB) measure. In addition, we are finalizing 10 episode-based measures that were previously made available to clinicians in feedback reports and met standards for reliability. Starting in performance year 2018, as performance feedback is available on at least an annual basis, the cost performance category contribution to the final score will gradually increase from 0 to the 30 percent level required by MACRA by the third MIPS payment year of 2021.

(v) Clinicians in MIPS APMs

We are finalizing standards for measures, scoring, and reporting for MIPS eligible clinicians across all four performance categories outlined in this section II.E.5.h of this final rule with comment period. Beginning in 2017, some APMs, by virtue of their structure, will not meet statutory requirements to be categorized as Advanced APMs. Eligible clinicians in these APMs, hereafter referred to as MIPS APMs, will be subject to MIPS reporting requirements and the MIPS payment adjustment. In addition, eligible clinicians who are in Advanced APMs but do not meet participation thresholds to be excluded from MIPS for a year will be subject to the scoring standards for MIPS reporting requirements and the MIPS payment adjustment. In response to comments, in an effort to recognize these eligible clinicians’ participation in delivery system reform and to avoid potential duplication or conflicts between these APMs and MIPS, we finalize an APM scoring standard that is different from the generally applicable standard. We finalize our proposal that MIPS eligible clinicians who participate in MIPS APMs will be scored using the APM scoring standard instead of the generally applicable MIPS scoring standard.

(vi) Scoring under MIPS

We are finalizing that MIPS eligible clinicians have the flexibility to submit information individually or via a group or an APM Entity group; however, the MIPS eligible clinician will use the same identifier for all

performance categories. The finalized scoring methodology has a unified approach across all performance categories, which will help MIPS eligible clinicians understand in advance what they need to do in order to perform well in MIPS. The three performance category scores (quality, improvement activities, and advancing care information) will be aggregated into a final score. The final score will be compared against a MIPS performance threshold of 3 points. The final score will be used to determine whether a MIPS eligible clinician receives an upward MIPS payment adjustment, no MIPS payment adjustment, or a downward MIPS payment adjustment as appropriate. Upward MIPS payment adjustments may be scaled for budget neutrality, as required by MACRA. The final score will also be used to determine whether a MIPS eligible clinician qualifies for an additional positive adjustment factor for exceptional performance. The performance threshold will be set at 3 points for the transition year, such that clinicians engaged in the program who successfully report one quality measure can avoid a downward adjustment. MIPS eligible clinicians submitting additional data for one or more of the three performance categories for at least a full 90-day period may qualify for varying levels of positive adjustments.

In future years of the program, we will require longer performance periods and higher performance in order to avoid a negative MIPS payment adjustment.

(vii) Performance Feedback

We are finalizing a process for providing performance feedback to MIPS eligible clinicians. Initially, we will provide performance feedback on an annual basis. In future years, we aim to provide performance feedback on a more frequent basis, as well as providing feedback on the performance categories of improvement activities and advancing care information in line with clinician requests for timely, actionable feedback that they can use to improve care. We are finalizing our proposal to make performance feedback available using a web-based application. Further, we are finalizing our proposal to leverage additional mechanisms such as health IT vendors and registries to help disseminate data contained in the performance feedback to MIPS eligible clinicians where applicable.

(viii) Targeted Review Processes

We are finalizing a targeted review process under MIPS wherein a MIPS eligible clinician may request that we review the calculation of the MIPS payment adjustment factor and, as applicable, the calculation of the additional MIPS payment adjustment factor applicable to such MIPS eligible clinician for a year.

(ix) Third Party Intermediaries

We are finalizing requirements for third party data submission to MIPS that are intended to decrease burden to individual clinicians. Specifically, qualified registries, QCDRs, health IT vendors, and CMS-approved survey vendors will have the ability to act as intermediaries on behalf of MIPS eligible clinicians and groups for submission of data to CMS across the quality, improvement activities, and advancing care information performance categories.

(x) Public Reporting

We are finalizing a process for public reporting of MIPS information through the Physician Compare Web site, with the intention of promoting fairness and transparency. We are finalizing public reporting of a MIPS eligible clinician's data; for each program year, we will post on a public Web site, in an easily understandable format, information regarding the performance of MIPS eligible clinicians or groups under MIPS.

5. Payment Adjustments

We estimate that approximately 70,000 to 120,000 clinicians will become QPs in 2017 and approximately 125,000 to 250,000 clinicians will become QPs in 2018 through participation in Advanced APMs; they are estimated to receive between \$333 million and \$571 million in APM Incentive Payments for CY 2019. As with MIPS, we expect that APM participation will drive quality improvement for clinical care provided to Medicare beneficiaries and to all patients in the health care system.

Under the policies finalized in this rule, we estimate that, between approximately 592,000 and 642,000 eligible clinicians will be required to participate in MIPS in its transition year. In 2019, MIPS payment adjustments will be applied based on MIPS eligible clinicians' performance on specified measures and activities within three integrated performance categories; the fourth category of cost, as previously outlined, will be weighted to zero in the transition year. Assuming that 90 percent of eligible clinicians of all practice sizes participate in the program, we estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments (\$199 million) and positive MIPS payment adjustments (\$199 million) to MIPS eligible clinicians, to ensure budget neutrality. Positive MIPS payment adjustments will also include an additional \$500 million for exceptional performance payments to MIPS eligible clinicians whose performance meets or exceeds a threshold final score of 70. These MIPS payment adjustments are expected to drive quality improvement in the provision of MIPS eligible clinicians' care to Medicare beneficiaries and to all patients in the health care system. However, the distribution could change based on the final population of MIPS eligible clinicians for CY 2019 and the distribution of scores under the program. We believe that starting with these modest initial MIPS payment adjustments, representing less than 0.2 percent of Medicare expenditures for physician and clinical services, is in the long-term best interest of maximizing participation and starting the Quality Payment Program off on the right foot, even if it limits the upside during the transition year. The increased availability of Advanced APM opportunities, including through Medical Home models, also provides earlier avenues to earn bonus payments for those who choose to participate.

6. The Broader Context of Delivery System Reform and Healthcare System Innovation

In January 2015, the Administration announced new goals for transforming Medicare by moving away from traditional FFS payments in Medicare towards a payment system focused on linking physician reimbursements to quality care through APMs (<http://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html#>) and other value-based purchasing arrangements. This is part of an overarching Administration strategy to transform how health care is delivered in America, changing payment structures to improve quality and patient health outcomes. The policies finalized in this rule are intended to continue to move Medicare away from a primarily volume-based FFS payment system for physicians and other professionals.

The Affordable Care Act includes a number of provisions, for example, the Medicare Shared Savings Program, designed to improve the quality of Medicare services, support innovation and the establishment of new payment models, better align Medicare payments with health care provider costs, strengthen Medicare program integrity, and put Medicare on a firmer financial footing.

The Affordable Care Act created the Center for Medicare and Medicaid Innovation (Innovation Center). The Innovation Center was established by section 1115A of the Act (as added by section 3021 of the Affordable Care Act). The Innovation Center's mandate gives it flexibility within the parameters of section 1115A of the Act to select and test promising innovative payment and service delivery models. The Congress created the Innovation Center for the purpose of testing innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care provided to those individuals who receive Medicare, Medicaid, or CHIP benefits. See <https://innovation.cms.gov/about/index.html>. The Secretary may through rulemaking expand the duration and scope of a model being tested if (1) the Secretary finds that such expansion (i) is expected to reduce spending without reducing the quality of care, or (ii) improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and (3) the Secretary finds that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.

The Innovation Center's portfolio of models has attracted participation from a broad array of health care providers, states, payers, and other stakeholders, and serves Medicare, Medicaid, and CHIP beneficiaries in all 50 states, the District of Columbia, and Puerto Rico. We estimate that over 4.7 million Medicare, Medicaid, and CHIP beneficiaries are or soon will be receiving care furnished by the more than 61,000 eligible clinicians currently participating in models tested by the CMS Innovation Center.

Beyond the care improvements for these beneficiaries, the Innovation Center models are affecting millions of additional Americans by engaging thousands of other health care providers, payers, and

states in model tests and through quality improvement efforts across the country. Many payers other than CMS have implemented alternative payment arrangements or models, or have collaborated in the Innovation Center models. The participation of multiple payers in alternative delivery and payment models increases momentum for delivery system transformation and encourages efficiency for health care organizations.

The Innovation Center works directly with other CMS components and colleagues throughout the federal government in developing and testing new payment and service delivery models. Other federal agencies with which the Innovation Center has collaborated include the Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Agency for Healthcare Research and Quality (AHRQ), Office of the National Coordinator for Health Information Technology (ONC), Administration for Community Living (ACL), Department of Housing and Urban Development (HUD), Administration for Children and Families (ACF), and the Substance Abuse and Mental Health Services Administration (SAMHSA). These collaborations help the Innovation Center effectively test new models and execute mandated demonstrations.

7. Stakeholder Input

In developing this final rule with comment period, we sought feedback from stakeholders and the public throughout the process such as in the 2016 Medicare PFS Proposed Rule; the Request for Information Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models (hereafter referred to as the MIPS and APMs RFI); listening sessions; conversations with a wide number of stakeholders; and consultation with tribes and tribal officials through an All Tribes' Call on May 19, 2016 and several conversations with the CMS' Tribal Technical Advisory Group. Through the MIPS and APMs RFI published in the **Federal Register** on October 1, 2015 (80 FR 59102 through 59113), the Secretary of Health and Human Services (the Secretary) solicited comments regarding implementation of certain aspects of the MIPS and broadly sought public comments on the topics in section 101 of the MACRA, including the incentive payments for participation in APMs and increasing transparency of PFPMs. We received numerous public comments in response to the MIPS and APMs RFI from a broad range of sources including professional associations and societies, physician practices, hospitals, patient groups, and health IT vendors. On May 9, 2016, we published in the **Federal Register** a proposed rule for the Merit-based Incentive Payment System and Alternative Payment Model Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (81 FR 28161 through 28586). In our proposed rule, we provided the public with proposed policies, implementation strategies, and regulation text, in addition to seeking additional comments on alternative and future approaches for MIPS and APMs. The comment period closed June 27, 2016.

In response to both the RFI and the proposed rule, we received a high degree of interest from a broad spectrum of stakeholders. We thank our many commenters and acknowledge their valued input

throughout the proposed rule process. We discuss and respond to the substance of relevant comments in the appropriate sections of this final rule with comment period. In general, commenters continue to support establishment of the Quality Payment Program and maintain optimism as we move from FFS Medicare payment towards an enhanced focus on the quality and value of care. Public support for our proposed approach and policies in the proposed rule focused on the potential for improving the quality of care delivered to beneficiaries and increasing value to the public—while rewarding eligible clinicians for their efforts. In this early stage of a new program, commenters urged CMS to maintain flexibility and promote maximized clinician participation in MIPS and APMs. Commenters also expressed a willingness and desire to work with CMS to increase the relevance of MIPS activities and measures for physicians and patients and to expand the number and scope of APMs. We have sought to adopt these sentiments throughout relevant sections of this final rule with comment period. Commenters continue to express concern with elements of the legacy programs incorporated into MIPS. We appreciate the many comments received regarding the proposed measures and activities and address those throughout this final rule with comment period. We intend to work with stakeholders to continually seek to connect the program to activities and measures that will result in improvement in care for Medicare beneficiaries. Commenters also continue to be concerned regarding the burden of current and future requirements. Although many commenters recognize the reduced burden from streamlined reporting in MIPS compared to prior programs, they believe CMS could undertake additional steps to improve reporting efficiency. We appreciate provider concerns with reporting burden and have tried to reduce burden where possible while meeting the intent of the MACRA, including our obligations to improve patient outcomes through this quality program.

In several cases, commenters made suggestions for changes that we considered and ultimately found to be inconsistent with the statute. In keeping with our objectives of maintaining transparency in the program, we outline in the appropriate sections of the rule suggestions from commenters that were considered but found to be inconsistent with the statute.

Commenters have many concerns about their ability to participate effectively in MIPS in 2017 and the program's impacts on small practices, rural practitioners, and various specialty practitioner types. We have attempted to address these concerns by including transitional policies and additional flexibility in relevant sections of the final rule with comment period to encourage participation by all eligible clinicians and practitioner types, and avoid undue impact on any particular group.

Commenters present substantial enthusiasm for broadening opportunities to participate in APMs and the development of new Advanced APMs. Commenters suggest a number of resources should be made available to assist them in moving towards participation in APMs and have submitted numerous proposals for enhancing the APM portfolio and shortening the development process for new APMs. In particular, commenters urged us to modify existing Innovation Center models so they can be classified as Advanced APMs. We appreciate commenters' eagerness to participate in Advanced APMs and to be a part of transforming care. While not within the scope of this rule, we note that CMS has developed in

conjunction with this rule a new strategic vision for the development of Advanced APMs over the coming years that will provide significantly enhanced opportunities for clinicians to participate in the program.

We thank stakeholders again for their considered responses throughout our process, in various venues, including comments to the MIPS and APMs RFI and the proposed rule. We intend to continue open communication with stakeholders, including consultation with tribes and tribal officials, on an ongoing basis as we develop the Quality Payment Program in future years.