I. CY 2019 Updates to the Quality Payment Program

1. Executive Summary

a. Overview

This final rule will make payment and policy changes to the Quality Payment Program starting January 1, 2019, except as noted for specific provisions elsewhere in this final rule. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015) amended title XVIII of the Act to repeal the Medicare sustainable growth rate (SGR) formula, to reauthorize the Children's Health Insurance Program, and to strengthen Medicare access by improving physician and other clinician payments and making other improvements. The MACRA advances a forward-looking, coordinated framework for clinicians to successfully participate in the Quality Payment Program, which rewards value in one of two ways:

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

As we move into the third year of the Quality Payment Program, we have taken all stakeholder input into consideration, including recommendations made by the Medicare Payment Advisory Commission (MedPAC), an independent congressional agency established by the Balanced Budget Act of 1997 (Pub. L. 105-33, enacted on August 5, 1997) to advise the U.S. Congress on issues affecting the Medicare program, such as payment policies under Medicare, the factors affecting expenditures for the efficient provision of services, and the relationship of payment policies to access and quality of care for Medicare beneficiaries. We will continue to implement the Quality Payment Program as required, smoothing the transition where possible and offering targeted educational resources for program participants. A few examples of how we are working to address stakeholder input are evident in our work around burden reduction and reshaping our focus of interoperability. We have heard the concern about process-based measures, and we are continuing to move towards the development and use of more outcome measures by way of removing process measures that are topped out and funding new quality measure development, as required by section 102 of MACRA. We have also developed new episode-based cost measures, with stakeholder feedback, for inclusion in the cost performance category beginning in 2019, with additional measure development occurring for potential inclusion in future years.

Additionally, we have also received feedback from stakeholders regarding the added value of the Quality Payment Program. To that point, CMS has begun a series of strategic planning sessions to (1) assess the current value of the program for clinicians and beneficiaries alike and

(2) implement the program in a way that is understandable to beneficiaries, as they are the core of the Medicare program.

As a priority for the Quality Payment Program Year 3, we are committed to continue using the framework established by the Patients over Paperwork initiative to assist in reducing clinician burden, implementing the Meaningful Measures Initiative, promoting interoperability, continuing our support of small and rural practices, empowering patients, and promoting price transparency.

Reducing Clinician Burden

We are committed to reducing clinician burden by simplifying and streamlining the program for participating clinicians. Examples include:

- Implementing the Meaningful Measures Initiative, which is a framework that applies a series of cross-cutting criteria to identify and utilize the most meaningful measures with the least amount of burden and greatest impact on patient outcomes;
- Promoting advances in interoperability; and
- Establishing an automatic extreme and uncontrollable circumstances policy for MIPS eligible clinicians.

Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

Regulatory reform and reducing regulatory burden are high priorities for CMS. To reduce the regulatory burden on the health care industry, lower health care costs, and enhance patient care, we launched the Meaningful Measures Initiative in October 2017.[1] This initiative is one component of our agency-wide Patients Over Paperwork Initiative,[2] which is aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that fosters operational efficiencies, and reduces cost associated with collection and reporting burden, while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures Framework has the following principles for identifying measures that:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;

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[1] Meaningful Measures web page: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.

[2] See Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html.

- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures);
- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

To achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in Table 30.

TABLE 30: Meaningful Measures Framework Domains and Measure Areas

Quality Priority	Meaningful Measure Area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections
	Preventable Healthcare Harm
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals
	End of Life Care according to Preferences
	Patient's Experience of Care
	Patient Reported Functional Outcomes
Promote Effective Communication and Coordination of Care	Medication Management
	Admissions and Readmissions to Hospitals
	Transfer of Health Information and Interoperability
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care
	Management of Chronic Conditions
	Prevention, Treatment, and Management of Mental Health
	Prevention and Treatment of Opioid and Substance Use Disorders
	Risk Adjusted Mortality
Work with Communities to Promote Best Practices of Healthy Living	Equity of Care
	Community Engagement
Make Care Affordable	Appropriate Use of Healthcare
	Patient-focused Episode of Care
	Risk Adjusted Total Cost of Care

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers and promoting operational efficiencies.

In the quality performance category under MIPS, clinicians have the flexibility to select and report the measures that matter most to their practice and patients. However, we have received feedback that some clinicians find the performance requirements confusing, and the program makes it difficult for them to choose measures that are meaningful to their practices and have more direct benefit to beneficiaries. For the 2019 MIPS performance period, we are finalizing the following updates: (1) adding 8 new MIPS quality measures that include 4 patient reported outcome measures, 6 high priority measures, and 2 measures on important clinical topics in the Meaningful Measures framework; and (2) removing 26 quality measures.

In addition to having the right measures, we want to ensure that the collection of information is valuable to clinicians and worth the cost and resources of collecting the information.

Promoting Interoperability Performance Category

As required by MACRA, the Quality Payment Program includes a MIPS performance category that focuses on meaningful use of certified EHR technology, referred to in the CY 2017 and CY 2018 Quality Payment Program final rules as the "advancing care information" performance category. As part of our approach to promoting and prioritizing interoperability of health care data, in Quality Payment Program Year 2, we changed the name of the performance category to the Promoting Interoperability performance category.

We have prioritized interoperability, which we define as health information technology, that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable law; and does not constitute information blocking as defined by the 21st Century Cures Act (Pub. L. 114-255, enacted December 13, 2016). We are committed to working with the Office of the National Coordinator for Health IT (ONC) on implementation of the interoperability provisions of the 21st Century Cures Act to have seamless but secure exchange of health information for clinicians and patients, ultimately enabling Medicare beneficiaries to get their claims information electronically. In addition, we are prioritizing quality measures and improvement activities that support interoperability.

To further CMS' commitment to implementing interoperability, at the 2018 Healthcare Information and Management Systems Society (HIMSS) conference, CMS Administrator Seema Verma announced the launching of the MyHealthEData initiative.[3] This initiative aims to empower patients by ensuring that they control their health care data and can decide how their data is going to be used, all while keeping that information safe and secure. The overall government-wide initiative is led by the White House Office of American Innovation with participation from HHS – including its CMS, ONC, and the National Institutes of Health (NIH) – as well as the U.S. Department of Veterans Affairs (VA). MyHealthEData aims to break down the barriers that prevent patients from having electronic access and true control of their own health records from the device or application of their choice. This effort will approach the issue of health care data from the patient's perspective.

For the Promoting Interoperability performance category, we require MIPS eligible clinicians to use 2015 Edition certified EHR technology beginning with the 2019 MIPS performance period to make it easier for:

- Patients to access their data.
- Patient information to be shared between doctors and other health care providers.

Continuing to Support Small and Rural Practices

We understand that the Quality Payment Program is a big change for clinicians, especially for those in small and rural practices. We intend to continue to offer tailored flexibilities to help these clinicians to participate in the program. For example, in this rule we are finalizing our proposal to retain a small practice bonus under MIPS by moving it to the quality performance category. We will also continue to support small and rural practices by offering free and customized resources available within local communities, including direct, one-on-one support from the Small, Underserved, and Rural Support Initiative along with our other no-cost technical assistance.

Further, we note that we are finalizing our proposal to amend our regulatory text to allow small practices to continue using the Medicare Part B claims collection type. We are also finalizing our proposal to revise the regulatory text to allow a small practice to submit quality data for covered professional services through the Medicare Part B claims submission type for the quality performance category, as discussed further in section III.I.3.h. of this final rule. Finally, in the CY 2018 Quality Payment Program final rule, we finalized a policy to allow small practices to continue to choose to participate in MIPS as a virtual group (82 FR 53598).

Empowering Patients through the Patients Over Paperwork Initiative

Our Patients Over Paperwork initiative establishes an internal process to evaluate and streamline regulations with a goal to reduce unnecessary burden, to increase efficiencies, and to improve the beneficiary experience.[4] This administration is dedicated to putting patients first,

[3] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-03-06.html.
[4] Patients Over Paperwork webpage available at https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/PatientsOverPaperwork.html.

empowering consumers of health care to have the information they need to be engaged and active decision-makers in their care. As a result of this consumer empowerment, clinicians will gain competitive advantage by delivering coordinated, high-value quality care.

The policies for the Quality Payment Program in this final rule promote competition and empower patients. We are consistently listening, and we are committed to using data-driven insights, increasingly aligned and meaningful quality measures, and technology that empowers patients and clinicians to make decisions about their health care.

In conjunction with development of the Patients Over Paperwork initiative, we are making progress toward developing a patient-centered portfolio of measures for the Quality Payment Program, including 7 new outcome measures included on the 2017 CMS Measures Under Consideration List,[5] 5 of which are directly applicable to the prioritized specialties of general medicine/crosscutting and orthopedic surgery. Finally, on September 21, 2018, CMS awarded 7 organizations new cooperative agreements to partner with the agency in developing, improving, updating, or expanding quality measures for Medicare's Quality Payment Program. Awardees will work to establish more appropriate measures for clinical specialties underrepresented in the current measure set with the goal of improving patient care, and focus on outcome measures, including patient-reported and functional-status measures, to better reflect what matters most to patients.[6]

b. Summary of the Major Provisions

In May 2018, CMS announced that 91 percent of MIPS eligible clinicians participated in the 2017 transition year. (See https://www.cms.gov/blog/quality-payment-program-exceeds-year-1-participation-goal.) This CY 2017 performance period data were incorporated for this final rule when estimating eligibility and payment adjustment for the CY 2019 MIPS performance period. One important finding is that many more clinicians than reported in the CY 2019 PFS proposed rule are expected to participate in MIPS using the group reporting option. This increase means more clinicians are covered in MIPS and are measured on their performance.

(1) Quality Payment Program Year 3

During the first 2 years of the program, we have heard concerns from clinicians that were not eligible to participate. Under MIPS, for year 3, we are expanding in this final rule the opportunities to participate, while still understanding the burden required to participate, to include physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dietitians or nutrition professionals in the list of MIPS eligible clinicians. We also are finalizing an opt-in policy that allows some

[5] Centers for Medicare & Medicaid Services. *List of Measures Under Consideration for December 1, 2017*. Baltimore, MD: US Department of Health and Human Services; 2017. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-List for 2017.pdf. Accessed May 4, 2018.

[6] CMS Awards Funding for Quality Measure Development, https://www.cms.gov/newsroom/press-releases/cms-awards-funding-quality-measure-development.

clinicians, who otherwise would have been excluded under the low-volume threshold, the option to participate in MIPS.

We believe the third year of the Quality Payment Program should build upon the foundation that has been established in the first 2 years, which provides a trajectory for clinicians moving to a performance-based payment system. This trajectory provides clinicians the ability to participate in the program through two pathways: MIPS and Advanced APMs.

(2) Payment Adjustments

As discussed in section VII.F.8. of this final rule, for the 2021 payment year and based on Advanced APM participation during the 2019 MIPS performance period, we estimate that between 165,000 and 220,000 clinicians will become Qualifying APM Participants (QP). As a QP, an eligible clinician is not subject to the MIPS reporting requirements and payment adjustment, and qualifies for a lump sum APM incentive payment equal to 5 percent of their aggregate payment amounts for covered professional services for the year prior to the payment year. We estimate that the total lump sum APM incentive payments will be approximately $600-800 million for the 2021 Quality Payment Program payment year.

Again, we estimate that approximately 798,000 clinicians would be MIPS eligible clinicians in the 2019 MIPS performance period, an increase of almost 148,000 from the estimate we provided in the CY 2019 PFS proposed rule, which reflects growth in group reporting and our ability to better capture group reporting. The final number will depend on several factors, including the number of eligible clinicians excluded from MIPS based on their status as QPs or Partial QPs, the number that report as groups, and the number that elect to opt-in to MIPS. In the 2021 MIPS payment year, MIPS payment adjustments, which only apply to covered professional services, will be applied based on MIPS eligible clinicians' performance on specified measures and activities within four integrated performance categories. We estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments ($390 million) and positive MIPS payment adjustments ($390 million) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality. Positive MIPS payment adjustments will also include up to an additional $500 million for exceptional performance to MIPS eligible clinicians whose final score meets or exceeds the additional performance threshold of 75 points that we are establishing in this final rule. However, the distribution will change based on the final population of MIPS eligible clinicians for the 2021 MIPS payment year and the distribution of final scores under the program.

2. Definitions

At §414.1305, subpart O—

- We are revising in this final rule the regulation to define the following terms:
  ++ Ambulatory Surgical Center (ASC)-based MIPS eligible clinician.
  ++ Collection type.
  ++ Health IT vendor.
  ++ MIPS determination period.
  ++ Submission type.
  ++ Submitter type.
  ++ Third party intermediary.

- We are revising in this final rule the definitions of the following terms:
  ++ High priority measure.
  ++ Hospital-based MIPS eligible clinician
  ++ Low-volume threshold.
  ++ MIPS eligible clinician.
  ++ Non-patient facing MIPS eligible clinician.
  ++ Qualified clinical data registry (QCDR).
  ++ Qualifying APM Participant (QP).
  ++ Small practice.

These terms and definitions are discussed in detail in relevant sections of this final rule.